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Testing a food supplement for reducing stress on students

Submission date	Recruitment status	[ ] Prospectively registered
14/01/2024	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/01/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2024	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is aimed to investigate the ability of a food supplement to influence the stress response in terms of mood in healthy adults students attending university examination sessions. The test product (SelectSIEVE ® Zen) is a dietary supplement based on plant extracts of lemon balm, elderberry and sacred basil, botanicals known to improve mental well-being. The first is widely used to promote sleep and reduce stress and anxiety while the second is a powerful adaptogen that can help the body react to any type of stress. Finally, elderberry shows excellent antioxidant properties to support cognitive functions.

Who can participate?
Adult male and female healthy volunteers aged between 18 and 40 years old.

What does the study involve?
There are two treatment periods (active and placebo) of around 28 days each, with a washout period of around 60 days. Participants take the products during two different examination sessions. They start taking the food supplement 2 weeks before the first exam they will have in the session and will continue to take it during the whole examination session for a total of 28+7 days of product intake. Each volunteer will attend at least two exams for each session (with an interval of a maximum of 3 weeks between the two exams). The expected duration of participation in the study is around 4 months, starting from the first examination session (28+7 days of product intake, 60 days of wash-out, 28+7 days of product intake).

What are the possible benefits and risks of participating?
The potential benefits associated with the use of the product are related to an improvement in quality of life in terms of mood and stress in healthy adult students during university exam sessions.
The product is manufactured according to the applicable national and international rules and regulations. All ingredients included in the product formula are approved for use in food/food supplements. The potential risks associated with the use of the product are related to both subjective and objective adverse events (AEs) (e.g., bloating, diarrhea, stomach ache). The occurrence of AEs related to individual susceptibility to specific ingredients in the product could be related to a biological phenomenon that is not avoidable and cannot be considered as AEs

due to product intake. Potential risks are assumed to be mild to moderate and are not expected to pose a risk to human health. Risks associated with the procedures involved in this study are judged as minor. All the measurements carried out will not be invasive and no side effects are expected from the measurement process except for blood withdrawal. Bleeding, bruising, lightheadedness (especially after donating blood), rash, skin irritation from tape or adhesive from an applied bandage, and soreness can be experienced after blood withdrawal.

Where is the study run from?
ROELMI HPC Srl (Italy)

When is the study starting and how long is it expected to run for?
July 2023 to April 2024

Who is funding the study?
ROELMI HPC Srl (Italy)

Who is the main contact?
Dr Ileana De Ponti, ileana.deponti@complifegroup.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Ileana De Ponti

ORCID ID
https://orcid.org/0000-0003-0579-7904

Contact details
Via Guido Rossa 1
Garbagnate Milanese
Italy
20024
+39 (0)3316841438
ileana.deponti@complifegroup.com

Additional identifiers

Protocol serial number
H.E.HU.HV.NEU00.030.00.00_NT0000712/23 Rev.02

Study information

Scientific Title
Clinical trial aimed to evaluate the efficacy of a food supplement in managing stress in university students: a double-blind, placebo-controlled, cross-over study

Acronym

StressZen

Study objectives
The study product is a dietary supplement based on plant extracts of lemon balm, elderberry and sacred basil, botanicals known to improve mental well-being. The first is widely used to promote sleep and reduce stress and anxiety while the second is a powerful adaptogen that can help the body react to any type of stress, both endogenous and exogenous. Finally, elderberry shows excellent antioxidant properties to support cognitive functions.

This study aims to investigate the ability of a food supplement to influence the stress response in terms of mood in healthy adult students attending university examination sessions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/08/2023, Independent Ethics Committee for Non-Pharmacological Clinical Investigations [Comitato etico indipendente per le indagini cliniche non farmacologiche] (Via XX Settembre 30/4, Genova, 16121, Italy; +39 (0)10 5454842; ssinf@messaggipec.it), ref: 2023/11

Primary study design
Interventional

Study design
Single-centre randomized double-blind placebo-controlled cross-over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stress

Interventions
The active food supplement intervention (SelectSIEVE ® Zen) is a dietary supplement based on plant extracts of lemon balm, elderberry and sacred basil, botanicals known to improve mental well-being. The first is widely used to promote sleep and reduce stress and anxiety while the second is a powerful adaptogen that can help the body react to any type of stress, both endogenous and exogenous. Finally, elderberry shows excellent antioxidant properties to support cognitive functions.

The placebo food supplement intervention is green food colour, maltodextrin and magnesium stearate.

At the screening visit, eligible participants will be enrolled according to a previously defined randomization list in a two-treatment period (active and placebo or vice versa) of around 28 days each (28+7), alternated with a washout period of around 60 days.
The participants will take the products in cross-over during two different examination sessions. Participants will start taking the food supplement 2 weeks before the first exam they will have in the session (1 cps/per day with a glass of natural water in the evening before going to bed)

and will continue to take it during the whole examination session for a total of 28+7 days of product intake. Each volunteer will attend at least two exams for each session (with an interval of a maximum of 3 weeks between the two exams).

A restricted randomization list is 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 was stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence was concealed from the in-site study director in sequentially numbered, opaque and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry number in the study). The A4 sheet reporting the unblinded treatment was folded to render the envelope impermeable to intense light. A masked allocation sequence was prepared for the staff delivering the intervention based on the subject entry number in the study.

Intervention Type
Supplement

Primary outcome(s)
1. Mood is assessed using the Profile of Mood State (POMS) at T2 (the day before the first examination) and T3 (the day before the second examination), and after the washout period, at T5 (the day before the first examination) and T6 (the day before the second examination).
2. The perception of stress is assessed using the Perceived Stress Scale (PSS) at T2 (the day before the first examination) and T3 (the day before the second examination), and after the washout period, at T5 (the day before the first examination) and T6 (the day before the second examination).
3. Cortisol level is measured by salivary swab at T1 (2 weeks before the first examination), T2 (the day before the first examination) and T3 (the day before the second examination), and then after a washout period (around 60 days), at T4 (2 weeks before the first examination), T5 (the day before the first examination) and T6 (the day before the second examination).
4. Product efficacy and other product properties are assessed using a self-assessment questionnaire 24 hours after the second examination at each exam session (T3 + 24 h and T6 + 24 h)

Key secondary outcome(s)
Product safety assessed using adverse events notification throughout the study

Completion date
15/04/2024

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Caucasian ethnicity
3. Age more than 18 years old (included)
4. Attending university and will have at least two exams per examination session
5. Not addicted to smoking and drinking
6. Have not been recently involved in any other similar study (at least 2 months of wash-out)
7. Under effective contraception (oral/not oral) therapy
8. Able to comply with the protocol and follow the protocol’s constraints and specific requirements

9. Commitment to use during the entire study period only the products to be tested
10. Commitment to not use products likely to interfere with the product to be tested
11. Commitment to not vary the normal daily routine (i.e. lifestyle, physical activity, etc.)
12. Subject agrees to not use any food supplement until study completion
13. Avoiding consumption of any food supplement or drugs that can interfere with CNS activity for at least 4 weeks prior to the study start
14. Willing to avoid alcohol assumption for the 24 hours prior to the test visits
15. Aware of the study procedures and have signed an informed consent form and a privacy policy
16. Available and willing to follow the procedure of the study protocol
17. Subjects registered with the National Health Service (NHS)
18. Subjects certifying the truthfulness of the personal data disclosed to the investigator

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Does not meet the inclusion criteria
2. Pathological psychological conditions related or not related to stress
3. Known hypersensitivity or allergy to one of the active ingredients
4. Any condition that the principal investigator deems inappropriate for participation
5. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
6. Subject with known or suspected food intolerance or food allergy
7. Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications
8. Pharmacological treatments (antidepressant, anxiolytic, psychotropic drugs, etc) known to interfere with the tested product
9. Severe concurrent diseases
10. Subjects with a history of drug, alcohol and other substance abuse
11. Subjects with active cancers or on chemotherapy
12. Having a diagnosed chronic disease (blood, cardio-vascular, psychiatric, neuro-degenerative, diabetes, cancer, liver, gastric, kidney etc) and/or under medical treatment

13. Clinical history with relevant presence of any disorder or administration of drugs/food supplement that can potentially interfere with the treatment under study
14. Subjects not able to be contacted in case of emergency
15. Subjects taking part or planning to participate to another clinical study during the study in the same or another investigation centre

Date of first enrolment
11/12/2023

Date of final enrolment
22/01/2024

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech srl spin-off Università della Calabria
Via P. Bucci snc
Rende
Italy
87036

Sponsor information

Organisation
ROELMI HPC Srl

Funder(s)

Funder type
Industry

Funder Name
ROELMI HPC Srl

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository on Complife/Nutratech 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 in a pdf file that is 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 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's raw data is allowed only by 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