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Detection of mental and physical conditions with heart rate variability

Submission date
08/05/2024

Recruitment status
No longer recruiting

Registration date
09/05/2024

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Study website

https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000051089

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Hiroaki Yoshikawa

ORCID ID
http://orcid.org/0000-0002-6350-5183

Contact details
Kakumamachi
Kanazawa
Japan
920-1192
+81 (0)76 264 5254
hiroaki@staff.kanazawa-u.ac.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/04/2021

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

Age group
Adult

Lower age limit
20 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
3-7-1 Minatomirai
Yokohama
Japan
220-0012
+81 (0)45 605 7100
soudan@adm.kanazawa-u.ac.jp

Sponsor type
Industry

Website
http://global.kyocera.com/

ROR
https://ror.org/025y1g718

Organisation
Kanazawa University

Sponsor details
Kakuma-machi
Kanazawa
Japan
920-1192
+81 (0)76 264 5111
hiroaki@staff.kanazawa-u.ac.jp

Sponsor type
University/education

Website
https://www.kanazawa-u.ac.jp/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/12/2025

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