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Testing plant-derived micronutrients (polyphenols) as food supplements to prevent /improve cognitive decline in ageing people

Submission date
12/07/2022

Recruitment status
No longer recruiting

Registration date
19/07/2022

Overall study status
Completed

Last Edited
01/08/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cognitive impairment and attention deficit are normal biological processes related to ageing. The aim of this study is to demonstrate the effect of a food supplement containing COGNIGRAPE™ in preventing the unavoidable cognitive impairment that occurs.

Who can participate?
Subjects aged 55 years old and over with possible cognitive impairment

What does the study involve?
Participants are asked to attend clinic visits at screening and after 14, 28, and 84 days of COGNIGRAPE™ intake. During the screening visit, the principal investigator informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects then fix the date for the first visit. During the first visit, the subjects will answer all the questions on the medical questionnaires given by the principal investigator. The participants are then randomly allocated to use the COGNIGRAPE™ food supplement or the placebo (dummy) product for 84 days. After 90 minutes of the first product intake subjects are asked to undergo the “Test delle campanelle”. All the measurements/assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 84 days with two intermediate checks at 14 and 28 days.

What are the possible benefits and risks of participating?
The potential benefit of participating is an improvement of cognitive function. All the ingredients included in the product are approved for their use in food supplements and are used at the permitted concentration. The potential risks associated with the use of the product are assumed to be mild to moderate and are not expected to pose a risk to health. Risks associated with the procedures involved in this study are judged as minor. All precautions will be taken to ensure that the risk is the lowest possible. All the measurements carried out are minimally invasive and no side effects are expected from the measurement process.

Where is the study run from?
Nutratech srl spin-off Università della Calabria (Italy)

When is the study starting and how long is it expected to run for?
April 2022 to March 2023

Who is funding the study?
BIONAP srl (Italy)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
H.E.HU.HV.NMM00.120.00.00_IT0002671/22

Study information

Scientific Title
Assessment of the efficacy of the food supplement COGNIGRAPE™ in preventing the cognitive impairment in an aged population: double-blind, randomized, placebo-controlled clinical study.

Acronym
COGNIGRAPE

Study objectives
The trial is aimed to evaluate the efficacy of the test product in improving the cognitive functions/performance of healthy male and female individuals

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2022, Comitato Etico Di Ateneo (CEA) Università della Calabria (Via Pietro Bucci Cubo 15/D - 87036 Arcavacata di Rende (CS), Italy; +39 (0)984 496940; cea@unical.it), ref: not provided

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Elderly subjects with a score ≥ 24 on the Mini-Mental State Examination (MMSE)

Interventions
COGNIGRAPE™ is a standardized powder extract from red grape juice containing high concentrations of active grape substances such as anthocyanins and proantocyanidins. Half of the test subjects will be randomized to receive the test product (250 mg in 2 capsules per day, in the morning after breakfast, with a glass of water) and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on subject entry number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.

Participants are asked to attend clinic visits at screening and after 14, 28, and 84 days of product intake. During the screening visit, the principal investigator informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The participants are then randomly allocated to use the COGNIGRAPE™ food supplement or the placebo (dummy) product for 84 days. All the measurements/assessments are carried out using non-invasive procedures. The total duration of each visit is 30 minutes. The study duration is 84 days with an intermediate check 90 minutes after the first product intake and after 14, 28, and 84 days of product use.

Intervention Type
Supplement

Primary outcome(s)
1. Attention deficit measured using the "test delle campanelle" 90 minutes after the first product intake
2. Cognitive impairment (problems with thinking, communication, understanding, and memory) measured using the Mini-Mental State Examination (MMSE) questionnaire at 14, 28, and 84 days

Key secondary outcome(s))
1. Neuropsychological Status measured using the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) questionnaire at screening and after 14, 28, and 84 days
2. Sustained and selective attention measured using a continuous performance test (CPT) questionnaire at screening and after 14, 28, and 84 days
3. Different cognitive domains (attention, memory, executive functions, and perceptive and praxis abilities) measured using the Short Neuropsychological Examination version 2 (ENB-2) questionnaire at screening and after 14, 28, and 84 days
4. Mood status measured using the Profile of Mood States (POMS) questionnaire at screening and after 14, 28, and 84 days

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Healthy individuals aged 55 years old and over
2. Reading, understanding, and signed approval of the informative consent
3. Available and willing to follow the procedure of the study protocol
4. The eligible subjects will be recruited for the study after examination and the establishment of a basic level of parameters, including scoring ≥ 24 on the Mini-Mental State Examination (MMSE)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Aged 54 years old and under
2. Clinical history with the relevant presence of any disorder or administration of drugs/food supplements that can potentially interfere with the treatment under study
3. Consumption of any memory-improving drugs or food supplements that can interfere with the CNS activity
4. Consumption of food or beverage enriched in polyphenols 24 hours before each visit
5. Smokers
6. Lack of compliance, defined as not using the correct CognigrapeTM dose or placebo for >1 week, and inability to give informed consent
7. BMI > 30
8. Pregnant and lactating women
9. Excessive alcohol consumption (> 5 drinks/week)
10. A history of drug, alcohol and other substance abuse
11. Known food intolerance or food allergy
12. Involved in a clinical or food study within the previous month
13. Unstable medical diseases (cardiac arrhythmias or ischemia, uncontrolled hypertension and hypotension, diabetes mellitus, kidney failure)
14. A history of paralysis or cerebral vascular accident
15. Active cancers or on chemotherapy
16. Other factors that limit their ability to cooperate during the study

Date of first enrolment
01/07/2022

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech srl spin-off Università della Calabria
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Sponsor information

Organisation
BIONAP srl

Funder(s)

Funder type
Industry

Funder Name
BIONAP srl

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, four digits, and a letter. Access to the study raw data is allowed only to the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/09/2024	01/08/2025	Yes	No