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Probiotic bacteria for work-related stress

Submission date
28/04/2021

Recruitment status
No longer recruiting

Registration date
29/04/2021

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Stress in the workplace can occur when employees feel they do not have the support of supervisors and/or colleagues and little control over work processes. This condition can affect the quality of work and life of employees. Worldwide, work-related stress is perceived as a burden. The existence of two-way communication between the brain and the gut, known as the gut-brain axis, has long been recognized. Recent advances have revealed that an imbalance of the gut microbiota (microorganisms) (dysbiosis) is present in many neurological diseases. Consequently, the importance of maintaining a balanced microbial community in the regulation of the gut-brain axis is also of fundamental importance in stress management. Therefore, the aim of this study is to find out whether two probiotic strains, Lactobacillus reuteri PBS072 and Bifidobacterium breve BB077, are effective as dietary supplements in the management of stress and sleep disorders.

Who can participate?
Adult workers aged 18-65

What does the study involve?
Participants are randomly allocated to take one capsule (active or placebo) per day for a period of 30 days, followed by a 4 weeks (30 days) wash-out. At the end of the wash-out period, participants take one capsule again per day for 30 days as the second treatment. Sleep quality and mood are assessed at the start of the study and after 30 days.

What are the possible benefits and risks of participating?
Participants may benefit from the regulation of gut microbiota achieved by the probiotics and eventually a reduction in work-related stress symptoms. No major risks from participating in the study are expected.

Where is the study run from?
University of Calabria (Italy)

When is the study starting and how long is it expected to run for?
December 2020 to August 2021

Who is funding the study?
University of Calabria (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
7582

Study information

Scientific Title
Efficacy of Lactobacillus reuteri PBS072 and Bifidobacterium breve BB077 in the prevention and treatment of work-related stress symptoms: a cross-over randomized trial

Acronym
ProWRS

Study objectives
Probiotics are able to counteract dysbiosis, which is linked to altered behavioral responses to stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2021, Comitato Etico di Ateneo, University of Calabria (P. Bucci, 87036, Rende (CS), Italy; +39 (0)984 496940; cea@unical.it), ref: 0007582

Study design
Single-center interventional double-blinded randomized controlled cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Work-related stress

Interventions
A cross-over clinical study will be carried out to evaluate the efficacy of the probiotic formulation composed of 2 × 10(9) CFU Lactobacillus reuteri PBS072 and 2 × 10(9) CFU Bifidobacterium breve BB077 in the prevention and/or treatment of work-related stress symptoms in employees through oral intake. During the study, the volunteers will take one capsule of product, active or placebo (first treatment) per day for a period of 30 days, followed by a 4 weeks (30 days) wash-out. At the end of the wash-out period, each volunteer will take one capsule again per day for 30 days of the second treatment. The two treatments will be randomly assigned.

Randomization: central computerized simple randomization
Intervention: 30 days Treatment A + 4 weeks (30 days) wash-out + 30 days Treatment B + 15 days follow-up

Intervention Type
Supplement

Primary outcome measure
Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and after 30 days

Secondary outcome measures

Subjective mood measured using the Profile of Mood States (POMS) at baseline and after 30 days

Overall study start date
12/12/2020

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Adults aged between 18 and 65 in good health
2. Willing to use only the products to be tested throughout the study period
3. Willing not to use similar products that could interfere with the product to be tested
4. Willing not to change normal daily routine (e.g. lifestyle, physical activity, etc)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
33

Key exclusion criteria
1. Subjects with known or suspected sensitization to one or more ingredients of the formulation in question
2. Subjects unable to communicate or collaborate with the investigator due to language problems, intellectual disability, or impaired brain function
3. People suffering from psychiatric disorders such as schizophrenia, or psychotic disorders such as bipolar disorder or substance use disorder
4. Use of herbal remedies or psychotropic drugs intended for depression taken in the last 2 weeks before baseline or during the study
5. Receive counseling or psychological therapy at the beginning or during the study
6. Participation in any clinical trial in the previous 3 months prior to baseline
7. Subjects who plan to take antibiotics during the treatment period

Date of first enrolment

25/03/2021

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Italy

Study participating centre
Università della Calabria
via P. Bucci
Rende (CS)
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87036

Sponsor information

Organisation
University of Calabria

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Sponsor type
University/education

Website
http://www.unical.it

ROR
https://ror.org/02rc97e94

Funder(s)

Funder type
University/education

Funder Name
Università della Calabria

Alternative Name(s)
Università della Calabria Campus di Arcavacata, University of Calabria, University of Calabria - Arcavacata Campus, Universidad de Calabria, UNICAL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal and presentation to scientific congresses within 1 year from study end.

Intention to publish date
31/08/2022

Individual participant data (IPD) sharing plan
Trial data will not be made available due to Italian regulations on data protection. Data will be held at DFSSN – University of Calabria, Rende, Italy.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes
Protocol file			04/05/2021	No	No
Results article		20/04/2023	12/06/2023	Yes	No