

Effect of fortified dairy products on mild cognitive impairment

Submission date 17/01/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/01/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to investigate whether milk products supplemented with milk fat globule membrane (MFGM), ketogenic fatty acids plus choline can delay cognitive decline in patients with mild cognitive impairment and an increased risk of Alzheimer's disease when compared to a control milk product. The findings from this study may have important implications for the development of dietary interventions to prevent or manage Alzheimer's disease.

Who can participate?

Adults aged 60 years or over with mild cognitive impairment

What does the study involve?

Participants use the study products daily for 12 months, attend three or four visits to the study center, and provide three or four blood samples and one cheek swab sample.

What are the possible benefits and risks of participating?

Participants may benefit from dairy-based snack products for free for 12 months and personal results from the blood samples and cognitive tests. Possible risks include inconvenience related to blood sampling and their body weight may slightly increase.

Where is the study run from?

Valio Ltd (Finland)

When is the study starting and how long is it expected to run for?

October 2023 to May 2026

Who is funding the study?

Valio Ltd (Finland)

Who is the main contact?

Dr Anu Turpeinen, anu.turpeinen@valio.fi

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

NutriSen 2.0

Study information

Scientific Title

Randomised controlled 12-month trial on the effects of dairy products fortified with brain nutrients on cognitive function in subjects with mild cognitive impairment

Acronym

NutriSen 2.0

Study objectives

Milk products supplemented with brain nutrients delay cognitive decline in subjects with mild cognitive impairment when compared to control milk products.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/12/2023, HUS Regional Committee on Medical Research Ethics (Stenbäckinkatu 9, Helsinki, 00290, Finland; +358 (0)40 359 4618; eettinen.toimikunta@hus.fi), ref: HUS 7906 2023

Study design

Randomized placebo-controlled double-blinded parallel intervention trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Mild cognitive impairment

Interventions

12-month parallel two-group intervention (active and control). Eligible participants are randomly assigned in block sizes of four to two groups (1:1), stratified by sex (male, female) and age (under 80 years, over 80 years).

The treatment group consumes a dairy product containing milk protein and brain nutrients daily for 12 months.

The control group consumes a dairy product containing milk protein and vegetable oil daily for 12 months.

Study visits are at baseline, 6 months and 12 months. Cognitive functioning is studied using the MoCa test, the severity of cognitive impairment is rated using the Clinical Dementia Rating scale, sum of boxes, walking speed is measured and a blood sample is collected for the analysis of biomarkers of neuronal degeneration.

Intervention Type

Mixed

Primary outcome(s)

Cognitive functioning studied using the Montreal cognitive assessment (MoCa) validated questionnaire at baseline, 6 months and 12 months

Key secondary outcome(s)

Current secondary outcome measures as of 25/06/2025:

1. The severity of cognitive impairment measured using the Clinical Dementia Rating scale, sum of boxes at baseline, 6 months and 12 months
2. Tau protein, neurofilament light chain and beta-amyloid measured from blood using ELISA /single molecule array (SIMOA) kits at baseline, 6 months and 12 months

3. Total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides analysed from plasma at baseline and 12 months with an enzymatic method.

4. Walking speed measured using 10-meter walk test at baseline, 6 months and 12 months

Previous secondary outcome measures:

1. The severity of cognitive impairment measured using the Clinical Dementia Rating scale, sum of boxes at baseline, 6 months and 12 months

2. Tau protein, neurofilament light chain and beta-amyloid measured from blood using ELISA /single molecule array (SIMOA) kits at baseline, 6 months and 12 months

3. Walking speed measured using 10-meter walk test at baseline, 6 months and 12 months

Completion date

31/05/2026

Eligibility

Key inclusion criteria

Participant inclusion criteria as of 29/04/2024:

1. Adults, age 60 years or over with knowledge of the Finnish language

2. Mild cognitive impairment as detected by MoCA at baseline, i.e., score ≤ 25 points OR apolipoprotein E (apoE) genotype 4/4 or 3/4

3. Willing to consume allocated study products

4. Must sign informed consent

Previous participant inclusion criteria:

1. Adults, age 60 years or over with knowledge of the Finnish language

2. Mild cognitive impairment as detected by MoCA at baseline, i.e., score ≤ 25 points

3. Willing to consume allocated study products

4. Must sign informed consent

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

60 years

Sex

All

Total final enrolment

155

Key exclusion criteria

1. MMSE (mini mental state evaluation) ≤ 24 at baseline
2. Alzheimer's disease
3. Milk allergy
4. Participation in another drug or dietary trial
5. Unable to walk independently
6. Severe frailty (Clinical Frailty Scale >6)
7. Abuse of drugs, alcohol or medications
8. Other diagnosis besides mild cognitive impairment affecting directly cognitive status, such as Parkinson's disease, schizophrenia, traumatic brain injury, under- or malnutrition, vitamin B12 deficiency, or severe depression
9. Severe psychiatric or neurologic condition decreasing patient's compliance

Date of first enrolment

29/01/2024

Date of final enrolment

20/05/2024

Locations

Countries of recruitment

Finland

Study participating centre

Valio Ltd

Meijeritie 6

Helsinki

Finland

00370

Sponsor information

Organisation

Valio Ltd,

Funder(s)

Funder type

Industry

Funder Name

Valio Ltd

Alternative Name(s)

Valio Ltd, Valio Oy

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Finland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Anu Turpeinen (anu.turpeinen@valio.fi).

IPD sharing plan summary

Available on request