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The effect of 8 weeks probiotic supplementation on sleep quality in adults aged 18 years and over

Submission date
05/11/2025

Recruitment status
Not yet recruiting

Registration date
20/11/2025

Overall study status
Ongoing

Last Edited
03/02/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Good quality sleep can be linked to good gut health. Several compounds that are produced by the bacteria in our gut play crucial roles in regulating physiological functions which are linked to sleep. This study aims to assess if consuming a probiotic supplement for 8 weeks can impact sleep quality. The study will use several parameters to quantify sleep quality including questionnaires and the wearing of an activity watch that tracks sleep patterns.

Who can participate?
We are looking to recruit adults aged from 18 to 65 years who are dissatisfied with their current sleep. We are looking for a specific group of people to take part in this project. This means that not everyone is eligible to take part. Exclusion criteria include:
1. Individuals who use any supplement or medication to support sleep.
2. Individuals who have allergies to any foods or supplements
3. Women who are pregnant, trying to become pregnant or lactating
4. Individuals who have history of gastrointestinal disease or conditions
5. Individuals who have used antibiotics within the last 1 month
6. Individuals who have any clinical condition which could impact sleep such as pulmonary, cardiovascular disorders or chronic pain.
7. Individuals who have used opioids or other drugs which could impact digestive transit within the last 1 month
8. Individuals who have been diagnosed with a clinical sleep disturbance
9. Individuals who live in an environment where there are external disturbances of sleep patterns such as living in a noisy environment or caring for small children
10. Night shift workers

What does the study involve?
If participants decide to take part in the study, they will register their interest through the TrialFlare app. Study documents will then be made available to them along with a pre-screening questionnaire. Participants will provide full informed consent and complete an eligibility questionnaire to determine eligibility based on the inclusion/exclusion criteria. If eligible,

participants will be included in the study and a research pack will be sent to their home address. Not everyone will be eligible. Participants who do not meet the criteria to join the study will be notified via the application.
Once participants have completed the screening process, they will be allocated to either the probiotic or placebo arm of the study. To ensure fairness, neither participants nor the researchers will know which treatment has been allocated until the study is completed. The tub containing the capsules will be coded with a letter. This is called blinding and helps prevent bias, meaning that the results of the study are less likely to be influenced by anyone's expectations or preferences.
When screening and randomisation have taken place, a research pack will be delivered to each participant's home address. This pack will include all the relevant equipment and information for the study to take place.
The package will include:
1. One activity watch
2. 12 saliva sample kits
3. Two stool sample kits
4. Two sample return packages for samples
5. Supplement
6. Study information sheet
7. Sampling instructions

Once the research pack has arrived, participants will be ready to start the study on a day of their choosing. The study will include an observation week and eight weeks of supplementation, running for a total of nine weeks. Please see the diagram below for a timeline of the study.
Firstly, participants will set up their activity watch using the instructions provided in the research pack. They will wear this watch for the duration of the study. Participants will also log into the Trialflare app using the details submitted during the screening process. When the smartwatch is set up and connected to the Trialflare app, the observation week will begin.
During the observation week, participants will wear the smartwatch 24 hours a day and collect stool and saliva samples. They will choose two consecutive days within this week to complete these samples. For the saliva samples, participants will place a cotton swab under the tongue for 1–2 minutes before sealing it in a tube. They will collect saliva samples immediately upon waking, then again 15 and 45 minutes later. Stool samples will be collected using a provided collection kit, which entails defecating into a collection tub and transferring part of the stool into a sample tube. Detailed instructions on how to complete both sample types will be included in the research pack.
At the end of the observation week, participants will be notified by the app to complete questionnaires about sleep, diet, and general wellbeing. These will all be completed through the application. Participants will then begin taking one supplement every morning for eight weeks.
Several different factors will be assessed during the study using questionnaires:
1. Diet will be assessed at the beginning, midpoint, and end of the study using the EPIC-FFQ questionnaire, which asks about the frequency of consumption of various foods.
2. Sleep quality will be assessed using the Pittsburgh Sleep Quality Questionnaire, which asks about sleep duration, quality, and conditions that may have affected sleep.
3. Gut symptoms will be assessed at the beginning and end of the study through a questionnaire asking about changes in flatulence, stool frequency, stool consistency, and bloating.
4. General health and anxiety will be assessed using the GAD-7 questionnaire, which asks about problems experienced over the previous two weeks.
5. Quality of life will be assessed through a questionnaire asking about concentration, mood, and positivity.
6. Participants will complete a weekly compliance check questionnaire so researchers can confirm continued participation and adherence to the study's timeline and guidelines.

7. Female participants will also complete menstrual cycle questionnaires to record their cycle phase at different points in the study. These questionnaires include questions about the start of the last menstrual cycle and discharge. This is an important aspect of the study as menstrual cycle phases can influence sleep.
After completing the 8-week supplementation period, participants will repeat the saliva and stool samples as done at the beginning of the study.
Once participants have completed these final samples, they will have fully completed the study and will be entitled to receive a £100 voucher. Participants may also keep their activity watch.

What are the possible benefits and risks of participating?
Benefits:
Participants will further our knowledge of the interaction between gut health and sleep. To express our thanks for the time given by participants, upon completion of the study they will receive a £100 Amazon voucher. Participants will also be able to keep the Garmin activity watch they wore throughout the study

Risks:
Consuming probiotics may cause mild, short-term side effects such as gas, bloating, or abdominal cramps. These symptoms are generally mild and typically resolve within a few days to a week.
It is not intended that participation in this research study will cause any discomfort or harm to participants. Participants will be asked to wear a Garmin watch for the duration of the study, including while sleeping. This may cause slight discomfort if it is not something they are accustomed to. Participants will also be required to complete both saliva and stool samples in their homes; however, neither of these procedures should cause any physical discomfort. Clear and precise instructions will be provided by the research team on how to complete both sample collections.
Female participants will be asked to complete a questionnaire about their menstrual cycle, which will include questions about the type of discharge they are experiencing. These questionnaires may feel intrusive. Participants can be assured that the questionnaire will be completed through an online form and that there will be no need to discuss any of the responses directly with the research team. The data submitted will be linked only to each participant’s identification number and cannot be traced back to them by anyone outside the research team.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
October 2025 to June 2026

Who is funding the study?
Sacco S.R.L. (Italy)

Who is the main contact?
Anthony Watson, Anthony.Watson@Newcastle.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Anthony Watson

ORCID ID
https://orcid.org/0000-0001-6124-9182

Contact details
School of Biomedical, Nutritional and Sports Science
Faculty of Medical Science
Newcastle Upon Tyne
United Kingdom
NE1 8ST
+44 (0)1912089003
Anthony.watson@newcastle.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ProSleep

Study information

Scientific Title
The effect of 8 weeks probiotic supplementation on sleep quality in adults

Acronym
ProSleep

Study objectives
Good quality sleep can be linked to good gut health (Smith et al., 2019). Several compounds that are produced by the bacteria in our gut play crucial roles in regulating physiological functions which are linked to sleep. This study aims to assess if consuming a probiotic supplement for 8 weeks can impact sleep quality. The study will use several parameters to quantify sleep quality including questionnaires and the wearing of an activity watch that tracks sleep patterns.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/10/2025, Faculty of Medical Sciences Ethics Committee (Faculty of Medical Sciences, Newcastle Upon Tyne, NE1 8ST, United Kingdom; +44 (0)191 2089003; fmsethics@ncl.ac.uk), ref: 62953

Study design
Between subjects placebo controlled, double blind, randomised controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Healthy adults with dissatisfaction with their current sleep

Interventions
An 8-week placebo-controlled intervention where participants will be randomised to either a placebo or active treatment regime. Participants will be randomised with the use of a Latin square. Treatment groups will be stratified for age and gender.

The active treatment is a probiotic sleep mix. This is a a food supplement containing corn starch, cellulose, magnesium stearate and a proprietary probiotic sleep mix.

The control treatment is a capsule which contains the same ingredients and the experimental treatment but without the probiotic sleep mix

Intervention Type
Supplement

Primary outcome(s)
Sleep quality measured using the Pittsburgh Sleep Quality Index at baseline and weeks 2, 4, 6, and 8 post supplementation

Key secondary outcome(s))
1. Sleep and physical activity measured using an actiwatch device worn on the non-dominant wrist for the duration of the study. Mean weekly data will be used for analysis. Outcomes will include:
1.1. Sleep onset latency
1.2. Total sleep time (recorded minutes asleep over entire sleep period)
1.3. Number of awakenings
1.4. Wake after sleep onset (recorded minutes awake during the entire sleep period following sleep onset)
Measured at baseline, weeks 1, 2, 3, 4, 5, 6, 7, and 8 post supplementation
2. Depression and anxiety measured using the Patient Health Questionnaire and General Anxiety Disorder questionnaires at baseline and weeks 2, 4, 6, 8 post supplementation
3. Digestive health assessed using the Gastrointestinal Symptom Rating Scale and Bristol Stool Chart at baseline and weeks 2, 4, 6, and 8 post supplementation
4. Quality of life measured using a series of questions and electronic visual analogue scales (including concentration, general mood, positivity etc) at baseline and weeks 2, 4, 6, 8 post dose

Other pre-specified outcome measures:
5. Habitual diet measured using the Epic Norfolk Food Frequency Questionnaire at baseline and 4, 8 weeks post supplementation
6. Menstrual cycle phase measured using the Menstrual Phase Identification Questionnaire

(MPIQ) in women only at baseline and weeks 2, 4, 6, and 8, post supplementation
7. Demographics and lifestyle questionnaires at baseline
8. Self-reported anthropometric measurements including height and weight at baseline and 8 weeks post supplementation
9. Compliance with study protocol qualitatively evaluated by questionnaire at baseline and weeks 1, 2, 3, 4, 5, 6, 7, and 8 post supplementation
10. Stool microbiome measured using 16s rRNA sequencing at baseline and 8 weeks 8 post supplementation
11. Saliva cortisol measured using enzyme-linked immunosorbent assay at baseline and 8 weeks 8 post supplementation

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 to 65 years
2. Adults who are dissatisfied with their current sleep

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Individuals who report any sleep-related supplement use such as Ashwagandha, Magnesium, Calms, Nytol etc.
2. Allergies to any foods
3. Pregnant, trying to become pregnant or lactating
4. History of gastrointestinal disease or conditions
5. Use of antibiotics within the last 1 month
6. Any clinical condition which could impact sleep such as pulmonary and cardiovascular disorders.

7. Use of opioids or other drugs which could impact digestive transit within the last 1 month
8. Clinical sleep disturbance
9. External disturbances of sleep patterns such us living in a noisy environment or caring for small children
10. Night shift workers

Date of first enrolment
01/04/2026

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Newcastle University
School of Biomedical, Nutritional and Sports Science
Faculty of medical science, Dame Margaret Barbour Building
Newcastle Upon Tyne
England
NE1 8ST

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type

Industry

Funder Name
Sacco S.R.L.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Anthony Watson (anthony.watson@newcastle.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes