

Probiotic supplementation with *Leuconostoc mesenteroides* OL3621 and cognitive performance in community-dwelling older adults

Submission date 04/03/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/03/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/03/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Plain English summary of protocol not provided at time of registration

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title

A randomized, double-blind, placebo-controlled pilot trial evaluating the effect of *Leuconostoc mesenteroides* OL3621 on ACE-III cognitive performance and gut–redox biomarkers in community-dwelling older adults.

Study objectives

This is an exploratory pilot study; secondary outcomes are hypothesis-generating.

Ethics approval required

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Ethics approval(s)

Approved 23/06/2022, University Bioethics Committee for Scientific Research (ul. Mikołowska 72A, Katowice, 40-065, Poland; +48322075433; komisjabioetyczna@awf.katowice.pl), ref: Resolution No. 6/2022

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Basic science, Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Influence of *Leuconostoc mesenteroides* OL3621 on cognitive performance in community-dwelling older adults.

Interventions

Randomization: computer-generated permuted-block method (block size = 4) to ensure a 1:1 allocation ratio.

Group assignments: double blinded. A trained research assistant was responsible for assigning participants to one of the two groups:

1. Probiotic group: tested formulation had a pharmaceutical form of capsules, containing *Leuconostoc mesenteroides* OL3621 (deposit number: KPD 1758) lyophilizate, maltodextrin, magnesium stearate and silicon oxide ($1,4 \times 10^{10}$ CFU per day; taken orally as a 370 mg capsule containing 7×10^9 CFU/capsule twice a day: morning and evening)
2. Placebo group: placebo capsules contained equal mass of fulfillment, while probiotic was substituted by maltodextrin (taken orally as a 370 mg capsule twice a day: morning and evening)

Intervention Type

Supplement

Primary outcome(s)

1. Cognitive ability measured using Addenbrooke's Cognitive Examination III (0–100) at baseline and week 12

Key secondary outcome(s)**Completion date**

15/11/2023

Eligibility**Key inclusion criteria**

1. Age between 55 and 85 years
2. Free from diagnosed Alzheimer's disease (as defined by NINCDS-ADRDA criteria)
3. Free from Parkinson's disease (according to UK PDS BB criteria)
4. Mini-Mental State Examination (MMSE) score above 24

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

55 Years

Upper age limit

85 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Clinically confirmed diabetes
2. Active substance abuse
3. Unstable ischemic heart disease
4. Uncontrolled hypertension
5. History of severe allergic reactions, or any other serious medical conditions that, in the investigator's opinion, might interfere with study procedures or supplement tolerability
6. Use of psychotropic drugs
7. Use of antibiotics and probiotics during the past 3 months
8. Major changes in diet in the last 3 months

Date of first enrolment

01/06/2023

Date of final enrolment

15/07/2023

Locations

Countries of recruitment

Poland

Sponsor information

Organisation

Olimp Laboratories Sp. z o.o.

Funder(s)

Funder type**Funder Name**

Narodowe Centrum Badań i Rozwoju

Alternative Name(s)

National Centre for Research and Development, The National Centre for Research and Development, Polish National Center for Research and Development, National Center for Research & Development, NCBR, NCBiR, NCRD

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Poland

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available