ISRCTN99002302 https://doi.org/10.1186/ISRCTN99002302

Studying whether two nucleotide-yeast-based food supplements can help maintain cognitive function in adults

Submission date
12/02/2026

Recruitment status
No longer recruiting

Registration date
02/03/2026

Overall study status
Completed

Last Edited
02/03/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia is an illness that affects memory, concentration, clear thinking, learning and problemsolving. These changes can become strong enough to affect everyday life. This study aims to find out whether two yeastbased food supplements, which contain high levels of natural substances called nucleotides, can help improve thinking and memory in older adults who have mild cognitive impairment. Mild cognitive impairment means a person has some problems with memory or thinking, but they can still manage most daily activities.

Who can participate?
Adults aged 60 to 85 years can take part if they have been diagnosed with mild cognitive impairment using a questionnaire called the Montreal Cognitive Assessment. People with scores between 20 and 25 on this test are suitable for the study.

What does the study involve?
This study takes place at one centre and lasts for about six months. It is randomised and placebocontrolled, which means participants are placed by chance into one of three groups: one taking the RiboDIET supplement, one taking the RiboMIX SC supplement, or one taking a placebo with no active ingredient. Neither the participants nor the researchers know who is in which group until the end of the study.

Participants take one capsule a day between meals for 24 weeks. They visit the study site three times: at the start, at 90 days and at 180 days. At each visit, they complete tests that measure memory, thinking and general wellbeing. These tests are called the MiniMental State Examination, the Montreal Cognitive Assessment and the Short Form12.

What are the possible benefits and risks of participating?
The supplements used in this study are already allowed for use in food supplements in the European Union and have a long history of safe use. No side effects are expected. However, participants are monitored throughout the study. Any suspected problems would be reported through the national safety reporting system and shared with the Ethics Committee.

Participants may experience improvements in memory and thinking, but this cannot be guaranteed.

Where is the study run from?
COMEGEN Soc. Coop. Sociale, Viale Maria Bakunin 41, Naples, Italy.

When is the study starting and how long is it expected to run for?
The study is planned to run from June 2025 to January 2026.

Who is funding the study?
The study is funded by Prosol Srl, based in Madone, Italy.

Who is the main contact?
Alessandra Baldi, alessandra.baldi.alimenti@gmail.com>
Lorenza Francesca De Lellis, lo.delellis2@gmail.com

Contact information

Type(s)
Public, Scientific

Contact name
Ms Alessandra Baldi

ORCID ID
https://orcid.org/0000-0002-2877-9445

Contact details
Viale delle Medaglie d'oro, 305
Rome
Italy
0136
+39 (0)3483854114
alessandra.baldi.alimenti@gmail.com

Type(s)
Public, Scientific

Contact name
Dr Lorenza Francesca De Lellis

Contact details
Via Domenico Montesano, 49
Naples
Italy
80131
+39 (0)3883810763
lo.delellis2@gmail.com

Type(s)

Principal investigator

Contact name
Dr Matteo Laringe

Contact details
Viale Maria Bakunin, 41 (Parco S. Paolo)
Naples
Italy
80126
+39 81/6174566
comegen@comegen.org

Additional identifiers

Study information

Scientific Title
Study of the efficacy and tolerability of two food supplements based on yeast extract, RiboDIET® (obtained from Kluyveromyces fragilis) and RiboMIX SC (obtained from Saccharomyces cerevisiae), as dietary sources of nucleotides, for the maintenance of cognitive function: single-center, randomized, placebo-controlled, parallel-arm, double-blind clinical trial

Acronym
COGNITIVE-RIBO25

Study objectives
The study was aimed at evaluating the efficacy of two food supplements based on yeast extracts with a high nucleotide content for the improvement of cognitive function in subjects who had Mild Cognitive Impairment (MCI) diagnosed through the questionnaire score of the Montreal Cognitive Assessment Evaluate between 20 and 25, which literature data indicate to be particularly suitable for the identification of MCI status.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/04/2025, Comitato Etico Territoriale Campania 1 (Via Mariano Semmola - INT "Fondazione Giovanni Pascale", Naples, 80131, Italy; +39 81/ 17770131 - 132 - 130; comitatoetico@istitutotumori.na.it), ref: 4/25

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Maintenance of cognitive function in subjects diagnosed with Mild Cognitive Impairment (MCI).

Interventions
A single-center, randomized, placebo-controlled, parallel-arm, double-blind clinical trial was conducted with a treatment period of 24 weeks (approximately 6 months). Participants consumed one capsule daily, between meals, of either RiboDIET® (obtained from Kluyveromyces fragilis) or RiboMIX SC (obtained from Saccharomyces cerevisiae) or a placebo, according to their randomization group. To mantain the double-blind design, the treatments (food supplements and placebo) were made unrecognizable as the packaging was identical, and the dosage forms were the same in color, shape, weight and taste. Each subject of the three experimental groups, during and after administration of the nutritional supplements or placebo, underwent the evaluation of the primary and secondary endpoints. During the entire treatment period, participants were required to travel to the experimental site for their scheduled visits (t0-baseline, t1-after 90 days of treatment and t2-after 180 days of treatment). During the study, the subjects could not use the drugs as indicated in the exclusion criteria and had to promptly notify the doctor of the intake of drugs, and the latter evaluated the possible interruption of the study by the subject. Moreover, they could not use food supplements.

The randomization sequence was generated by a statistician using STATA 16 software (Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC), and subjects were assigned to each of the three treatment groups in a random and unpredictable manner using simple randomization (1:1:1 allocation ratio). This procedure minimizes the “selection bias”, i.e. systematic differences between the baseline characteristics of the groups being compared (prognostic and treatment response imbalance). The hiding of the randomization list protects the allocation sequence until assignment, and is stored in an inviolable place in the experimental center. Both the generation of the allocation sequence and the randomization list was separated through the use of sealed envelopes. These envelopes were prepared by a person not involved in the trial from a clinical point of view, must be opaque, sealed, stapled and numbered in order conforming to that of the randomization list, and subsequently stored in a sealed cabinet. The experimenter who enrolled the subjects, and who gave them one of the two treatments in comparison by opening the next envelope each time, remained unaware of the randomization list.

Intervention Type
Supplement

Primary outcome(s)

1. Cognitive functions measured using the Mini-Mental State Examination (MMSE) questionnaire and the Montreal Cognitive Assessment (MOCA) test at baseline (t0), after 3 months (t1) and after 6 months of treatment (t2)

Key secondary outcome(s)
1. General quality of life measured using the Short Form-12 (SF-12) test at baseline (t0) and after 6 months of treatment (t2)

Completion date
20/01/2026

Eligibility

Key inclusion criteria
1. Between the ages of 60 and 85 years
2. Able to understand and sign the informed consent
3. Able to understand and comply with the requirements of the protocol
4. Negative HIV test
5. Score between 20 and 25 on the Montreal Cognitive Assessment (MoCA)
6. Total score of 14 on Instrumental Activities of Daily Living (IADL) plus Activities of Daily Living (ADL)
7. Geriatric Depression Scale (GDS) score between 0 and 5
8. Score between 0 and 4 on the Generalized Anxiety Disorder questionnaire (GAD7)
9. Not taking and not having recently taken drugs, including antidiabetics and drugs acting on the nervous system such as antidepressants, anxiolytics or opiates
10. Not taking antibiotics or not having taken antibiotics in the last four weeks, or in the last six months depending on the intensity and duration of the antibiotic treatment

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
60 Years

Upper age limit
85 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. With age under 60 or over 85 years
2. Individuals with Montreal Cognitive Assessment (MoCA) scores below 20 or above 26
3. Individuals who did not show a willingness to collaborate

4. Individuals who had difficulty travelling to the study site on time
5. Individuals considered unsuitable by the investigator due to other medical conditions that were incompatible with enrolment or required medication (for example: active systemic diseases, diabetes, neurological or psychiatric conditions, including cognitive disorders that made it impossible to complete questionnaires)
6. Individuals with HIVacquired immunodeficiency
7. Individuals with severe visual or hearing impairments
8. Individuals with known allergies to any ingredients in the investigational products (active or placebo)
9. Individuals who abuse alcohol, drugs, nicotine, caffeine or theine
10. Individuals who were taking medication

Date of first enrolment
11/06/2025

Date of final enrolment
20/06/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Prosol Srl

Funder(s)

Funder type

Funder Name
Prosol Srl

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available