

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Response and Adaptation of the Cardiac Autonomic System to Functional High-Intensity Interval Training with Respiratory Face Masks: Impacts of Training Period and Face Mask Modality During Covid-19 Pandemic in Healthy Men

Protocol summary

Study aim

Increasing health and prevention

Design

Exercise program: including high-intensity interval training for 2 and 4 weeks with an intensity of 80 to 90% of maximum heart rate, three sessions per week, three times in each session in three groups, interval training (6 subjects), interval training + surgical mask (6 subjects), exercise Interval + N95 mask (6 subjects) was done.

Heart rate variability indices were evaluated before and after the training period.

Settings and conduct

The project in the sports clinic of the University of Mazandaran used a treadmill with a 12-lead electrocardiogram, a body composition device, a pulse oximeter and scales, exercises and sports tests with and without masks performed from 8 am to 2 pm.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-40 years old, with no history of chronic illness, including; arthritis, diabetes, high blood pressure, cancer, heart attack, chronic cough and bronchitis, no orthopedic injury, and no smoking history. Exit criteria: have Spo₂ less than 95%, have at least one sign/symptom of fever or acute respiratory illness, history of travel to another country/state within 14 days before experience and close contact with confirmed COVID-19 patient by RT-PCR test.

Intervention groups

surgical and N95 mask, high-intensity interval training

Main outcome variables

Increase cardiac autonomic function by decreasing sympathetic activity and increasing parasympathetic heart rate variability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100205003281N2**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **retrospective**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

01125263818

Email address

v.dabidi@umz.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

2020-08-22, 1399/06/01

Actual recruitment end date

2020-09-20, 1399/06/30

Trial completion date

2020-11-15, 1399/08/25

Scientific title

Response and Adaptation of the Cardiac Autonomic System to Functional High-Intensity Interval Training with Respiratory Face Masks: Impacts of Training Period and Face Mask Modality During Covid-19 Pandemic in Healthy Men

Public title

"Effect of Exercise Training and Face Mask on the Cardiac Autonomic System"

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Those who do not have a History of Arthritis Those who do not have a History of Diabetes Those who do not have a History of High Blood Pressure Those who do not have a History of Cancer Those who do not have a History of Heart Attack Those who do not have a History of Chronic Cough and Bronchitis Those who do not have Orthopedic Injuries Those who have no History of Smoking

Exclusion criteria:

Have SpO2 Less than 95% Have at Least one Sign/Symptom of Fever or Acute Respiratory Disease Presence of Clinical Signs that any other Disease cannot explain Including; Systolic Blood Pressure Less than 90 mm Hg; Diastolic Blood Pressure greater than 95 mm Hg History of Travel to another Country/State within 14 Days before Experience and Close Contact with Confirmed COVID-19 Patient by RT-PCR Test

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Actual sample size reached: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a number was assigned to each of the participants. Then, the numbers were placed inside the era sphere, and each name removed was placed in the following groups: Interval training, N95 mask interval training, and Surgical mask interval training

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Mazandaran

Street address

Pasdaran Ave, University of Mazandaran

City

Babolsar

Province

Mazandaran

Postal code

4741613534

Approval date

2021-02-13, 1399/11/25

Ethics committee reference number

IR.UMZ.REC.1399.011

Health conditions studied

1

Description of health condition studied

Cardiac Autonomic System of Healthy Men

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

heart rate variability time-domain changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

Cubius software

2

Description

heart rate variability frequency-domain changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

Cubius software

3

Description

heart rate variability nonlinear-domain changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

Cubius software

4

Description

Body composition changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

body composition device

5

Description

SPO2 changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

pulse oximeter

6

Description

Body weight changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

scales

7

Description

Blood pressure changing

Timepoint

Before the intervention, 14 and 28 days after high-intensity interval training with a mask and without a mask

Method of measurement

Blood pressure monitor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: high-intensity interval training group including air squats, push-ups, lunges, high knee, jumping lunges, butterfly, jump squats, seated leg circles, and back extension exercises with a surgical mask, for 2 to 4 weeks, three times a week, Three times per session

Category

Lifestyle

2

Description

Intervention group: high-intensity interval training group including air squats, push-ups, lunges, high knee, jumping lunges, butterfly, jump squats, seated leg circles, and back extension exercises with an N95 mask, for 2 to 4 weeks, three times a week, Three times per session

Category

Lifestyle

3

Description

Control group: high-intensity interval training group including air squats, push-ups, lunges, high knee, jumping lunges, butterfly, jump squats, seated leg circles, and back extension exercises with out mask, for 2 to 4 weeks, three times a week, Three times per session

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Mazandaran Sports Clinic

Full name of responsible person

Valiollah, Dabidi Roshan

Street address

Pasdaran Street- University of Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Mazandaran

Full name of responsible person

Valiollah, Dabidi Roshan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Mazandaran

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Mazandaran

Full name of responsible person

Masomeh Fallah

Position

Ph.D degree Student

Latest degree

Master

Other areas of specialty/work

Sport physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Mazandaran

Full name of responsible person

Valiollah Dabidi Roshan

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

Contact

Name of organization / entity

University of Mazandaran

Full name of responsible person

Masoumeh Fallah

Position

Ph.D degree Student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Subjects' information is confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The consent form is available

When the data will become available and for how

long

Access period starts 8 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

After printing the results, the use of documents is

allowed.

From where data/document is obtainable

Corresponding Author:Valiollah, Dabidi Roshan

What processes are involved for a request to access data/document

Two weeks after the request and pledge not to use the data

Comments