ISRCTN14450697 https://doi.org/10.1186/ISRCTN14450697

Effect of fortified dairy products on mild cognitive impairment

Submission date	Recruitment status	[X] Prospectively registered
17/01/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/01/2024	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/06/2025	Mental and Behavioural Disorders	[X] 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)
Principal investigator

Contact name
Dr Reijo Laatikainen

Contact details
Booston Ltd, Viikinkaari 6
Helsinki
Finland
00780
+358 (0)40 7171753
reijo.laatikainen@booston.fi

Type(s)
Public, Scientific

Contact name
Dr Anu Turpeinen

Contact details
Valio Ltd, Meijeritie 6
Helsinki
Finland
00370
+358 (0)50 3981108
anu.turpeinen@valio.fi

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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