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An exploratory study investigating how perceived stress is associated with physical symptoms such as poor sleep, abdominal discomfort, and increased susceptibility to colds among office workers.

Submission date	Recruitment status	[X] Prospectively registered
11/12/2025	Recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
18/12/2025	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
16/12/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stress has become a significant health concern among working populations in Europe. Indeed, various factors such as work-related pressure, interpersonal relationships, and long working hours overlap, expose many people to chronic stress. The present study aims to investigate the relationships between perceived stress and associated physical symptoms in European office workers. Furthermore, based on the findings obtained, we will also explore a subgroup of office workers who are characterized by high levels of perceived stress and a tendency to develop physical symptoms. This exploratory approach will provide foundational data for the design of future interventional studies of probiotics to prevent or mitigate stress-related symptoms, thereby contributing to the maintenance and improvement of health and quality of life in working populations.

Who can participate?
Healthy volunteer office workers, aged 20 to 65 years inclusive, who are willing and capable to complete a daily electronic diary during the 6-week study period.

What does the study involve?
Approximately 150 volunteers will be screened. During the screening visit, an informed consent will first be signed. Afterwards, information will be collected and eligibility will be checked to evaluate if the participants are eligible to be included in the study. A total of 75 healthy office workers will be included in the study. The study period will last 6 weeks and involve 4 visits (including the screening visit). Visits will be conducted every 2 weeks.
For all the enrolled participants:
• Blood samples and saliva samples will be collected (Visit 2 and Visit 4)
• Electronic questionnaires will be completed by the participants (Visit 1, 2 and 4)
• Vital signs will be measured (visit 1)

• Assessment of upper respiratory tract infections symptoms by physician (visit 2, 3, 4)
• (Serious) Adverse Events will be collected and tracked (everyday)

What are the possible benefits and risks of participating?
There are no direct benefits expected for the participants. The goal is to better understand the impact of perceived stress on sleep, abdominal symptoms and Upper Respiratory Tract Infections symptoms and thus to offer better insights in the future.
The taking of blood (around 26 ml of blood) may (rarely) cause pain, bleeding, bruising or infection localised around the injection site. Similarly, some participants may feel dizzy or even faint during the procedure. The staff who take the blood will do all they can to keep these discomforts to a minimum.

Where is the study run from?
This study is being led by Yakult Honsha European Research Center for Microbiology VOF, with help from Harmony Clinical Research (CRO) in Flanders, Belgium.

When is the study starting and how long is it expected to run for?
January 2026 to April 2026.

Who is funding the study?
Yakult Honsha, Japan

Who is the main contact?
1. Mr Kazunori Suda, kazunori.suda@yher.be
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Perceived stress and its impact on sleep, abdominal symptoms, and cold symptoms: An exploratory study in office workers.

Acronym
YHER25-STR

Study objectives
The primary objective of this study is to characterise the relationships between perceived stress and stress-related physical symptoms (sleep quality, gastrointestinal symptoms and upper respiratory tract infection symptoms) in European office workers. Secondary objectives are to examine how these symptoms differ across levels of perceived stress; to explore associations between perceived stress, hormonal markers (e.g. cortisol, noradrenaline) and immune function parameters (e.g. number and activity of immune cells); and to identify a subgroup of office workers with high perceived stress and a tendency to develop physical symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/11/2025, Committee for Medical Ethics UZA-UA (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 3 821 38 97; ethisch.comite@uza.be), ref: 7965

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Perceived stress and stress-related symptoms (sleep disturbance, abdominal symptoms, common cold symptoms).

Interventions
This is an observational cohort study (specifically, with a short-term prospective cohort) without therapeutic procedures in office workers. Venous blood samples and saliva samples are collected for biomarker analysis related to stress and immune function. No therapeutic or behavioral intervention is administered.

Intervention Type
Other

Primary outcome(s)
1. The association between perceived stress levels and qualiy of sleep, abdominal symptoms and symptoms of URTIs measured using questionnaires at week 2 and 6

Key secondary outcome(s))
1. The association between salivary cortisol levels and qualiy of sleep, abdominal symptoms and symptoms of URTIs measured using ELISA and questionnaires at week 2 and 6

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. A female or male participant, aged 20 to 65 years inclusive at the time of screening
2. Healthy office workers as defined in the below definition:
2.1. An individual who has continuously lived in Europe for at least the past five years.
2.2. An individual who works a minimum of 4 days per week and commutes to the office at least 3 days per week (excluding those whose home is considered their office).
2.3. Individuals with reduced working hours, are eligible if they work at least 60% of full time hours. (For instance, an individual in the following scenario would be accepted: Monday and Tuesday – full days, Wednesday and Thursday – half days, and working in the office on Monday, Tuesday, and Wednesday.)
2.4. An individual who is deemed to spend more than half of their working hours each day engaged in desk work.
2.5. Individuals working night shifts are excluded from the study. Only those who work day shifts are considered eligible to participate.
3. Willing and capable to complete a daily electronic diary during the 6-week study period.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
20 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. High IPAQ activity level at screening.
2. Known difficulty providing saliva and blood samples.
3. Participant suffering from pollinosis, chronic rhinitis or asthma.
4. Participant suffering from active periodontitis or gingivitis
5. Participant being an active smoker/ vaper at the time of the Screening visit or actively smoking/ vaping in the past six months (more than 5 cigarettes per day).
6. Females of child-bearing potential who are pregnant or planning to become pregnant during the study duration.
7. History of a diagnosed mental illness or sleep disorders.
8. Participant suffering from serious liver, kidney, lung or gut diseases (excluding Irritable Bowel Syndrome (IBS)).
9. Receiving current medical treatment, except if stable (at the discretion of the investigator) on the medication for at least the past six months.

10. Regularly consuming probiotics or fermented milk (more than twice a week)
11. Taking drugs or supplements within the past three months that might affect the outcome of the study, such as anti-depressants, anti-psychotics, anti-anxiety medications, anti-insomnia medication, corticosteroids (including topical), melatonin, St. John's Wort, anti-histamines, and tryptophan.
12. History of influenza vaccination or infection within the past month, or the plan to be vaccinated during this study.
13. Being deemed ineligible for this study by a physician, based on blood pressure, pulse rate, or other reasons.

Date of first enrolment
06/01/2026

Date of final enrolment
19/03/2026

Locations

Countries of recruitment
Belgium

Sponsor information

Organisation
Yakult Honsha European Research Center for Microbiology VOF

Funder(s)

Funder type

Funder Name
Yakult Honsha

Alternative Name(s)
Yakult

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date