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Research Article

Benefits of A Multiple-Plant-Based Nutritional Supplement in Older Adults with Dementia. Six-Month Double-Blind-Active-Comparator Study

Ng B[1,2], Colimon N[1], Beltran G[3], Torres N[4] and Canas MA[4]*

[1]*Nuevo Atardecer, Geriatric Center, USA*

[2]*Sun Valley Research Center, USA*

[3]*Instituto de Inovacion para la Salud Integral, USA*

[4]*MAP, USA*

Abstract

Dementia is a worldwide public health phenomenon, such that the World Health Organization published guidelines for cognitive decline and dementia risk reduction, in 2019. In these guidelines, proper nutrition is highlighted as an important factor to prevent dementia. However, there is brevity of information about the role of proper nutrition, in patients with established dementia. A prospective 6-month-active comparator-controlled study was conducted, to evaluate the effectiveness of a multiple-plant-based nutritional supplement (study group) *versus* a single-plant-based supplement (control group). The outcome measures included the Mini Mental Status Exam (MMSE), the Neuropsychiatric Inventory (NPI), body weight, dynamometer grip strength, walking speed, arm circumference, and the tricipital skinfold. There were 11 subjects in the study group and 9 subjects in the control group. Results were significantly different in MMSE (p=0.001) and NPI (p=0.002) scores, dynamometer grip strength (p=0.000), and walking speed (p=0.000) all favoring the study group. Body weight, arm circumference, and tricipital skinfold, were not significantly different, but favored the study group. The sample was too small to generalize these results but are important enough to suggest that proper nutrition does have an impact in patients with established dementia; furthermore, that a multiple-plant-based supplement may be better than a single-plant-based one. Replicating this study with a larger sample is recommended.

Keywords: Multiple-plant-based; Dementia; Older adults; Nutritional supplement; Nutrition; Dementia; Plant-based supplements; Cognition; Behavior

Background

In 2019 fifty-seven million people worldwide were estimated to meet diagnostic criteria for dementia, this prevalence was projected to near triple by 2050, with two thirds living in low-and-middle income countries [1]. Once the diagnosis of dementia is established, it is anticipated that most patients die within the next 4-6 years. The World Health Organization cognitive decline and dementia risk reduction guidelines in 2019 include recommendations for appropriate management of different aspects such as, physical activity, diet, overweight or obesity, tobacco and alcohol use, hypertension, and diabetes in the prevention of the onset of dementia. However, these guidelines have different degrees of certainty, due to lack of harmonization, insufficient long term randomized controlled trials, and especially limited evidence from low-and-middle-income countries, where the prevalence of dementia is rapidly increasing [2].

Nonetheless, these guidelines have provided a place to start, in the daily care of patients at risk of dementia, especially highlighting the importance of proper nutrition [3]. Unfortunately, the information available for patients who already meet diagnosis of dementia, is limited [4]. Beyond the dietary ingredients and/or components, very little is available on the actual process of patients feeding themselves or being fed. In other words, there is brevity of evidence on patients whose ability to self-feed is compromised, either due to dysphagia, apraxia, motility deficits, psychiatric disorders, or cognitive under appraisal of the importance of nutrition [5,6]. In an attempt to reduce this gap, this study compares two plant-based-nutritional supplements, comparable in presentation, preparation, and ease-to swallow, for patients with dementia, except in the origin and mixture of the ingredients.

Methods

This is a pilot six-month prospective active-comparator-controlled study approved by the Mexicali General Hospital Committee on Ethics in Research (GHCER), under the registration number 02-01-HGMXL/LVD/FNA/TecNu-2019-08-21-253, on 11/14/2019. The study participants were recruited from the study site approved by the GHCER. The informed consent process included the study participant and a family member and/or legal guardian. This project was conceived from the start as a pilot study, and it was considered that a total of 40 subjects would suffice to test our hypothesis. However, due to the changes and modifications in the operation of the Geriatric Center during the pandemic, the sample was reduced to 20 subjects. Due to safety reasons, the center ceased to take new patients temporarily. This modification was approved by the Ethics committee on 12.12.2020. Every patient was assessed at monthly intervals by a blinded rater. The group assignment was based on a simple number

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***Corresponding author:** Bernardo Ng, Sun Valley Research Center, 2417 Marshall Ave, Suite 1 Imperial, CA 92251, USA, Tel: +1-760-355-0161; Fax: +1-760-355-0173

randomization for 40 subjects. As patients were consented, they were assigned a number according to a randomization list, and those that had an even number received the study product, those that had an odd number the control product.

Inclusion criteria

1. Diagnosis of dementia, of any etiology, which live permanently at the Nuevo Atardecer Geriatric Center.
2. Both genders.
3. Stable medical, psychiatric and/or surgical conditions.
4. Capable of walking independently, even with an assistive device (i.e., cane, walker).

Exclusion criteria

1. Superimposed delirium at the time of consent.
2. Unstable medical, psychiatric and/or surgical conditions.
3. Acute medical, psychiatric and/or surgical conditions at the time of consent.
4. Inability to walk independently.

Study site

The Nuevo Atardecer Geriatric Center, approved site by the GHCER, is in the city of Mexicali, Mexico, and provides medical and nursing care services, to older adults with various degrees of cognitive, psychiatric, and physical needs 24 hours a day. Residents at this facility, receive physical and occupational therapy, music therapy, physical exercise, yoga lessons, and individualized nutrition, besides ongoing nursing, and medical care. Both geriatricians and psychiatrists provide continued care, and as necessary, physicians of other specialties are consulted.

Products tested

Study Product (SP): The study product is a powdered professional nutritional support, marketed under the name VD® Line. These are foods with high nutritional density, high fiber content, and polyphenols (antioxidants), that do not increase the consumer's glucose levels, and have no added sugar, salt, gluten, eggs, dairy, fat, or cereals, so it can be consumed daily by adults, children, pregnant women, elderly, even if they have diabetes, hypertension or metabolic conditions; and whether they lead a sedentary life or not (www.lineavd.com).

The SP is marketed under two different presentations Veggie Drink® and Leggu Drink®. The former is made from 18 vegetables and 4 fruits, and the latter of 6 legumes. A 15 gram portion of the former and a 15 gm portion of the latter (measure scoop included) dissolved in water or any non-carbonated drink is equivalent to approximately 30% of the WHO recommended daily requirements respectively. Each 15 gm serving contains approximately 7.0 gm of protein, 0.8 gm of fat, and 7.6 gm of carbohydrates.

Control Product (CP): The control product is soy protein based, marketed under the name Soyarel®. The ingredients include soy flour, brown sugar, cocoa, corn syrup, partially hydrogenated soy oil, soy lecithin, ten xanthan, and goma guar. Each 25 gm serving contains approximately 4.5 gm of protein, 1.1 gm of fat, and 15.7 carbohydrates (www.dulcerel.com).

Product administration

Both products were delivered to the Geriatric Center, in identical containers, only identified by the subject number. The subjects received the products twice-a-day, during midmorning and midafternoon. Staff documented each administration in the nutrition records, along with the documentation of the rest of the daily meals. All patients' meals were supervised by staff, requiring different levels of assistance.

Outcome measures

Demographic and clinical parameters: The demographic parameters include age and gender. The clinical parameters include cognitive and comorbid diagnoses, and concomitant medications. Other clinical measures include handgrip strength; walking speed, arm circumference, tricipital skinfold, and body weight.

- Handgrip strength was measured with a dynamometer in kilograms and served as an estimate for muscle strength. Norms vary by age, gender, and side-of-hand. The mean strength for healthy men right-hand 70 years and older is 33 kg, and the mean strength for women right-hand 70 years and older is 20 [7].
- Walking speed is an item taken from the Short Physical Performance Battery (SPPB), and consists of measuring the time, in seconds, taken to walk a straight 4-meter-line. This is a measure that predicts the risk of frailty of older adults [8].
- Arm circumference is measured in centimeters and serves as an estimate for body composition and nutritional status. It is measured at the midpoint between the acromion and olecranon processes on the shoulder blade and the ulna of the arm. An arm circumference less than 12.5 cm suggests malnutrition and greater than 13.5 cm is considered normal [9].
- Tricipital skinfold, was measured with a caliper in millimeters, serves as a parameter to estimate fat tissue, and can range from 15.5 mm to 25.5 mm in normal weight women [10].
- Body weight was measured in kilograms, and it is a component of the body mass index, which is an estimate for nutritional status [11].

Mini Mental Status Examination (MMSE)

This clinical scale measures multiple cognitive functions, including attention, executive functioning, gnosis, language, memory, orientation, praxis, prosody, and visuospatial proficiency. It has 11 items that can score a maximum of 30 points. The higher the score the better the cognitive function [12].

Neuropsychiatric Inventory (NPI)

The NPI is a validated clinical scale that assesses the caregiver's perception of the severity of 12 dementia-related psychiatric and behavioral symptoms and the level of distress experienced by the caregiver because of these symptoms. The NPI symptom severity section, ranges from 0-36 and the NPI distress section score ranges from 0-60. In both sections the higher scores indicate more severe symptoms and distress, respectively. In a nursing home population, the minimal clinically important difference has been determined to be 2.8-3.2 points for severity and 3.1-4.0 points for distress [13].

Statistical analysis

Propensity Score Matching (PSM) was used, which is a quasi-experimental statistical technique that attempts to estimate the effect of an intervention on an outcome variable, by accounting for the

covariates that predict receiving the treatment. In the context of this clinical trial, which corresponds to a double-blind study, the outcome variables the clinical scales (i.e., nutrition, cognition) with the main binary treatment variable ingesting-or-not-ingesting the supplement in question? The covariates are measurable clinical factors that act as controls and are added to the model to avoid bias. A nonparametric equality-of-medians test was used to contrast the measurements between the two groups, especially those that correspond to quantitative scales.

Endpoints

The main endpoint was the duration of the study, which was planned and executed for six months. It was based on the review of oral nutritional supplements, where they suggested that in order to find a change between a study and a control group, the study should last at least six months [4].

Results

There were eleven subjects (n=11) in the Study Group (SG) and eight (n=8) in the Control Group (CG). Five of the subjects in the SG, and 3 in the CG were male. The average age in the SG was 81.3 and in the CG were 81.8. All participants had a diagnosis of a cognitive deficit disorder, with one in the SG and one in the CG with vascular dementia; five in the SG and six in the CG with Alzheimer's disease; and five in the SG and one in the CG with mixed dementia. The demographic and diagnostic features of the two groups showed no statistical differences and are summarized in Table 1 and 2.

Given the small sample, and the variations in concomitant medications, they were tallied by class (i.e., antipsychotics, antihypertensives), with antipsychotics and antidepressants resulting on top of the list as the most prescribed. There were no statistical differences between the groups, as to the number of subjects on each class of medications (Table 3).

Table 1: Demographic variables.

	Study Group	Control Group
N=19	11	8
Demographics		
Age (average)	81.3	81.8
Sex (male)	5 (45%)	3 (37%)

Table 2: Clinical variables.

	Study Group	Control Group	
N=19	11	8	
	n (%)	**n (%)**	**p value**
Cognitive Diagnosis			
Vascular Dementia	1 (9%)	1 (12%)	0.811
Alzheimer Dementia	5 (45%)	6 (75%)	0.198
Mixed Dementia	5 (45%)	1 (12%)	0.127
Comorbidities			
Hypertension	8 (72%)	5 (62%)	0.636
Diabetes	4 (36%)	3 (37%)	0.96

The differences in MMSE (p=0.001), NPI (p=0.002), hand-grip dynamometer (p=0.000), and walking speed (p=0.000) were all significant favoring the study group. The differences in arm circumference (p=0.178), tricipital skinfold (p=0.624), and body weight (p=0.641) were not statistically significant. However, there was a greater weight gain in the study group. These results are summarized in Table 4.

Discussion

This is a pilot study that compared two different plant-based nutritional supplements. The study product contains the combination of multiple vegetable, fruit, and legume proteins; and the control product is exclusively made of one legume protein. The patients were recruited from a geriatric center, where they received 24-hour care. There were no significant differences between the two groups, regarding age, sex, cognitive, and comorbid diagnoses.

Table 3: Concomitant Medications.

	Study Group	Control Group	p value
N=19	11	8	
Antipsychotic	7	6	
Antidepressant	3	3	
Antiepileptic	4	0	
Antihypertensive	4	4	
Oral hypoglycemics	1	0	0.286
Insulin	0	1	
Cholinesterase inhibitor	4	2	
Memantine	4	4	
Acetaminophen or Aspirin	3	1	
MVI or iron	1	0	

From the cognitive and behavioral point of view, the patients in the study group were more compromised to start with, as noted by their baseline MMSE and NPI scores, which poses the question about the comparability of the two groups. At end-of-study, both groups showed minor improvement in their MMSE scores, while the NPI improved in the study group and got worse in the control group. Should this be replicated in a larger sample, it would be of considerable value given that one of the main burdens in the care of patients with moderate-to-severe cognitive decline, such as the patients in this study, is the behavioral symptoms associated to their dementia. Consequently, an intervention relatively simple, as it is a nutritional supplement, would have an important impact in the lives of patients and caregivers. However, such a conclusion cannot be clearly drawn with the results of this study.

The handgrip strength measured with the dynamometer was virtually unchanged in the study group, while the control group exhibited deterioration, suggesting that the former maintained muscle strength. On the other hand, walking speed improved in both groups, with a greater improvement in the study group. These two differences were statistically significant and may suggest that the patients in the study group showed a tendency to be stronger and faster. The other clinical measures, including arm circumference, tricipital skinfold, and body weight, were not clinically significant either; however, body weight gain, which was greater in the study group, was the most noticed outcome by staff at the center.

The results suggest that a multiple-plant-based nutritional supplement may potentially offer greater benefit in this population, compared to a single-plant-based one, in cognition, behavior, strength, speed, and body weight.

The main limitation of this study is the sample size that unfortunately was not larger due to operational changes at the study site driven by the COVID-19 pandemic. On the other hand, one of the strengths is the comparison of two generally comparable nutrition supplements in presentation, preparation, and ease-to swallow, yet different in the origin and mixture of ingredients. The study product was a multiple-plant-based while the control product was a one-plant-based, where the former includes a 1:1 carbohydrate-to-protein ratio, while the latter had a 3.5:1 carbohydrate-to-protein ratio.

We believe that while no definite conclusions cannot be drawn based on these results, they represent a robust enough signal, to

Table 4: Outcome measures.

	Study Group		Control Group		
	Baseline	End-of-study	Baseline	End-of-study	p value
MMSE	8.7	11.2	15.3	17	0.001
NPI	5.3	4.6	2.8	4	0.002
Dynamometer (kg)	14.1	14.6	10.7	6.2	0
Walk speed (seconds)	10	6.5	12.4	10.4	0
Arm circumference (cm)	27.5	28.8	26.8	27	0.178
Tricipital fold (mm)	13	16.5	15.3	15.3	0.624
Body weight (kg)	65.5	71.1	62.5	54.7	0.641

A nonparametric equality-of-medians test was used to contrast the measurements between the two groups.

strongly recommend replicating this study with a larger sample [14,15].

Author's Contributions

Bernardo Ng protocol design, protection of the blind, original manuscript draft. Nancy Colimon subject recruitment, informed consent, project management, education and information to subjects and their families. Guillermo Beltran blinded clinical ratings. Nelson Torres acquisition, preparation, and distribution of nutritional supplements. Maria Alejandra Canas statistical analysis. All authors contributed to the manuscript writing.

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Conflict of Interest

Nelson Torres works for MAP.

Data Availability Statement

Study data are available upon request.

Ethics Approval Statement

This is a six-month prospective active-comparator-controlled study approved by the Mexicali General Hospital Committee on Ethics in Research (GHCER), under the registration number 02-01-HGMXL/LVD/FNA/TecNu-2019-08-21-253.

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