



Observational Study to Evaluate the Effectiveness of Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B Vitamins and Folic Acid Supplementation (Cogitix®) In the Control of Cognitive Disorders.

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Abstract

Considering that in a growing elderly population mild cognitive impairment (MCI) are increasing in prevalence worldwide and that currently no high-quality evidence exists to support pharmacologic treatments, there is a need to find new therapeutic approaches, including natural ones, to reduce the risk of developing cognitive deficits.

The aim of this study is to evaluate the effectiveness of Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation (Cogitix) in maintaining and/or improving cognitive performances .

Thirty consecutive adult patients attending at ASP S. Margherita Pavia – University of Pavia with MCI score between 24 and 28 or preMCI 27-28 were treated with Cogitix, 1 cp/day , for 3 months. Cognitive status assessment will be evaluated at baseline and at the end of treatment using MMSE test. MCI medium value at baseline was 24,9 and after 3 months has become 25,8 and that in 67% of patients there was an improvement , although not statistically significant, by one or two points in the score. In preMCI status there was an improvement by one point in the score in 33% of patients. The study also confirmed that Cogitix-based products are able, in a short period of treatment, to improve blood parameters such as cholesterol, triglycerides and homocysteine.

Treatment was well tolerated (on a numerical scale from 1 to 10 the average score was 9,5. The compliance of patients was optimal, no side effect was reported and no weight gain occurred.

Data from our study are encouraging to be confirmed by further investigations considering higher dosages, longer treatment periods and more selected population.

Received 22 Jan., 2025; Revised 03 Feb., 2025; Accepted 05 Feb., 2025 © The author(s) 2025.

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I. INTRODUCTION

In a growing elderly population, mild cognitive impairment (MCI) and age related cognitive decline (ARCD) are increasing in prevalence worldwide. Population aging is a relatively new phenomenon in human history and this epochal change in epidemiology is causing problems that have never been faced before on a social and health level. A growing population of elder subjects and unhealthy diets are nowadays leading to the increase in the prevalence of different age-related diseases, being cognitive impairment one of the most prevalent ones.(1)

Mild cognitive impairment is defined as the symptomatic predementia stage on the continuum of cognitive decline, characterized by objective impairment in cognition that is can interfere with activities of daily living. The prevalence of MCI in adults aged 65 years and older is 10% to 20%; risk increases with age and men appear to be at higher risk than women. In older patients with MCI, clinicians should consider depression, polypharmacy, and uncontrolled cardiovascular risk factors, all of which may increase risk for cognitive impairment and other negative outcomes.(2) . MCI is

widely considered a transition stage between normality and dementia. (3) The annual rate in which MCI progresses to dementia varies between 8% and 15% per year, implying that it is an important condition to identify and treat. (4) Researchers have found that up to 40% and even as many as 65% of people with MCI will progress to Alzheimer's disease or a related progressive dementia. (5) The loss of cognitive functions in a person with disruption of the ability to perform daily living activities in the presence of unaltered consciousness is widely accepted to mean dementia. This condition is associated with poor performance scores in various neuropsychological tests. The concept of mild cognitive impairment (MCI) was developed to describe the situation of abnormal scores on objective cognitive assessment with intact ability to maintain activities of daily living. Such individuals may complain of memory problems, but still manage to independently accomplish all their customary tasks. Usually, their ability to function well is based on compensation for these difficulties, such as increased reliance on a calendar or on reminder notes, lists, etc. In some cases, these memory difficulties are a sign that worsening memory loss is on the horizon. (6) Usually recognition and assessment of people with suspected dementia in any setting (community, primary care or secondary care) requires a brief test of cognitive function or the use of informant questionnaires, or both. The brief cognitive evaluations needed are usually paper-and-pencil tests that are easy to administer, take no longer than 10 minutes to complete, involve major executive functions and yield an objective score. This final score is useful in determining which individuals need a more comprehensive evaluation. One of these brief cognitive tests is the Mini-Mental State Examination (MMSE), which has become the best-known and the most often used short screening tool for providing an overall measure of cognitive impairment in clinical, research and community settings, although it is now the subject of copyright issues. The Mini Mental State Examination correlates well with sophisticated neuropsychological test batteries and differentiates MCI from normal elderly or dementia. (7) : MMSE is a 30-question assessment of cognitive function that evaluates attention and orientation, memory, registration, recall, calculation, language and ability to draw a complex polygon. Advantages of the MMSE include rapid administration, availability of multiple language translations and high levels of acceptance as a diagnostic instrument amongst health professionals and researchers : the presence of cognitive decline is determined by the total score. Traditionally, a 23/24 cut-off has been used to select patients with suspected cognitive impairment or dementia . Currently no high-quality evidence exists to support pharmacologic treatments for MCI and studies of cholinesterase inhibitors showed no benefit on cognitive outcomes or reduction in progression from MCI to dementia . Moreover, there are no high-quality, long-term studies identifying pharmacologic or dietary agents that either improve cognition or delay progression in patients with MCI. (8)

The association between Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation, brain health, cognitive function and mood has been the subject of intensive research. Studies have demonstrated that Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation play a role in multiple aspects of brain physiology and biological activity with different mechanisms of action: increasing the fluidity of neuronal membranes , interacting directly with membrane bound proteins such as enzymes, ion channels and transporters, and glucose transporters thus influencing signal transduction and synaptic activity, as precursors to anti-inflammatory eicosanoids and inducing the synthesis of resolvins and neuroprotectins, with effects on endothelial function and therefore may impact cerebral blood flow and anti-apoptotic effects that can help to maintain healthy axons and synaptic structures. The pertinence of clarifying the effects Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation on brain health is underlined by findings that Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation consumption is low or very low in both developed and developing countries worldwide and modern western diets are notably deficient in Phosphatidylserine, Bacopa E.S., Choline, Homotaurine, Resveratrol, Group B vitamins and Folic acid supplementation (9-21).

Cogitix does not contain gluten and does not contain lactose. The use of Cogitix supplement, based on its characteristics, is hypothesized that it can give an advantage in improving cognitive performance in patients suffering from initial cognitive impairment.

AIM

The aim of this study is to evaluate the effectiveness of Cogitix supplementation in the control of cognitive disorders.

Primary endpoint is determine the effectiveness of Cogitix® in maintaining and/or improving cognitive performances investigated by means of tests (MMSE).

Secondary endpoints were determine the correct dosage of supplement and evaluate the tolerability the product

II. MATERIALS AND METHODS

Our clinical study consisted of a consecutive of 30 adult Caucasian patients (10 male, 20 female) attending at AMBULATORY FOR COGNITIVE DISORDERS AND DEMENTIA (CDCD), GERIATRIC HOSPITAL ASP IDR S. Margherita Pavia – University of Pavia (Italy).

Inclusion criteria was patients with cognitive disorders (MCI – Pre-MCI) and exclusion criteria was patients already in therapy with Anticholinesterasics, Anti-NMDA and other therapies with food supplements. Patients' clinical characteristics are in table 1.

They were treated with Cogitix 1 cp/day for 3 months. Informed consent was obtained from all individual participants included in the study.

Cognitive status assessment will be determined using test tools (neuropsychological tests: MMSE). Based on clinical data collected in a specific form data collection will also be evaluated whether within this selected patient population will be assisted to a reduction in blood chemistry parameters such as: Cholesterol, Triglycerides and Homocysteine. The assessments, through a special collection form data, will be made at the baseline (nosographic classification e neuro-geriatric visit) , and after 90 days.

Table 1: Characteristics of the study patients

Variable	N (%)
Total N= 30	
Sex	
Male	10 (33%)
Female	20 (67 %)
Age (mean-range)	65 (51 -75)
Diagnosis	
MCI	24 (80 %)
PreMCI	6 (20 %)

III. RESULTS AND DISCUSSION

Taking into account the total population medium MCI at baseline was 25,5 (24-28) while at the end of treatment the medium value was 26,3 (25-29). Patients' data are in table 2.

Considering the 24 patients with MCI diagnosis medium value at baseline was 24,9 (24-26) while at the end of treatment the medium value was 25,8 (25-27): in 16 there was an improvement (67%) by one or two points in the score , in 7 (29 %) the value has not changed and only in 1 patient the value dropped by one point.

When dividing the population by gender, greater improvement was seen in women (13 out of 17) than in men (3 out of 7).

If we analyze the data of 12 patients under the age of 65, 11 out of 12 had an improvement in the MCI score.

Considering the 6 patients with PreMCI diagnosis medium value at baseline was 27,7 (27-28) while at the end of treatment the medium value was 28 (27-29): in 2 there was an improvement (33%) by one point in the score , in 4 (67 %) the value has not changed .

Patient	Gender	Age	Diagnosis	MMSE1	MMSE2
GL	F	65	MCI	26	27
PM	F	60	MCI	24	26
CG	F	67	MCI	25	25
AB	M	51	MCI	26	25
LP	F	59	MCI	25	27
LG	F	59	PreMCI	28	29
PE	F	62	MCI	25	25
SG	M	68	MCI	25	26
SL	F	60	MCI	24	26
BL	M	68	MCI	25	26
PF	F	67	MCI	26	27
RS	F	62	PreMCI	27	28
AN	F	53	MCI	25	26
CP	F	58	MCI	25	26
SC	M	55	MCI	24	27

BV	F	64	MCI	24	26
LM	F	63	MCI	25	27
BF	F	70	PreMCI	28	28
MG	M	67	MCI	26	26
CA	F	65	MCI	24	25
EM	F	75	MCI	25	25
SC	M	68	MCI	24	25
AF	F	71	MCI	25	25
GE	F	75	MCI	25	26
BD	F	69	MCI	24	25
RM	M	66	PreMCI	27	28
EP	M	69	PreMCI	28	27
FP	F	75	MCI	26	25
AB	M	70	MCI	25	26
CD	M	73	PreMCI	28	28

Table 2 :Patient's data

Regarding the blood values detected an improvement was observed in all parameters: total cholesterol medium value at baseline was 210 mg/dl (176-260) while at the end of treatment medium value was 194,4 (160-224) : in 18 patients (60%) we have observed an improvement. triglycerides medium value at baseline was 170 mg/dl (127-224) while at the end of treatment medium value was 149 (120-189) : in 27 patients (90 %) we have observed an improvement.

homocysteine medium value at baseline was 19,7 μ mol/L (12-31) while at the end of treatment medium value was 15 μ mol/L (11-21) : in 23 patients (76 %) there was a drop in blood count.

Treatment was well tolerated (on a numerical scale from 1 to 10 the average score was 9,5 , range 8 -10) .The compliance of patients was optimal, no side effect was reported and no weight gain occurred.

In addition, 12 out of 30 patients (40%) reported an improvement in generalized fatigue and apathy which has had a positive impact on their daily lives.

Considering that in a growing elderly population mild cognitive impairment (MCI) are increasing in prevalence worldwide and that currently no high-quality evidence exists to support pharmacologic treatments, there is a need to find new therapeutic approaches, including natural ones, to reduce the risk of developing cognitive deficits.

The concept of mild cognitive impairment (MCI) was developed to describe the situation of abnormal scores on objective cognitive assessment with intact ability to maintain activities of daily living.

Thanks to specific tests it is possible to identify patients at risk of developing initial situations which, as they evolve, can lead to initial cognitive deficits.

One of these brief cognitive tests is the Mini-Mental State Examination (MMSE), which has become the best-known and the most often used short screening tool for providing an overall measure of cognitive impairment in clinical, research and community settings, although it is now the subject of copyright issues

In our study we treated 30 adult caucasian patients with Cogitix 1 cps/day for 3 months : patients have MCI score between 24 and 28 and have been evaluated with MMSE at baseline and at end of treatment.

Considering that , medium value at baseline was 24,9 and after 3 months has become 25,8 and that in 67% of patients there was an improvement , although not statistically significant, by one or two points in the score, we would like to conclude that this type of treatment could be useful in this patient setting.

Logically these preliminary data should be confirmed in subsequent studies where the dosage could be increased and the duration of treatment prolonged.

Moreover, on the basis of the results obtained, it would be worth designing a study that includes only patients under the age of 65 where it would be more logical to start the treatment.

The study also confirmed that the components contained in Cogitix, in a short period of treatment, to improve blood parameters such as cholesterol, triglycerides and homocysteine.

Also in this case it would be worth activating a subsequent confirmatory study using the product at a higher dosage and for a longer treatment period.

IV. CONCLUSION

Our study has that supplementation with Cogitix may be useful in the treatment of MCI without side effects and with good compliance of patients. In addition blood parameters such as cholesterol, triglycerides and homocysteine have improved in treated patients. Data from our study are encouraging to be confirmed by further investigations considering higher dosages, longer treatment periods and more selected population.

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