CLINICAL STUDY

Oral Nutritional Supplementation Improves Cognitive Function and Reduces Frailty in Malnourished Older Adults

Prasani Wickramawardhane*, Neil A King†, Ranil Jayawardena‡

*Health and Wellness Unit, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka
†School of Exercise and Nutrition Sciences, Faculty of Health, Queensland University of Technology, Brisbane, Queensland, Australia
‡Dept. of Physiology, Faculty of Medicine, University of Colombo, Colombo, Sri Lanka

Abstract

Background: Malnutrition in older adults is associated with cognitive decline and frailty. Improving nutritional status might be an effective approach to mitigate cognitive decline and frailty. This study assessed the effect of an oral nutritional supplement (ONS) on cognitive function and frailty in malnourished older adults. **Methods:** This is an open-labeled, parallel-group, randomized controlled trial. Fifty older adults (age ≥60 years) with/or at risk of malnutrition (Mini Nutrition Assessment score ≤11) were randomized into an intervention (IG) or control (CG) group (1:1 ratio). Participants in the IG received 200 mL of an ONS (57 g/day [247 kcal/serving, 12 g protein]) before bedtime for 12 weeks, whereas the CG received 200 mL of water. Cognitive function, frailty, and ability to perform activities of daily living (ADLs) were assessed at baseline and after 12 weeks using the Montreal Cognitive Assessment (MoCA), a five-criteria frailty assessment, and the Barthel Index (BI), respectively. **Results:** A sample of 42 older adults (IG: n = 20, and CG: n = 22) completed the study. The IG experienced a significant improvement in the MoCA score compared to the CG (ΔMoCA score:1.90 ± 2.34 vs. −1.50 ± 3.33; $p < 0.001$). The five-criteria frailty assessment score in the IG declined significantly from 3.30 ± 0.92 to 2.35 ± 1.20 ($p = 0.002$), indicating an improvement in frailty status. In contrast, there was no significant change in the frailty status of the CG participants ($p = 0.67$). The IG also exhibited a significant improvement in performing their ADLs compared to the CG (ΔBI score: 0.30 ± 0.47 vs. −0.18 ± 0.66; $p < 0.001$). **Conclusion:** Regular ONS as a bedtime meal for 12 weeks may effectively improve cognitive function and reduce frailty in older adults with malnutrition, likely due to the indirect effects of improved nutritional status.

Keywords: Barthel index, cognitive function, malnutrition, MoCA, older adults, oral nutritional supplement, frailty

Address for correspondence
Dr Prasani Wickramawardhane
Faculty of Medicine,
University of Colombo, Sri Lanka
E-mail: salujaprasani@gmail.com

Background

Cognitive frailty, a condition in which physical frailty and mild cognitive impairment (MCI) coexist[1], poses a complex challenge in the realm of older adult health. Older adults with frailty have a significantly greater risk of developing MCI and vice versa[2]. A meta-analysis including 14 studies with 57,559 older adults whose ages ranged from an average of 71.5 to 93.6 years demonstrated that the prevalence of cognitive frailty ranged between 2.5% and 50%[3]. It is associated with a range of adverse health outcomes, including functional disability (e.g., falls), worsened quality of life, hospitalization, increased hospital stays, incidence of dementia, and increased risk of overall mortality[4]. Findings from an Italian longitudinal study on aging suggest that the earlier cognitive frailty is identified and managed, the more likely it is to be reversible[5]. Thus, feasible and effective strategies to promote cognitive function are needed.

Nutrition is a strong and modifiable risk factor associated with cognitive frailty[6]. Older adults with malnutrition exhibit poorer cognitive performance and are more susceptible to frailty[7]. Unintentional weight loss, insufficient caloric intake, specific nutrient deficiencies, and unhealthy dietary patterns might increase the risk of physical frailty[1,8]. Older adults with malnutrition might not consume sufficient amounts of high-quality protein and/or other micronutrients that play crucial roles in cognitive and physical function solely through reduced food intake. Oral nutritional supplements (ONS) can be used to provide energy, high-quality protein, and micronutrients and are recommended to meet the basic nutritional needs of such individuals when the diet alone is not sufficient[9].

The literature has identified several crucial nutrients, such as protein, vitamin D, vitamin B, vitamin K, and long-chain

polyunsaturated fatty acids (PUFAs), that play pivotal roles in the cognitive function of older adults[10]. A review indicated that dietary protein and amino acids are associated with lower rates of cognitive decline and dementia[11]. A higher intake of vitamin D, either with or without calcium, is associated with improved cognitive function and a lower risk of Alzheimer's disease[12]. Folic acid and cobalamin supplementation significantly improved cognitive function, where the combination of folic acid and cobalamin was superior to supplementing either one alone in older adults with MCI[13]. Higher serum phylloquinone status in older adults has been correlated with better performance in verbal episodic memory, and higher dietary intake of vitamin K was also linked with less severe subjective memory complaints among older adults[14]. Karr and colleagues suggested that n-3 PUFA supplementation may independently prevent cognitive decline in older adults[15].

In addition, prior studies have demonstrated the beneficial effects of specialized ONSs containing high-quality protein, vitamin D, and other micronutrients on mass lean mass[16], physical function[17], and nutritional status[18] in malnourished older adults, which may have a positive impact on frailty status, cognitive function, and an individual's ability to live independently.

In this context, we propose that multiple nutritional supplements may lead to greater improvements in cognitive function than each nutrient alone. The objective of the current study was to examine the effects of an ONS containing sufficient amounts of high-quality protein and other essential micronutrients on cognitive function, frailty status, and the Barthel Index (BI) in institutionalized older adults with malnutrition.

Methods

Study design

This study is a randomized-controlled, open-label, parallel-group study, conducted between February 2023 and May 2023 at Moratuwa Social Services Elders Home, Colombo, Sri Lanka. Potential participants were enrolled, as follows: 1) aged 60 years or above; 2) Mini Nutritional Assessment short-form (MNA-SF) score ≥11; 3) subjects with intolerance to milk products, any acute medical conditions, inability to consume food orally and no capacity consent were excluded; and 4) subjects also excluded if they were bedridden or on an end-of-life care pathway. The detailed protocol regarding the methodology has been published elsewhere[19], and a summary is given below.

The protocol was approved by the Ethics Review Committee of the Sri Lanka Medical Association (ERC/22-005). This trial was registered at the Sri Lanka Clinical Trial Registry (SLCTR/2022/021). Permission to access the elderly care residence was obtained from the National Secretariat for Elders, Sri Lanka. All the participants voluntarily provided written informed consent prior to study participation. Completed versions of the CONSORT checklist and flow chart for randomized controlled trials were both completed following study completion and included for references (Fig. 1).

Intervention

The sample size was estimated at 25 participants in each group, based on the percentage of those who achieved at least 5% weight gain in the intervention group (IG) compared to the control group (CG) with a power test of 80%, a significance level of 5%, and a dropout rate of 20%. The detailed sample size calculation is presented previously published study protocol[19]. The participants were randomly assigned to either the IG or CG (allocation ratio: 1:1) via a simple random sampling technique[19].

The IG received ONS dissolved in 200 mL of water (Entrasol Platinum, Kalbe Pvt. Ltd., Indonesia), while the CG received 200 mL of water. The ONS utilized in the study contained 247 kcal energies; 12 g of protein; 2.8 µg of vitamin D; 219 mg of calcium; 125 µg of folic acid; 0.7 µg of vitamin B12; and 1 g of PUFA and other essential micronutrients. The participants were instructed to consume ONS daily before bedtime (between 9 and 10 PM) for 12 weeks. The total energy consumed by both the IG and CG participants was monitored via 24-hour dietary recalls at the beginning and end of the study.

Study outcomes

Cognitive function, frailty status, and ability to perform activities of daily living (ADLs) were assessed at baseline (Week 0), and postintervention (Week 12) visits.

Assessment of cognitive function

The cognitive assessment was conducted individually in a quiet environment free of distractions or disruptions, using standardized instructions, and was primarily administered by one investigator (PW). The Montreal Cognitive Assessment (MoCA) was used to assess the participants' range of cognitive functions including executive functions, memory, language, and orientation. Scores ≥26 (out of 30) are deemed normal for healthy adults, whereas scores <26 indicate potential cognitive impairment (18-25: mild; 10-17: moderate; <10: severe)[20]. The administration of MoCA typically took 15 to 20 minutes.

Assessment of frailty status

The frailty assessment was conducted by the same investigator (PW), using the modified version (Supplementary Document 1) of health and aging studies frailty criteria, where frailty was measured as a complex variable on the basis of five indicators: weakness, slowness, weight loss, exhaustion, and low physical activity[21-23]. A score of zero indicated normal status, a score of 1-2 points suggested prefrailty, and a score of 3-5 points indicated frailty[21,24].

Assessment of ability to perform ADLs

The BI was used to assess the participants' ability to perform ADLs. The BI questionnaire was administered by a trained research assistant. Participants self-reported their level of independence regarding ADL. The BI comprises 10 items: bowel, bladder, grooming, toilet use, feeding, transfer, mobility, dressing, stairs, and bathing. Total possible scores range from 0 to 20, with lower scores indicating increased disability[25].

Statistical analysis

Statistical analysis was performed using SPSS software version 23 (SPSS Inc., Chicago, Il, USA). Primary analyses were performed on per-protocol basis and included only participants who completed the study. Individuals were analyzed in the group to which they were randomized considering their level of adherence to the treatment[19]. The data are presented as the means ± SDs. For all the statistical analyses, $p < 0.05$ indicated statistical significance. Baseline characteristics and raw scores of the cognitive test, frailty assessment, and BI were compared between groups with independent sample *t*-tests for continuous variables and *Chi*-square tests for categorical variables, as appropriate. Continuous variables were tested for normality using Shapiro-Wilk test. Since all the variables were distributed normally, the MoCA score, five fried model indicators, frailty score, and BI score were compared within groups and between baseline and after 12 weeks of intervention using paired sample *t*-tests, and differences (Δ score = score at 12 weeks minus that at baseline) were compared between groups using independent sample *t*-tests. The magnitude of the effect size was evaluated using Cohen's d index. To determine whether the cognitive response to ONS was influenced by age and level of education, analysis of covariance (ANCOVA) was performed. Furthermore, cross-tabulation analysis was conducted to analyze the distributions of cognitive impairment and frailty diagnoses in the IG and CG.

Results

Baseline characteristics

Among the 50 older adults who were randomized, 42 (IG: n = 20 and CG: n = 22) completed the study (Fig. 1). The results herein are reported for the 42 participants who completed the study. The study participants' mean (±SD) age was

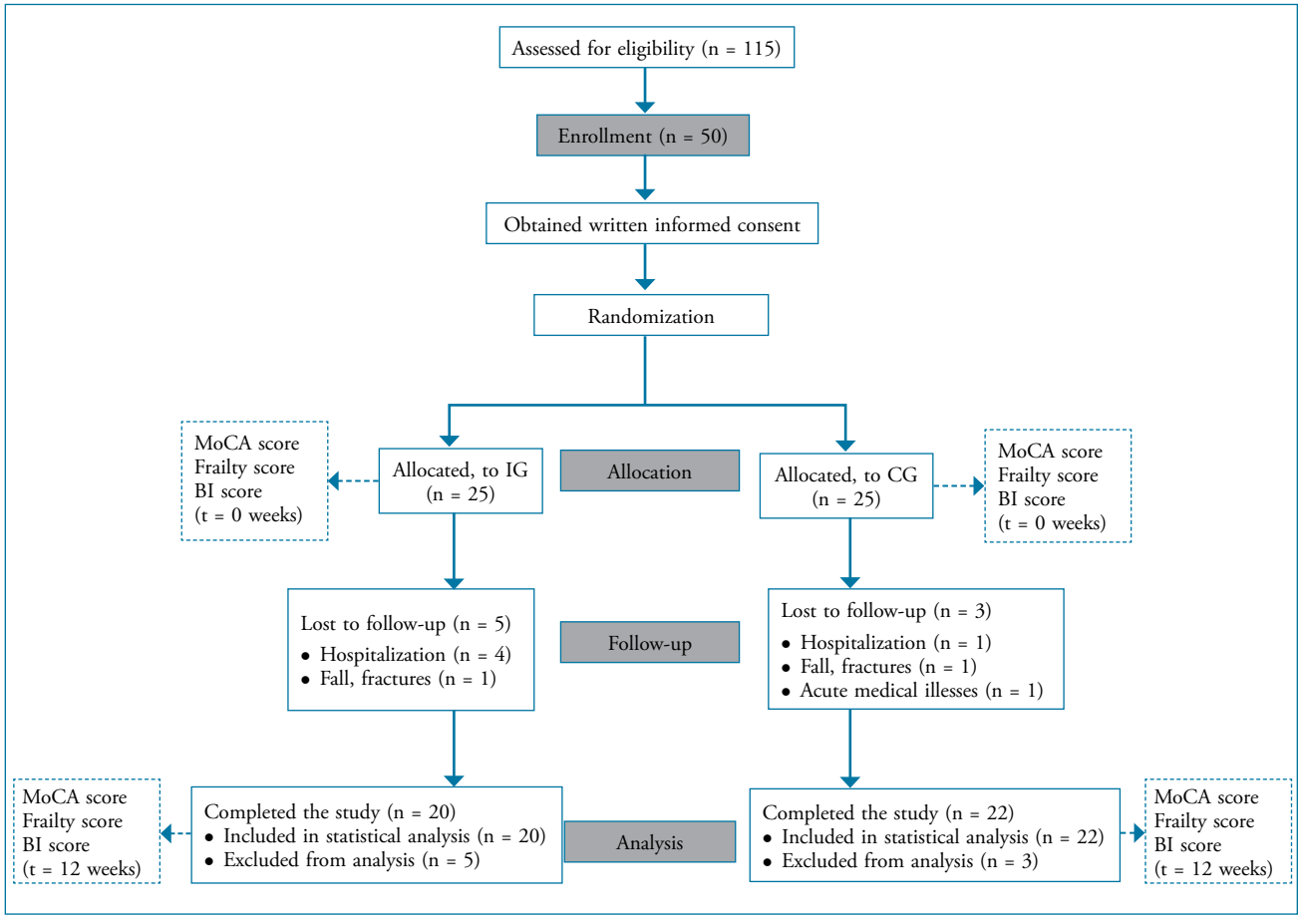


Figure 1. CONSORT flow diagram.

IG = Intervention group; CG = Control group; MoCA = Montreal cognitive assessment; BI = Barthel index.

Table 1. Demographic and Baseline Characteristics of Participants (n = 42)

Variables	Intervention group (n = 20)	Control group (n = 22)	P value[a]
Age (years)	75.4 ± 6.1	74.8 ± 5.2	0.73
Gender (n)			0.59
Male	7 (35.0)	6 (27.3)	
Female	13 (65.0)	16 (73.7)	
Level of education (n)			0.81
No schooling	3 (12.0)	2 (9.1)	
Primary education only	13 (52.0)	13 (59.1)	
Ordinary level	3 (12.0)	5 (22.7)	
Advanced level	1 (4.0)	1 (4.5)	
Diploma/Degree	0 (0.0)	2 (9.1)	
Duration of staying at the elderly care residence (years)	5.20 ± 5.23	4.49 ± 4.22	0.60
MNA score	8.72 ± 1.95	9.56 ± 1.45	0.12
BMI kg/m²	18.65 ± 2.09	18.46 ± 1.98	0.77
MoCA score	14.20 ± 6.70	16.95 ± 6.59	0.19
Cognitive status (n)			0.75
Normal	1 (5.0)	1 (5.0)	
Mild impairment	7 (35.0)	11 (50.0)	
Moderate impairment	6 (30.0)	6 (27.0)	
Severe impairment	6 (30.0)	4 (18.0)	
Five-criteria frailty assessment score	3.30 ± 0.92	3.36 ± 0.79	0.81
Frail status (n)			0.31
Normal	0 (0.0)	0 (0.0)	
Pre-frail	4 (20.0)	2 (9.0)	
Frail	16 (80.0)	20 (91.0)	
Barthel Index score	19.15 ± 1.14	19.00 ± 1.69	0.74

Values are mean ± SD for continuous variables and n (%) for categorical variables.

*P value statistically significant.

[a]Independent sample *t*-test or *Chi*-square test.

MNA = Mini nutrition assessment; BMI = body mass index; MoCA = Montreal cognitive assessment.

75.1 ± 5.7 years, and the majority were female (n = 36). There were no significant differences in demographics, baseline physical characteristics, body mass index (BMI), cognitive status, frailty, or BI between the IG and CG (Table 1).

Effect of ONS on cognitive function

At baseline, the mean MoCA score indicated that both the IG (14.35 ± 6.68) and the CG (16.95 ± 6.59) fell within the range for moderate cognitive impairment, which is defined as scores between 10 to 17 (Fig. 2). After 12 weeks of intervention, the IG showed significant improvement in cognitive function compared with the CG (ΔMoCA score: 1.90 ± 2.34 vs. −1.50 ± 3.33; p < 0.001) (Table 2), with a larger effect size (Cohen's d = 0.75). Similarly, there was a significant difference in the ΔMoCA score (F [1,38] = 7.752, p = 0.008) between the two groups while adjusting for possible confounding variables (Table 3). Furthermore, among the IG participants, the proportion of those with severe cognitive impairment declined by 10%, and 5% improved to a normal cognitive status (p < 0.001) (Table 2). Conversely, in the CG, participants had a decrease in the mean MoCA score from 16.95 ± 6.59 to 15.45 ± 7.05 (p = 0.04), with proportions of severe, moderate, and MCI ranging from 18%, 27%, and 50%, respectively, at baseline to 23%, 36%, and 41%, respectively, at Week 12 (p < 0.001) (Table 2).

Effect of ONS on frailty status

The changes in frailty diagnosis and indicators are presented in Table 2 and Figure 3. The five-criteria frailty assessment score in the IG decreased significantly from 3.30 ± 0.92 to 2.35 ± 1.20 (p = 0.002), indicating an improvement in frailty status. In contrast, there was no significant change in the frailty status of the CG participants (from 3.36 ± 0.79 to 3.41 ± 0.73; p = 0.67). Additionally, the change in the five-criteria frailty assessment score between the two groups was significantly different (ΔFrailty score: −0.55 ± 0.68 vs. 0.05 ± 0.49; p = 0.02).

Effect of ONS on the ability to perform ADLs

Compared with the CG, the IG significantly improved the BI score after 12 weeks of the trial (ΔBI score: 0.30 ± 0.47 vs. −0.18 ± 0.66; p < 0.001) (Table 2).

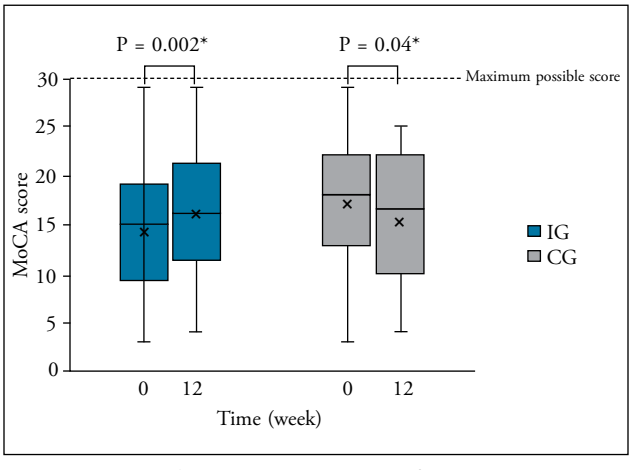


Figure 2. Montreal cognitive assessment performance.

Scores of 26 or more (out of a possible 30-point total) are considered normal; scores <26, 10-17, and <10 indicate mild, moderate, and severe cognitive impairment, respectively.

Boxes (IG: blue; CG: grey) represent interquartile ranges, with horizontal lines indicating the median, whiskers represent the maximum and minimum values, and the cross indicates the median.

*P value statistically significant (Paired sample *t*-test).

MoCA = Montreal cognitive assessment; IG = Intervention group; CG = Control group.

Table 2. Mean Differences in Cognitive Function, Frailty Status, and Barthel Index after 12 Weeks of Intervention Between the Intervention and Control Group

Variables	Intervention group (n = 20)		P value[a]	Control group (n = 22)		P value[b]	P value[c]
	Pre-value	Post-value		Pre-value	Post-value		
MoCA score	14.20 ± 6.70	16.10 ± 6.71	0.002*	16.95 ± 6.59	15.45 ± 7.05	0.04*	
ΔMoCA score	1.90 ± 2.34			−1.50 ± 3.33			<0.001*
Cognitive status (n)			<0.001*			<0.001*	
Normal	1 (5.0)	2 (10.0)		1 (5.0)	0 (0.0)		
Mild impairment	7 (35.0)	6 (30.0)		11 (50.0)	9 (41.0)		
Moderate impairment	6 (30.0)	8 (40.0)		6 (27.0)	8 (36.0)		
Severe impairment	6 (30.0)	4 (20.0)		4 (18.0)	5 (23.0)		
Five-criteria frailty assessment score	3.30 ± 0.92	2.35 ± 1.20	0.002*	3.36 ± 0.79	3.41 ± 0.73	0.67	
ΔFive-criteria frailty assessment score	−0.55 ± 0.68			0.05 ± 0.49			0.002*
Frail status (n)			0.01*			0.75	
Normal	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.)		
Pre-frail	4 (20.0)	9 (45.0)		2 (9.0)	1 (5.0)		
Frail	16 (80.0)	11 (55.0)		20 (91.0)	21 (95.0)		
BI score	19.15 ± 1.14	19.45 ± 1.06	<0.001*	19.00 ± 1.69	18.82 ± 1.68		0.09
ΔBI score	0.30 ± 0.47			-0.18 ± 0.66			<0.001*

Values are mean ± SD.

*P value statistically significant.

[a]Paired sample *t*-test.

[b]Independent sample *t*-test.

MoCA = Montreal cognitive assessment; BI = Barthel index.

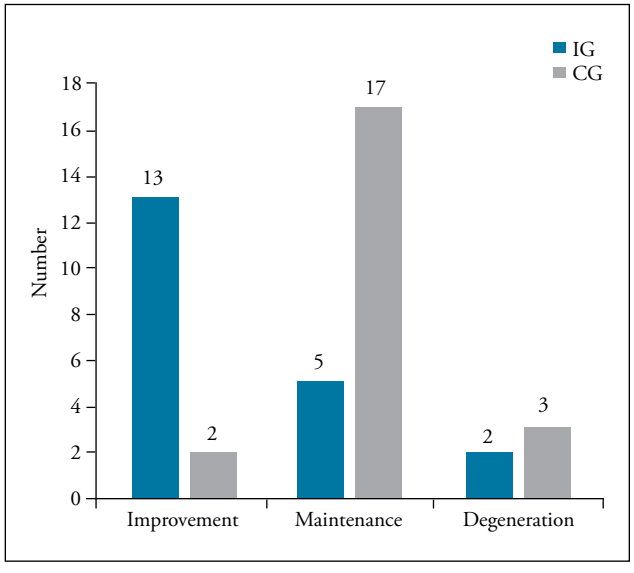


Figure 3. Comparison of improvement levels through frail parameters after the ONS intervention. The bars and digits indicate the level of sum of frail parameter score. Changes of improvement, maintenance and degeneration levels though sum of frail parameter before and after the ONS intervention were compared between the IG and CG.

IG = Intervention group; CG = Control group.

Discussion

Cognitive impairment and physical frailty are widely debated as inevitable clinical markers of biological aging and are considered complex aging syndromes[26]. Poor nutrition in older adults can exacerbate these conditions by negatively impacting cognitive and physical functioning. This, in turn, hinders independent living and reduces quality of life. Interventions that prevent cognitive impairment and frailty are urgently needed. Adequate caloric[27] and protein intake[28] in elderly individuals is positively associated with memory function and reduces the risk of cognitive impairment. Moreover, deficiencies in certain micronutrients, such as vitamin D, vitamin B, vitamin K, long-chain PUFAs, and antioxidants, can intensify brain physiological mechanisms that may increase vulnerability to DNA damage in neurons, which contributes to cognitive decline[29]. This study is the first to evaluate whether ONS with adequate caloric, protein, and other micronutrients can improve cognitive function in older adults with malnutrition in institutionalized settings within the Asian context.

Few studies in the literature have investigated the direct impact of ONS on cognitive function in older adults, and inconsistent findings have been reported. For example, Faxén-

Table 3. Adjusted* Means Differences in Cognitive Status after 12 Weeks of Intervention Between the Intervention and Control Group.

	Intervention group (n = 20)	Control group (n = 22)	P value
	Adjusted mean	Adjusted mean	
ΔMOCA score	1.13 ± 0.72	−1.65 ± 0.68	0.008**

*Adjusted for age and educational level. **P value statistically significant.
MoCA = Montreal cognitive assessment; BI = Barthel index.

Irving reported a decline in cognitive function following ONS[30], whereas another study by Lauque reported an improvement in cognitive function among older adults who received ONS[31]. Both studies utilized the Mini-Mental State Examination (MMSE) to assess cognitive function. However, the findings of the study by Faxén-Irving have certain limitations due to its nonrandomized design. These inconsistencies highlight the need for further research, particularly well-designed, large-scale randomized controlled trials, to elucidate the effects of ONS on cognitive function in older adults. The discrepancies in findings could be attributed to differences in study design, population characteristics, the specific composition of the ONS used, and the duration of the intervention.

The relatively rapid change in cognitive function observed in the present study may be related to the ONS containing additional calories, protein, and essential micronutrients. The ONS used in this study provided a significant amount of 247 calories in addition to the participants' regular diet[18]. In a cohort study conducted among 1,559 older adults aged 70 to 84 years, individuals whose caloric intake was below the recommended daily amount were more susceptible to cognitive impairment than those who met the recommended caloric intake[27]. The ONS contained a substantial amount of carbohydrates, which could provide sufficient glucose to the brain, ensuring that it remains metabolically active. Energy deprivation can lead to cognitive decline due to the inability of the brain to perform essential functions effectively[32]. Thus, the additional calories and nutrients from the ONS may have helped improve cognitive function by supplying the necessary energy and nutrients to support brain health and overall metabolic processes.

Energy intake from carbohydrates, protein, or fat can enhance cognitive function independently of elevated blood glucose levels, indicating that each macronutrient has unique effects on cognitive function[33]. The ONS used in this study contained a substantial amount of carbohydrates (32 g), protein (12 g), and fat (8 g), which significantly increased the participants' overall protein intake[18]. These macronutrients likely contributed to the observed improvements in cognitive function. Carbohydrates provide a primary source of glucose for the brain, ensuring that it remains metabolically active[34]. Proteins support the synthesis of neurotransmitters and the maintenance of muscle mass, both of which are crucial for cognitive health[35]. Fat, particularly essential fatty acids, is vital for maintaining cell membrane integrity and supporting neural function[36]. The balanced composition of these macronutrients in the ONS may have collectively enhanced the cognitive function of the participants. Reduced absorption of protein is a common issue in elderly individuals, often due to atrophic gastritis. This condition impairs the stomach's ability to produce sufficient gastric acid, leading to decreased protein digestion and absorption[37,38]. ONS can help mitigate this problem, as they contain whey protein, which has higher bioavailability than dietary protein sources do. Whey protein is more easily digested and absorbed, ensuring that older adults receive adequate protein to support their nutritional needs and maintain muscle mass and cognitive function[39,40].

In addition to energy and macronutrients, specific micronutrients play a significant role in cognitive function. Numerous studies have investigated the association between vitamin D and cognitive impairment, with the vast majority finding that lower vitamin D levels are significantly associated with MCI[41].

However, relatively few randomized controlled trials have investigated the impact of supplementary vitamin D on cognitive function in older adults, particularly those who are malnourished. In our study, ONS provided 2.8 μg (112 IU) of vitamin D. This supplementation led to a mean increase of 9.20 ng/mL in the serum vitamin D level in the IG, which was significantly greater than that in the CG[18]. One of the possible explanations for this positive result might be the improvement in the serum vitamin D level in the IG. These findings suggest that vitamin D supplementation, even at modest levels, can have a positive effect on cognitive function in older adults, potentially through its various neuroprotective and neuroregulatory roles. In addition to vitamin D, ONS also contains B vitamins, which are crucial for cognitive function. B vitamins play essential roles in brain health, influencing energy production, DNA synthesis, and repair, as well as neurotransmitter function[42].

Thus, the comprehensive nutrient profile of the ONS, including both vitamin D and B vitamins, appears to have contributed significantly to the observed cognitive improvements in the study participants.

Frailty is a prevalent condition in institutionalized settings and is commonly associated with increased mortality and disability among older adults[43]. Moraes and colleagues reported that nutritional supplements alone may not effectively manage frailty in community-dwelling older adults[44]. However, it

remains unclear whether interventions effective in community settings are equally valid for institutionalized populations, who often present with higher rates of disability, multimorbidity, and geriatric syndromes. Abizanda et al demonstrated that a combined intervention of nutritional supplementation and physical exercise improved the quality of life of older adults in institutionalized settings. Our study extends this research by showing that ONS alone can positively impact frailty status in institutionalized older adults. Specifically, ONS led to significant improvements in physical indicators such as BMI, gait speed, hand grip strength, and overall frailty score.

These results suggest that ONS supplementation contributes to better functional outcomes, as evidenced by BI scores, indicating greater independence in ADL. This study underscores the potential of targeted nutritional interventions in managing frailty and enhancing health outcomes among institutionalized older adults.The main strengths of this study are the controlled, supervised administration of the supplement and the high follow-up rate with 100% compliance, which can be attributed to the extensive support provided by caregivers who routinely monitor ONS consumption. A higher follow-up rate is crucial for minimizing potential bias and ensuring the accuracy of the study findings. However, the generalizability of these results can be subjected to certain limitations as the current study was conducted within a single elderly care institution.

The selected elderly care residence for the study accommodates a large number of older adults, currently housing 200 individuals. This number is significant compared to other elderly care institutions in Sri Lanka, and 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, the findings may be applicable to other elderly care and community settings. Additionally, the older adults in this institution exhibit a variety of medical conditions and comorbidities, suggesting that the findings may also be applicable to health care settings. A larger-scale study involving multiple institutes would provide more comprehensive and representative outcomes.

Furthermore, the short duration of ONS administration in our study limits our ability to assess the sustainable effect of ONS.

Conclusion

Supplementation with an ONS, along with a regular diet, significantly improves cognitive function, reduces frailty, and supports independent living among malnourished older adults living in residential care. Future studies should include multiple elderly care institutions and community settings to increase the generalizability of the findings. Extending the duration of ONS administration will help assess the long-term sustainability and effectiveness of ONS.

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Authors' contributions

Prasani Wickramawardhane contributed to data curation, formal analysis, project administration, and writing the original draft of the manuscript. Neil A King and Ranil Jayawardena critically reviewed and edited the manuscript. Ranil Jayawardena conceptualized and supervised the study.

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Data availability

The datasets analyzed in the current study are available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

The protocol was approved by the Ethics Review Committee of the Sri Lanka Medical Association (ERC/22-005). Written informed consent was obtained from all participants.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no known completing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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