# Detection of mental and physical conditions with heart rate variability

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/05/2024		☐ Protocol		
<b>Registration date</b> 09/05/2024	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 27/01/2025	Condition category  Mental and Behavioural Disorders	[] Individual participant data		

# Plain English summary of protocol

Background and study aims.

Evaluating fatigue is essential in assessing mental, physical, and occupational health. However, there is no conclusive evidence of the usefulness of heart rate variability (HRV) in assessing mental fatigue. The aim of this study is to evaluate mental fatigue using HRV.

## Who can participate?

Men and women aged 20 to 65 years who have received annual health check-ups and have been found to have no health concerns.

#### What does the study involve?

Participants are randomly allocated to either complete simple calculation tasks or to take a rest. HRV is measured using a wearable ECG monitor system. Fatigue and mood are measured before and after the intervention

What are the possible benefits and risks of participating? Participants receive reasonable compensation. Participating takes about 3 hours.

Where is the study run from?

- 1. KYOCERA Corporation (Japan)
- 2. Kanazawa University (Japan)

When is the study starting and how long is it expected to run for? April 2021 to September 2022

Who is funding the study?

- 1. KYOCERA Corporation (Japan)
- 2. Kanazawa University (Japan)

Who is the main contact?

Prof. Hiroaki Yoshikawa, hiroaki@staff.kanazawa-u.ac.jp

# Contact information

## Type(s)

Public, Scientific, Principal investigator

#### Contact name

Prof Hiroaki Yoshikawa

#### **ORCID ID**

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#### Contact details

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

UMIN000046352

# Study information

#### Scientific Title

Research on mental and physical conditions detected by heart rate variability analysis

#### Acronym

**RMPCDHRVA** 

#### **Study objectives**

Heart rate variability can detect mental fatigue.

## Ethics approval required

Ethics approval required

# Ethics approval(s)

approved 16/06/2021, Kanazawa University Medical Ethics Review Committee (13-1 Takaramachi, Kanazawa, 920-8640, Japan; +81 (0)76 265 2100; rinri@adm.kanazawa-u.ac.jp), ref: 2021-031 (3720)

#### Study design

Single-center interventional randomized controlled trial

## Primary study design

Interventional

# Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

Detection of mental fatigue in healthy adults

#### **Interventions**

Participants were randomized in a 1:1 ratio to the intervention or control groups using a computer-generated random number sequence for simple random allocation. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes prepared by an independent research team member.

The researchers compared heart rate variability (HRV) indexes after calculations with those after rest. They used Uchida-Kraepelin test (UKT) sheets for loading calculation tasks. The UKT is a serial addition test requiring participants to perform calculations as fast and accurately as possible within 30 min. This was achieved using pre-printed paper containing 15 lines of random, single-digit, horizontally aligned numbers. Participants were instructed to begin a new line for each minute of the test regardless of their position on the content line. Each line contained an excess of calculations such that the subjects could not finish any line for a particular minute before being prompted to move on to the start of the next minute by the examiner's prompting. This test is usually performed for repeated 15 min of work and 5 min rest cycles. The researchers adopted four cycles. They used UKT sheets only to load mental fatigue and did not evaluate the scores. As a control, they asked participants to take a rest. The researchers prepared easy and calm books so participants could read them. The duration of rest was 80 minutes, adjusted to calculation tasks.

## Intervention Type

Behavioural

# Primary outcome(s)

Heart rate variability (HRV) indexes measured using wearable electrocardiogram (ECG) devices before and after the intervention

# Key secondary outcome(s))

- 1. Fatigue measured using the visual analog scale (VAS) before and after the intervention
- 2. Mood measured using Profile of Mood States 2nd Edition (POMS2) before and after the intervention

#### Completion date

30/09/2022

# **Eligibility**

# Key inclusion criteria

- Received annual health check-ups and found to have no health concerns
- 2. Aged 20-65 years

## Participant type(s)

Healthy volunteer

# Healthy volunteers allowed

No

# Age group

Adult

## Lower age limit

20 years

# Upper age limit

65 years

#### Sex

Αll

# Total final enrolment

140

## Key exclusion criteria

- 1. Implanted cardiac pacemaker
- 2. Arrhythmia
- 3. Taking medicine that affects autonomic nervous functions, such as a beta-blocker

#### Date of first enrolment

08/06/2022

# Date of final enrolment

06/08/2022

# Locations

# Countries of recruitment

Japan

# Study participating centre Kanazawa University Health Service Center

Kakumamachi Kanazawa Japan 920-1192

# Study participating centre

# **KYOCERA Corporation**

3-7-1 Minatomirai Yokohama Japan 220-0012

# Sponsor information

# Organisation

Kyocera (Japan)

#### **ROR**

https://ror.org/025y1g718

# Organisation

Kanazawa University

#### **ROR**

https://ror.org/02hwp6a56

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Kyocera (Japan)

#### **Funder Name**

Kanazawa University

## Alternative Name(s)

, , Kanazawa-dai, Kindai, KU

## **Funding Body Type**

Government organisation

# **Funding Body Subtype**

Universities (academic only)

#### Location

Japan

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. The type of data that will be shared are the data obtained during the study in a spreadsheet format, and the approval form of the ethical committee.

# IPD sharing plan summary

Published as a supplement to the results publication

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/01/2025	27/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes