

Detection of mental and physical conditions with heart rate variability

Submission date 08/05/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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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

1. 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

All

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
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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
Study website	Study website	11/11/2025	11/11/2025	No	Yes