

Study on the effects of a natural food supplement on memory and daily function in people with mild to moderate Alzheimer's disease

Submission date 01/07/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/07/2026	Overall study status Completed	☐ Protocol
Last Edited 30/07/2026	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

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Additional identifiers**Study information****Scientific Title**

Nutraceuticals in Alzheimer's disease

Acronym

NAD

Study objectives

The aim of this interventional study is to evaluate the effect of these nutraceutical compounds on the cognitive performance of a cohort of patients with mild-to-moderate Alzheimer's disease. Given the extensive neurological damage caused by Alzheimer's disease, our nutraceutical formulation, which is safe and composed of naturally occurring compounds with neurotrophic and anti-inflammatory properties, may help preserve the integrity of the extracellular matrix, modulate the production of pro-inflammatory cytokines, prevent neuronal degeneration, improve neurological function—particularly cognitive impairment, memory deficits, and depressive symptoms—and potentially delay disease onset and slow its progression.

Ethics approval required

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Ethics approval(s)

Approved 15/05/2023, Interprovincial Ethics Committee – Area 1, Apulia, Italy (c/o Ospedali Riuniti di Foggia-Via Pinto 71122, Foggia, 71122, Italy; +39 881 732464; segreteriacomitatoetico@ospedaliriunitifoggia.it), ref: 88/CE/2023

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Prevention, Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Mild cognitive impairment, early dementia

Interventions

Clove (*Syzygium aromaticum*) liquid extract: 42 mg/day, of which beta-caryophyllene 37.8 mg, terpenes 4.2 mg

- Myrrh liquid extract: 24 mg/day, of which furanodienes 19.2 mg, terpenes 4.8 mg

- Boswellia serrata powder: 42 mg/day, of which boswellic acids 27.3 mg, amyris 8.4 mg

- Microalgae oil extract: 1,853 mL/day, titrated 550 mg in DHA (1000 mg/day) and 3.1 mg in EPA (5.7 mg/day)

- Flavoring: lemon and sweet orange essential oils

The placebo consisted of: edible linseed oil, flavoring (lemon and sweet orange essential oils) as above. Patients were equally allocated to the two arms according to randomization

Duration is 6 months

Intervention Type

Supplement

Primary outcome(s)

1. Psychometric assessments measured using Clinical Dementia Rating (CDR) at baseline, 3 months, 6 months

2. Psychometric assessment measured using mini mental state examination (MMSE) at baseline, 3 months, 6 months

Key secondary outcome(s)

1. Depressive state measured using Zung score at baseline, 3 months, 6 months

2. Neurodegenerative biomarkers measured using light neurofilaments -ELISA method at baseline, 3 months, 6 months

3. Neurodegenerative biomarkers measured using amyloid beta-ELISA method at baseline, 3 months, 6 months

4. Neurodegenerative biomarkers measured using pTAU-ELISA method at baseline, 3 months, 6 months

Completion date

21/08/2024

Eligibility

Key inclusion criteria

Patients aged 65–85 years with cognitive impairment ranging from mild cognitive impairment to mild/moderate dementia, as assessed by the Clinical Dementia Rating (CDR) scale (scores 0.5–2)

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 Years

Upper age limit

85 Years

Sex

All

Total final enrolment

46

Key exclusion criteria

1. CDR scores <0.5 or >2
2. Recent stroke or transient ischemic attack
3. Unstable heart disease
4. Renal and hepatic failure
5. Oncologic patients
6. Inability to provide consent or refusing to provide informed consent

Date of first enrolment

18/07/2023

Date of final enrolment

21/06/2024

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Pharmaceutica San Marco

Funder(s)

Funder type

Funder Name
Pharmaceutica San Marco

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/07/2026	30/07/2026	Yes	No