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Can N-PEP-12 dietary supplementation improve the attention, cognition, and mental wellbeing of middle-aged and older healthy adults?

Submission date
21/03/2023

Recruitment status
No longer recruiting

Registration date
03/04/2023

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
The global older population is growing, particularly in developed countries. Typical mental performance is a vital aspect of quality of life and wellbeing. The basic mechanisms involved in attention, perception, memory, and learning are referred to as cognitive functions. Most studies on healthy individuals suggest that attention, working memory, and information processing speed deteriorate gradually between the ages of 20 and 60. Previous research has found that the peptides in N-PEP-12 exhibit qualities similar to those seen in naturally occurring peptide growth factors, such as increasing neurite outgrowth, improving neuronal survival, and protecting against metabolic stress. The study will assess the impact of N-PEP-12 dietary supplementation on attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints.

Who can participate?
Middle-aged and older healthy adults with subjective cognitive function complaints

What does the study involve?
Four visits for clinical evaluation, over a period of 180 days. The subjects will be part of three groups (45mg N-PEP-12, 90mg N-PEP-12, and placebo (lactose).

What are the possible benefits and risks of participating?
The potential benefit of N-Pep-12 is the positive impact on the attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints. The main risk for patients is developing adverse events, which are carefully assessed in order to establish a detailed safety profile of the intervention.

Where is the study run from?
Foundation of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN) (Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii) (Romania)

When is the study starting and how long is it expected to run for?
October 2022 to December 2025

Who is funding the study?
SSNN (Romania)

Who is the main contact?
Dr Nicoleta Jemna, nicoleta.jemna@brainscience.ro (Romania)

Contact information

Type(s)
Principal investigator

Contact name
Prof Fior-Dafin Muresanu

ORCID ID
https://orcid.org/0000-0002-9536-1153

Contact details
Mircea Eliade 37
Cluj Napoca
Romania
400364
+40 756 027 452
dafinm@ssnn.ro

Type(s)
Scientific

Contact name
Dr Nicoleta Jemna

Contact details
Mircea Eliade 37
Cluj Napoca
Romania
400364
+40 756 027 452
nicoleta.jemna@brainscience.ro

Type(s)
Public

Contact name
Dr Nicoleta Jemna

Contact details

Mircea Eliade 37
Cluj Napoca
Romania
400364
+40 756 027 452
nicoleta.jemna@brainscience.ro

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
FSNANO08032022

Study information

Scientific Title
The impact of N-PEP-12 dietary supplementation on attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints

Acronym
N-HANCE

Study objectives
This study assesses the impact of N-PEP-12 dietary supplementation on attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2022, Ethics Committee UMF ''Iuliu Hatieganu'' Cluj Napoca (8 Victor Babes Street, Romania; 0264-597256; etica.cercetare@umfcluj.ro), ref: AVZ 294

Study design
Randomized placebo-controlled double-blind study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints

Interventions

Previous research has found that the peptides in N-PEP-12 exhibit qualities similar to those seen in naturally occurring peptide growth factors, such as increasing neurite outgrowth, improving neuronal survival, and protecting against metabolic stress. This study's rationale is based on these previously documented properties that have the potential to impact the attentional performance, cognition, and mental wellbeing of middle-aged and older healthy adults with subjective cognitive function complaints.

Dietary supplement: MemoProve/Cebrium
Memoprove and Cebrium are two brands of the N-PEP-12 peptide-based nutritional supplement available in film-coated pills or capsules.

Control: Lactose, placebo (identical to intervention)

Study Group 1: 45mg N-PEP-12
Study Group 2: 90mg N-PEP-12
Study Group 3: Placebo (Lactose)

Visit 1 - (Study day 0) - Screening - will consist of the baseline assessment - demographic data and the patient's medical history and risk factors will be collected. Also, the informed consent will be signed and the patient will be randomized.
Visit 2 - (Study day 30) will be an efficacy evaluation.
Between Visit 1, Visit 2 and Visit 3 - (Study day 90) patients shall receive their treatment, based on the group they have been allocated at baseline: Placebo, 45mg N-PEP-12 or 90 mg N-PEP-12.
Between Visit 3 and Visit 4 - (Study day 180) the patients shall continue the treatment with the two N-PEP-12 groups unchanged and the initial Placebo group receiving 90 mg N-PEP-12.

This study will be conducted under double-blind conditions in order to keep investigators, other study personnel, and patients unaware of treatment allocation. A unique randomization number will be assigned to patients who fulfill the inclusion and exclusion criteria (patient number). This number is the next available randomization number in ascending order from 001 to, for example, 999 of a predefined randomization plan, and it identifies the treatment assigned to a unique patient in a double-blind manner, from a random list generated in advance by a biometrician chosen by the coordinator. Patients will be randomly allocated to the study groups in a 1:1:1 ratio.

A sealed random code list and sets of sealed envelopes are prepared. Based on the random list sealed, opaque randomization/emergency envelops will be provided as follows:
1. To the study center to break blinding if reasonable suspicion of harm to the patient exists
2. To the person assigned to prepare the ready-to-use-infusion
3. To the study coordinator

When the randomization envelopes are opened, the person who opened them will date (day, hour) and sign them. Any premature unblinding of the Investigational Product should be noted as soon as possible and explained to the Coordinator. The complete study will be unblinded after the database is closed and the analysis populations are identified.

Intervention Type

Supplement

Primary outcome(s)

The three following primary outcome variables will be measured using the Test of Attentional Performance (TAP) at 0, 30, 90 and 180 days:
1. Alertness (phasic alertness)
2. Working Memory (difficulty level 3)
3. Divided Attention

Key secondary outcome(s))
The following secondary outcome variables will be measured at 0, 30, 90 and 180 days:
1. IQ measured using the Wechsler Adult Intelligence Scale (WAIS-IV) - Digit Span Forward, Backward (DSF, DSB)
2. Stress measured using the Perceived Stress Scale (PSS)
3. Mood measured using the Brief Mood Introspection Scale (BMIS)
4. Sleep quality measured using the Sleep Quality Scale (SQS)
5. Health-related quality of life measured using the EuroQol EQ-5D-5L questionnaire

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Sign the informed consent form and fully understand the test content, process and possible adverse reactions, and be able to complete the study according to the test plan requirements
2. Aged ≥50 years old or ≤75 years old, male or female (including the boundary value)
3. Male body weight ≥50kg, female body weight ≥45kg, and 18.0 ≤BMI ≤29.9 kg/m2
4. No clinically significant cognitive impairment (MoCA > 25)
5. Self-reported subjective cognitive complaints
6. Literacy to complete tests

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
50 years

Upper age limit
75 years

Sex
All

Total final enrolment
276

Key exclusion criteria
1. History of drug abuse or alcohol abuse (drank more than 14 units/week of alcohol: 1 unit =285 ml beer, 25 ml spirits or 100 ml wine)
2. Gastric sleeve patients
3. History of drug abuse within 5 years prior to screening, or urine drug screening test was positive
4. Other clinically major diseases, such as decompensated, in the investigator's judgment (such as neuropsychiatric system, cardiovascular system, urinary system, digestive system, respiratory system, metabolic endocrine system, blood system, skin diseases, immune diseases, tumors, etc)
5. Participation in another clinical trial within 3 months prior to enrollment
6. Pre-existing and active major neurological disease
7. Injury of writing hand influencing cognitive or other outcome measures, in the investigator’s judgment.

Date of first enrolment
03/03/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Romania

Study participating centre
RoNeuro Institute for Neurological Research and Diagnostic
Mircea Eliade Street, 37
Cluj-Napoca
Romania
400364

Sponsor information

Organisation
Foundation of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN)
(Fundatia pentru Studiul Nanoneurostiintelor si Neuroregenerarii)

Funder(s)

Funder type
Research organisation

Funder Name
Foundation of the Society for the Study of Neuroprotection and Neuroplasticity

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2		27/06/2024	No	No