ISRCTN12762846 https://doi.org/10.1186/ISRCTN12762846

Effect of antioxidants on stress, work fatigue, and metabolic syndrome in employees of a private corporation in Mexico City

Submission date 04/03/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/04/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/05/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Elvia Pérez Soto

ORCID ID
https://orcid.org/0000-0002-5673-0825

Contact details
National School of Medicine and Homeopathy, National Polytechnic Institute
Guillermo Massieu Helguera 239
Ciudad de México
Mexico
07320
5557296000 ext. 55571
elvperezs@ipn.mx

Additional identifiers

Study information

Scientific Title

Effect of Apple polyphenols, carotenoids, and anthocyanins on stress, work fatigue, and metabolic syndrome in employees of a private corporation in Mexico City

Acronym
BIOSTRESSMET

Study objectives
To evaluate the effect of antioxidant supplements as a preventive and therapeutic strategy against stress, work fatigue, oxidative stress, inflammation and metabolic syndrome in workers of a private corporation subjected to a high workload.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/08/2025, Bioethics Committee of Escuela Nacional de Medicina y Homeopatía-IPN (Guillermo Massieu Helguera # 239, Col. La Escalera., Ciudad de México, 07320, Mexico; +1 5557296000 ext. 55596; cbioetica.enmh@ipn.mx), ref: CBE/002/2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Work-related stress, work-related fatigue, and metabolic syndrome

Interventions
Oral administration Dietary supplements
Randomisation will be computer-generated (Excel) by an independent researcher. Participants will be randomly allocated into one of four parallel groups. Each group will receive a specific intervention for 6 months, administered twice daily (5 mL in the morning and 5 mL in the evening, after meals) orally.
• Group 1: Dietary Supplement 2.0 Marine Algae (40 mg astaxanthin, 13.2 mg fucoxanthin, 84 mg apple polyphenols).

• Group 2: Dietary Supplement 2.1 Marine Algae Premium (166 mg anthocyanins, 194.8 mg total xanthophylls, 125 mg apple polyphenols).
• Group 3: Dietary Supplement 3.0 Astaxanthin special formula (500 mg/day from Haematococcus pluvialis).
• Group 4 (control): Placebo consisting of purified water, citric acid, sorbic acid, allulose, and flavoring.

The study will follow a double-blind design, ensuring that neither the investigators nor the participants are aware of the allocation of the intervention.

Intervention Type
Supplement

Primary outcome(s)
1. Work-related stress measured using Validated stress assessment questionnaire (IMSS test and Work Stress Questionnaire) at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period)

2. Work-related fatigue measured using Fatigue Severity Scale- Work Adaptation to the Mexican workin population at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period).

3. Hair Cortisol Concentrations measured using Competitive immunoassay at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period)

Key secondary outcome(s)
1. Biochemical markers (glucose, total lipids, total cholesterol, triglycerides, HDL-cholesterol, non HDL cholesterol, LDL-cholesterol, atherogenic index, urea, Blood urea nitrogen, creatinine, uric acid, HbA1c measured using Acredited medical diagnostic laboratory at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period)

2. Inflammatory cytokines (TNF-α, IL-1β, IL-6, IL-10) measured using Enzyme-linked immunoassay (ELISA) at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period).

3. Oxidative stress biomarkers measured using Analytical techniques (Ferric reducing ability of plasma or FRAP assay, lipoperoxidation, nitric oxide and enzymatic activity of catalase) at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period).

4. Gene expression related to metabolism and inflammation (Nrf2/ARE, NFκB, AP1, HNF4, P38 MAPK 1, ACM1,2,3) measured using Real-time PCR at T0 (prior to supplementation), T1 (months after starting supplementation), and T2 (6 months after starting supplementation: end of intervention period).

Completion date
28/11/2025

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. Male or female workers
3. Full-time employees working on-site at a private corporate office in Mexico City
4. At least 1 year of continuous in-person work prior to study commencement
5. Fixed work shift
6. Minimum of 1 year of work experience
7. Mentally healthy status
8. Body Mass Index (BMI) > 20 kg/m² (WHO classification)
9. Signed informed consent

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
20 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
95

Key exclusion criteria
1. Presence of neurodegenerative conditions
2. Current pregnancy or lactation
3. Diagnosis of hypothyroidism
4. Psychiatric disorders
5. Dyed hair (to avoid bias in biomarker analysis)
6. Use of alternative dietary supplements prior to study participation

Date of first enrolment
16/05/2025

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
Mexico

Sponsor information

Organisation
Instituto Politécnico Nacional

ROR
https://ror.org/059sp8j34

Funder(s)

Funder type

Funder Name
Secretaría de Investigación y Posgrado, Instituto Politécnico Nacional

Alternative Name(s)
Secretaría de Investigación y Posgrado del Instituto Politécnico Nacional, SIP, IPN

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Funder Name
BioMaussan

Funder Name
Biodesarrollos Valmex SA de CV

Results and Publications

Individual participant data (IPD) sharing plan
Yes, anonymized individual participant data will be shared upon reasonable request to the principal investigator, after publication of the main results. Data will include baseline characteristics, primary and secondary outcomes, and biomarker measurements. Access will be granted to qualified researchers for academic purposes only.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			23/03/2026	No	No
Other publications	Pilot, exploratory, quasi-experimental intervention	27/04/2026	18/05/2026	Yes	No
Protocol file		19/03/2026	23/03/2026	No	No