DOI: 10.1002/alz.041959



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## Dementia care research (research projects; nonpharmacological)/Therapeutic strategies and interventions

# Evaluation of the effectiveness of the neuro-nutraceutical SYNAID® on a broad-spectrum sample (subjects with dementia, cognitively preserved and with depression): Results of a 24-month prospective clinical trial

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## Abstract

**Background:** the increasing number of subjects with dementia in the world and the failure of drug therapies, has inspired the scientific community undertake new forms of intervention to tackle the disease such us primary prevention (reduction of risk factors, cognitive reserve). Neuro-nutraceutical research and resulting treatments are increasingly affirming, preventing or slowing down cognitive impairment; contributing to achieve neuroplasticity. The purpose of this study was to assess the efficacy and safety of neuro-nutraceutical SYNAID® (INPHA Duemila Srl) in patients with cognitive impairment (combination with anticholinerasic drugs) and in cognitively preserved subjects with or without anxiety and depression.

**Method:** Exclusion criteria: 1) psychiatric diagnosis; 2) severe sensory deficits. Inclusion criteria: 1) subjects with MCI (amnestic and vascular), 2) subjects with Alzheimer's dementia, with vascular dementia, with mixed dementia; 3) cognitively preserved subjects with or without anxiety and depressive disorders. The enrolled patients (280) were divided into 2 groups by open-randomised method: the treatment group (grT) with the administration of SYNAID® one tablet/day for 24 months and the control group (grC) that did not take the neuro-nutraceutical. The groups were analysed by Student and compared at baseline, 6, 12, 18, 24 months from the beginning of treatment. The cognitive outcome was evaluated by administration of the following tests: MMSE; CDR; CDT; RAVLT; FVL. The result of psychic state evaluated through CES-d, the result psycho-behavioural symptoms associated with dementia via NPI. Functional outcome via IADL scale. The quality of life outcome through QoL-SF12.

**Result:** grT compared to the grC showed a significant increase in scores at the MMSE, RAVLT, FVL, CDT, IADL and QoL-SF12 tests and a significant reduction in scores at CES-d and NPI. There were no side effects, no adverse events following the intake of neuro-nutraceuticals. The dropouts were 20 (9 grT and 11 grC).

**Conclusion:** The study demonstrates that prolonged intake of SYNAID® improves memory and other neuropsychological functions in cognitively preserved subjects (neuro-protective effect), and in patients with Alzheimer's and/or vascular dementia and in patients with mild cognitive impairment (MCI). Furthermore, significant improvements were found in the mood outcome, in the daily functional capabilities and in the quality of life outcomes in all treated subgroups.

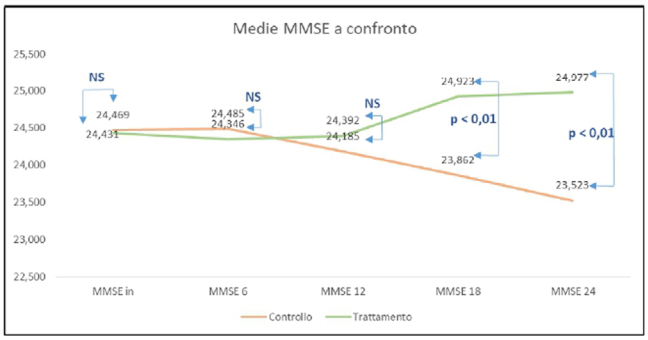


**FIGURA 1:** Andamento test MMSE effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 1**

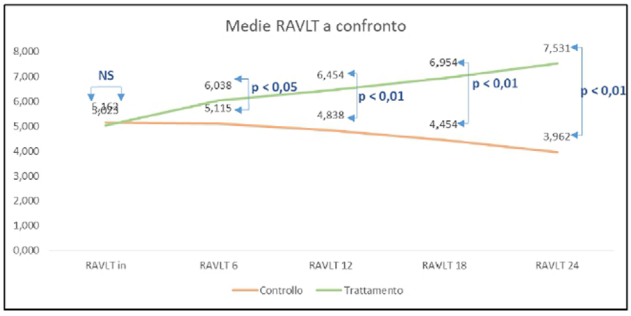


**FIGURA 2:** Andamento test RAVLT effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 2**

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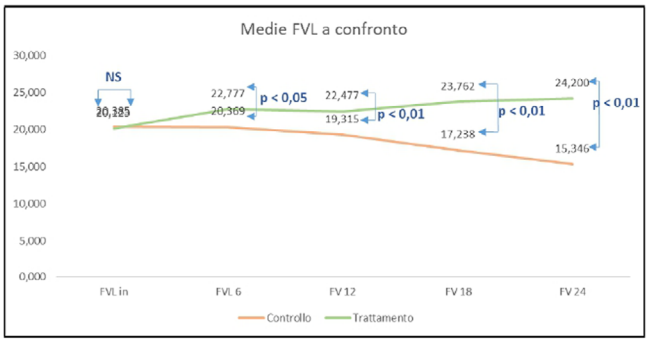


**FIGURA 3:** Andamento test FVL effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 3**

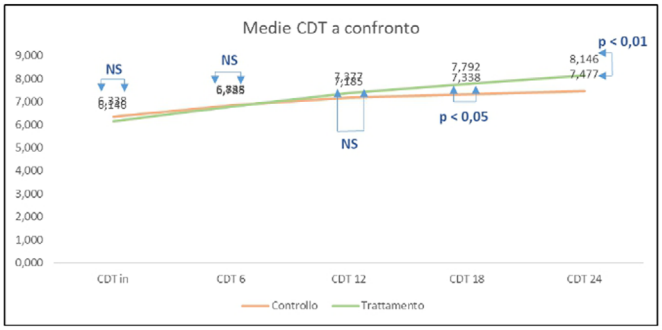


**FIGURA 4:** Andamento test FVL effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 4**

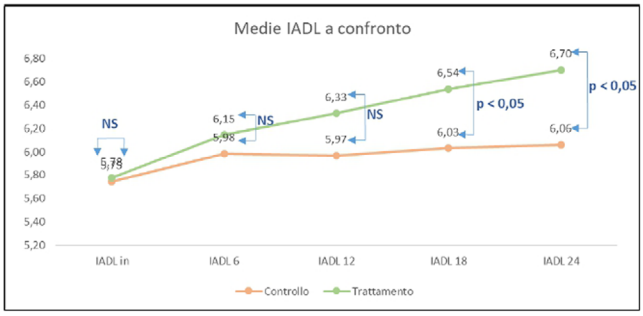


**FIGURA 5:** Andamento test IADL effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 5**

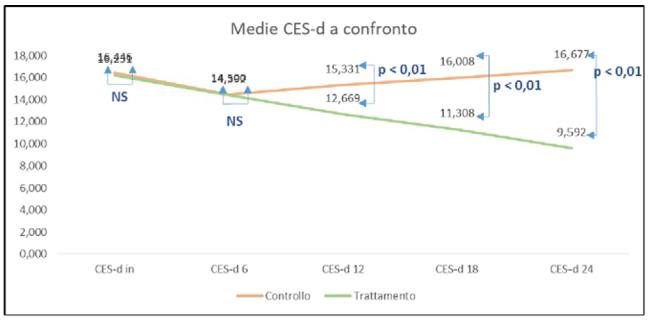


**FIGURA 6:** Andamento test CES-d effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 6**

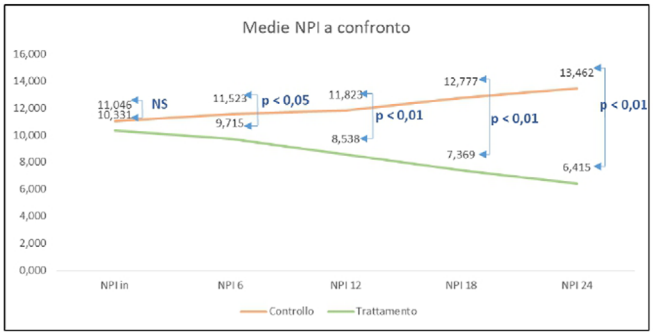


**FIGURA 7:** Andamento test NRI effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 7**

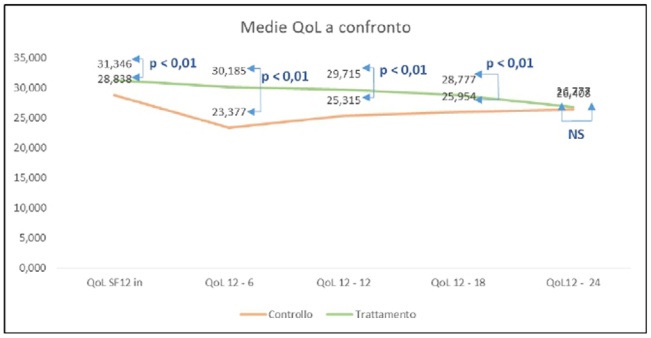


**FIGURA 8:** Andamento test QoL effettuato sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale

**FIGURE 8**

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## TABLE 1

| | CONTROLLO (N.130) | TRATTAMENTO (N.130) | *p-value* TRA I GRUPPI |
|---|---|---|---|
| **Sesso %** | 32% m; 68% f | 25% m; 75% f | |
| **Età media** | 70 | 70 | NS |
| **Scolarizzazione media** | 10,71 | 10,39 | NS |
| **Diagnosi** | 20% nor;<br>23% VD;<br>8% aMCI;<br>11% svMCI;<br>18% AD;<br>6% ans;<br>9% dep;<br>4% Mix | 19% nor;<br>25% VD;<br>9% aMCI;<br>9% svMCI;<br>18% AD;<br>5% ans;<br>11% dep;<br>4% Mix | |
| **CDR in entrata media** | 0,66 | 0,65 | NS |

**TABELLA 1:** Caratteristiche generali della popolazione studiata - Diagnosi: nor= normale; VD= demenza vascolare; aMCI= Mild Cognitve Impairment amnestico; svMCI= Mild Cognitive Impairment vascolare; AD= demenza di Alzheimer; ans= disturbo d'ansia; dep= disturbo depressivo; Mix= demenza di Alzheimer con demenza vascolare.

## TABLE 2

| **Media** | **MMSE in** | **MMSE 6** | **MMSE 12** | **MMSE 18** | **MMSE 24** |
|---|---|---|---|---|---|
| **Controllo** | 24,47 | 24,48 | 24,18 | 23,86 | 23,52 |
| **Trattamento** | 24,43 | 24,35 | 24,39 | 24,92 | 24,98 |
| | | | | | |
| **Media** | **RAVLT in** | **RAVLT 6** | **RAVLT 12** | **RAVLT 18** | **RAVLT 24** |
| **Controllo** | 5,16 | 5,12 | 4,84 | 4,45 | 3,96 |
| **Trattamento** | 5,02 | 6,04 | 6,45 | 6,95 | 7,53 |
| | | | | | |
| **Media** | **FVL in** | **FVL 6** | **FV 12** | **FV 18** | **FV 24** |
| **Controllo** | 20,38 | 20,37 | 19,32 | 17,24 | 15,35 |
| **Trattamento** | 20,12 | 22,78 | 22,48 | 23,76 | 24,20 |
| | | | | | |
| **Media** | **CDT in** | **CDT 6** | **CDT 12** | **CDT 18** | **CDT 24** |
| **Controllo** | 6,34 | 6,84 | 7,18 | 7,34 | 7,48 |
| **Trattamento** | 6,15 | 6,78 | 7,38 | 7,79 | 8,15 |
| | | | | | |
| **Media** | **IADL in** | **IADL 6** | **IADL 12** | **IADL 18** | **IADL 24** |
| **Controllo** | 5,75 | 5,98 | 5,97 | 6,03 | 6,06 |
| **Trattamento** | 5,78 | 6,15 | 6,33 | 6,54 | 6,70 |
| | | | | | |
| **Media** | **CES-d in** | **CES-d 6** | **CES-d 12** | **CES-d 18** | **CES-d 24** |
| **Controllo** | 16,45 | 14,50 | 15,33 | 16,01 | 16,68 |
| **Trattamento** | 16,23 | 14,39 | 12,67 | 11,31 | 9,59 |
| | | | | | |
| **Media** | **NPI in** | **NPI 6** | **NPI 12** | **NPI 18** | **NPI 24** |
| **Controllo** | 11,05 | 11,52 | 11,82 | 12,78 | 13,46 |
| **Trattamento** | 10,33 | 9,72 | 8,54 | 7,37 | 6,42 |
| **Media** | **QoL SF12 in** | **QoL 12 - 6** | **QoL 12 - 12** | **QoL 12 - 18** | **QoL12 - 24** |
| **Controllo** | 28,84 | 23,38 | 25,32 | 25,95 | 26,41 |
| **Trattamento** | 31,35 | 30,18 | 29,72 | 28,78 | 26,78 |

**TABELLA 2:** Andamento dei test effettuati sui volontari nel gruppo di controllo e di trattamento a tempo 0 (in), 6, 12, 18, 24 mesi dal basale.