Cellular stress and effects on mitochondrial DNA

Submission date 16/07/2025	Recruitment status Recruiting	Prospectively registered
		Protocol
Registration date	Overall study status	Statistical analysis plan
18/07/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
18/07/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

This study looks at how levels of a specific type of DNA, called cell-free mitochondrial DNA (ccf-mtDNA), change in female students after they go through stressful lab situations. When ccf-mtDNA levels go up, it usually means the body is going through a kind of stress response that affects the mitochondria (the parts of cells that produce energy). During this response, mitochondria are exposed to more harmful molecules called reactive oxygen species (ROS), which can damage them. Although there isn't a lot of long-term research yet, repeated exposure to this kind of stress over time may lead to problems with how mitochondria work, which could eventually cause disease.

Who can participate?

Female healthy volunteers between the ages of 18 and 30 years

What does the study involve?

Participants are randomly allocated to listen to either a mindfulness meditation audio or an educational podcast and then undergo a lab stressor. There are also two blood draws that occur with an interval of 70-80 minutes.

What are the possible benefits and risks of participating?

Possible benefits of this study are that it reinforces positive health practices. Furthermore, the scholarly community may be informed by the assessed associations between stress exposure responses and measures of cellular stress through ccf-mtDNA analyses. The potential psychological risks may be from the IAPS photos, which are emotion-evoking pictures systematically derived to elicit moderate levels of psychological stress. The potential risks of IAPS photo viewing have been carefully considered, and all images have been carefully screened and approved by the clinical research psychologist (P. Ritvo) clinically supervising this study. The blood draw study phase may also be associated with a potential low physical risk that will be managed through strict adherence to proper health protocols, with blood sampling supervised by an experienced study co-investigator ([A. Josse, PhD]) who will supervise a certified member of her team at York University.

Where is the study run from? York University (Canada)

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

Who is funding the study? York University (Canada)

Who is the main contact?

Jasmin Tiwana, jasmin56@my.yorku.ca

Contact information

Type(s)

Public, Scientific, Principal investigator

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Type(s)

Principal investigator

Contact name

Dr Paul Ritvo

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

2025-130 - YORK UNIVERSITY HPRC

Study information

Scientific Title

Cellular stress and effects on mitochondrial DNA: an assessment of stress reduction and protective factors

Acronym

CS-REDUX

Study objectives

The objective is to assess levels of circulating cell-free mitochondrial DNA (ccf-mtDNA) in young, healthy female university students after inducing a lab stressor using the International Affective Picture System (IAPS). Participants will be randomly allocated to either a mindfulness meditation audio or an educational podcast prior to being exposed to a lab stressor based on IAPS photographs.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 29/04/2025, Human Participants Review Sub-Committee, York University Ethics Review Board (4700 Keele Street, Toronto, M3J 1P3, Canada; +1 (0)416 736 2100 ext 55914; ore@yorku.ca), ref: 2025-130

Study design

Single-centre interventional single-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Healthy female students who are subjected to normal stress

Interventions

Participants are randomized using a computer random number generator on Microsoft Excel to either a mindfulness meditation audio (30 minutes) or an educational podcast on tariffs and economic activity (30 minutes) prior to being exposed to a lab stressor based on IAPS photographs.

Intervention Type

Behavioural

Primary outcome(s)

ccf-mtDNA levels within blood measured using quantitative polymerase chain reaction (qPCR), specifically following the MitoQuicLy protocol, at baseline (pre-stress time 0) and after the conduct of comparison interventions (mindfulness meditation audio, podcast audio) and the lab stress induction and a 20-minute rest period. The final blood draw follows the initial blood draw after the above activities, which in total sum up to 70 minutes.

Key secondary outcome(s))

Mood measured using the Profile of Mood States (POMS) at baseline (pre-stress time 0) and after the conduct of comparison interventions (mindfulness meditation audio, podcast audio) and the lab stress induction and a 20-minute rest period. The final mood state measures follow the activities described above, which sum up to 70 minutes.

Completion date

30/05/2026

Eligibility

Key inclusion criteria

- 1. Females between 18 and 30 years of age
- 2. Maintain residency in Canada
- 3. General good health as defined by no history of asthma, current cancer diagnosis or treatment, myocardial infarction, and systematic immune diseases
- 4. Non-smokers

Participant type(s)

Healthy volunteer, Learner/student

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

30 years

Sex

Female

Key exclusion criteria

- 1. Pregnant and/or lactating women
- 2. Current or previous (during the last 3 months) diagnosable or self-reported mental health problems

- 3. Chronic or acute physical disabilities or injuries
- 4. Current intake of prescribed medications that may interfere with endocrine, nervous and immune system operations (the only exceptions are oral contraceptives)
- 5. No antibiotic use, known infections and vaccination symptoms
- 6. No new tattoos within 2 weeks of the blood withdrawal

Date of first enrolment

29/05/2025

Date of final enrolment 29/05/2026

Locations

Countries of recruitment

Canada

Study participating centre York University 4700 Keele Street Toronto Canada M3J 1P3

Sponsor information

Organisation

York University

ROR

https://ror.org/05fq50484

Funder(s)

Funder type

Not defined

Funder Name

York University

Alternative Name(s)

York University (Toronto), Université York, York University | Toronto ON, YU, YorkU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Jasmin Tiwana (jasmin56@my.yorku.ca).

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