Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Sep 2026

Effect of Eight Weeks of HIIT and Omega-3 Supplementation on Inflammatory Variables, Lung Ventilation, and HRV in Young Male Smokers

Protocol summary

Study aim

The present study aims to investigate the Effect of Eight Weeks of HIIT and Omega-3 Supplementation on Inflammatory Variables, Lung Ventilation, and HRV in Young Male Smokers

Design

Randomized clinical trial with a control group, factorial design, single-blind, non-drug (phase N/A), conducted on 60 young male smokers. Randomization was performed using SPSS version 27

Settings and conduct

This study is conducted in Erbil, Iraq, examining the effects of HIIT and omega-3 supplementation in young male smokers. Participants are randomly assigned using sealed envelopes, and the study is single-blind, meaning participants are unaware of their group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: daily smoking of 11–20 cigarettes, general health, no use of medications/supplements affecting outcomes, no regular exercise, and written consent. Exclusion criteria: incomplete protocol, absence from more than two sessions, irregular supplement intake, new illness or injury, smoking cessation, and missing assessments.

Intervention groups

HIIT + Placebo group: participants perform HIIT and receive a daily placebo without active ingredients. HIIT + Omega-3 group: participants perform HIIT and simultaneously receive daily omega-3 supplementation. Omega-3 group: participants receive daily omega-3 supplementation only, without performing any exercise. Control + Placebo group: participants do not perform any exercise and receive a daily placebo identical to the omega-3 supplement but without active ingredients.

Main outcome variables

IL-6; hs-CRP; IL-6/hs-CRP ratio; CC16; SP-D; CC16/SP-D ratio; FEV1; FVC; FEV1/FVC ratio; LF Power, HF Power, LF/HF ratio; SDNN, rMSSD; SBP, DBP, RHR; TNF-α and cortisol; SpO_2; VO_2max; vVO_2max; sleep quality; health-related quality of life; general health; perceived stress; nicotine dependence; COPD assessment; dyspnea assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251208068255N1**
Registration date: **2026-02-18, 1404/11/29**
Registration timing: **prospective**

Last update: **2026-02-18, 1404/11/29**
Update count: **0**

Registration date

2026-02-18, 1404/11/29

Registrant information

Name

Badrkhan Rashwan Ismael

Name of organization / entity

University of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 935 705 9284

Email address

rashwanismael.b@tabrizu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-06, 1404/12/15

Expected recruitment end date

2026-03-25, 1405/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Eight Weeks of HIIT and Omega-3 Supplementation on Inflammatory Variables, Lung Ventilation, and HRV in Young Male Smokers

Public title

Effect of HIIT and Omega-3 on Inflammation, Lung, and HRV in Young Male Smokers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Current male smokers in Erbil city, 18 to 25 years old Smoking 11 to 20 cigarettes per day over the past year No history of specific diseases such as diabetes, cardiovascular or respiratory diseases No history of food allergies No history of drug use No history of taking anti-inflammatory drugs, beta-2 agonists, and any supplements (such as vitamins, omega-3 supplements, protein drinks, amino acids, etc.) in the past three months or during the study No history of any regular exercise or physical activity in the past six months. Information on personal and family history of atopic diseases, diet.

Exclusion criteria:

Individuals with advanced cardiovascular disease, clinically significant arrhythmias, severe COPD or FEV1 less than 50% predicted, uncontrolled hypertension, or any acute or chronic illness incompatible with the safe implementation of the exercise protocol People with a history of allergy to fish oil or omega-3, continuous use of omega-3 supplements in the last three months, use of smoking cessation medication, and addiction to other tobacco and narcotic substances (except cigarettes in the target groups) were excluded from the study. During the research, lack of cooperation in completing the protocol, absence from more than two to three training sessions in sports groups, irregular use of supplements (less than 80% of the prescribed dose) Failure to attend the pre-test and post-test Starting a new medication or supplement that affects research variables The occurrence of a new acute or chronic disease, musculoskeletal injury, or cardiopulmonary problems related to the intervention Quitting smoking during the study period Request for voluntary withdrawal from further cooperation

Age

From **18 years** old to **25 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure balance in baseline characteristics and minimize potential confounding factors, participants who meet the eligibility criteria after initial screening will first be stratified based on anthropometric characteristics, velocity at VO2max (vVO_2max), and smoking duration. Then, using stratified randomization with blocking and an equal allocation ratio (1:1:1:1), participants will be assigned to four groups of 15 participants each: HIIT + Placebo: performing high-intensity interval training and receiving a daily placebo without active ingredients. HIIT + Omega-3 Supplementation: receiving both HIIT and daily omega-3 supplementation. Omega-3 Supplementation: receiving daily omega-3 supplementation only, without exercise. Control + Placebo: no exercise and receiving a placebo similar to omega-3. The unit of randomization will be the individual participant, with no cluster randomization. The random allocation sequence will be generated using SPSS software (version 27) and a computer-based random number generator, conducted by an investigator independent of participant recruitment, intervention, and assessment. To reduce selection bias, allocation concealment will be ensured using opaque, sequentially numbered, sealed envelopes, which will be opened only after baseline assessments and confirmation of study eligibility. Outcome assessors will be blinded to group allocation during both pre- and post-intervention assessments. This randomization approach is expected to ensure a balanced distribution of baseline variables across groups, reduce allocation bias, and increase the internal validity of the study results.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants will be blinded to group allocation; that is, they will not know whether they are assigned to HIIT + placebo, HIIT + omega-3 supplementation, omega-3 supplementation only, or control + placebo groups. This will be ensured by providing supplements and placebos in a similar format and standardizing exercise sessions for intervention groups while maintaining equivalent procedures for control groups. The principal investigator and other investigators responsible for study design and supervision will be aware of group allocation and are therefore not blinded. Healthcare personnel or caregivers (if involved in delivering supplements or exercise sessions) will also be aware of group allocation and are not blinded. Outcome assessors and data collectors will remain blinded to group assignment, and pre- and post-intervention data will be collected without knowledge of participant allocation to minimize assessment bias. No Data Safety and Monitoring Board (DSMB) will be involved in this study, and data analysis will be performed by investigators, who are therefore not

blinded. This design ensures minimization of outcome assessment bias while fully complying with ethical requirements of informed consent.

Placebo

Used

Assignment

Factorial

Other design features

This study employs a factorial design with four parallel groups to evaluate the independent and combined effects of HIIT training and omega-3 supplementation on inflammatory markers, pulmonary ventilation, and HRV in male smokers. A unique feature of this study is the use of stratified randomization with block design to ensure baseline balance across groups in terms of anthropometric characteristics, vVO_2max, and smoking duration. Additionally, outcome assessors are blinded, and participants are unaware of the intervention received, while investigators and care providers are informed of group allocation. This design allows assessment of both independent and interactive effects of the two interventions and minimizes bias in outcome evaluation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tabriz University of Medical Sciences

Street address

Golasht Street - Tabriz University of Medical Sciences - Central Building No. 2 - Third Floor, Vice Chancellor for Research and Technology

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2025-12-28, 1404/10/07

Ethics committee reference number

IR.TABRIZU.REC.1404.213

Health conditions studied

1

Description of health condition studied

Chronic Smoking / Nicotine Use

ICD-10 code

.

ICD-10 code description

.

Primary outcomes

1

Description

Interleukin-6 (IL-6)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Serum IL-6 levels will be determined using commercially available human ELISA kits (ZellBio, Germany), based on the sandwich enzyme-linked immunosorbent assay (ELISA) method.

2

Description

C-reactive Protein (CRP)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Serum CRP levels will be measured using the CRP US kit (USA). Quantitative determination of high-sensitivity C-reactive protein (hs-CRP) in human serum will be performed by the immunoturbidimetric assay, according to the manufacturer’s instructions.

3

Description

IL-6/hs-CRP

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

The IL-6 to hs-CRP ratio is calculated by dividing the serum concentration of IL-6 (expressed in pg/mL) by the serum concentration of hs-CRP (expressed in mg/L).

4

Description

Clara Cell Protein (CC16)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or

omega-3 supplementation.

Method of measurement

Serum Clara Cell Protein (CC16) levels will be determined using commercially available human ELISA kits (ZellBio, Germany), based on the sandwich enzyme-linked immunosorbent assay (ELISA) method.

5

Description

Surfactant Protein D (SP-D)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Serum Surfactant Protein D (SP-D) levels will be determined using commercially available human ELISA kits (ZellBio, Germany), based on the sandwich enzyme-linked immunosorbent assay (ELISA) method.

6

Description

CC16/SP-D

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

The CC16 to SP-D ratio is calculated by dividing the serum concentration of CC16 by the serum concentration of SP-D.

7

Description

Forced Vital Capacity (FVC)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Forced vital capacity was assessed before and after the study using a portable spirometer (EasyOne®, ndd Medical Technologies, Zurich, Switzerland) in accordance with standard guidelines. Participants were seated on a chair, a nose clip was applied, and the mouthpiece of the device was placed in the mouth. Following a maximal deep inspiration, they immediately performed a forceful and maximal expiration through the mouthpiece sensor to determine FVC.

8

Description

Forced Expiratory Volume in one Second (FEV1)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Forced expiratory volume in the first second (FEV1) was assessed before and after the study using a portable EasyOne® spirometer (ndd Medical Technologies, Zurich, Switzerland), in accordance with standard guidelines. Participants were seated, a nose clip was applied, and the mouthpiece was placed in the mouth. After performing a maximal deep inspiration, they immediately executed a rapid and forceful expiration through the mouthpiece. The volume of air exhaled during the first second was recorded as FEV1.

9

Description

FEV1/FVC

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

FEV1 and FVC are expressed as percentages of the predicted values.

10

Description

Standard Deviation of NN (SDNN)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

SDNN indicates overall heart rate variability in the time domain, calculated as the standard deviation of all normal-to-normal R-R intervals. Measurement is performed at baseline and post-intervention under the same environmental and physiological conditions as LF and HF Power. Full Option software is used for ECG data analysis.

11

Description

Root Mean Square of Successive Differences (rMSSD)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

rMSSD reflects parasympathetic modulation of heart rate, calculated as the square root of the mean squared differences of successive normal-to-normal R-R intervals. Measurement conditions are identical to SDNN and are used to assess the autonomic response to training and supplementation interventions.

12

Description

High Frequency (HF-HRV)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

HF Power represents parasympathetic (vagal) modulation of the heart. Measurement conditions are identical to LF Power: 20 minutes seated, controlled environment, and paced breathing. ECG signals are analyzed with Full Option software (CARDIOSCAN II, Version 12.2.0017a, USA), and HF Power is expressed in ms^2.

13

Description

Low Frequency (LF-HRV)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

LF Power reflects autonomic nervous system activity, modulated by both sympathetic and parasympathetic branches. Measurement is performed at baseline and post-intervention for 20 minutes while participants are seated in a comfortable, temperature-controlled room (22–24°C) with dim lighting and minimal auditory distractions. Participants are connected to a three-channel digital Holter ECG (VX3+ Digital Holter Recorder, DMS Service, USA), and breathing is paced at 12 breaths per minute using a metronome. ECG signals are analyzed in the frequency domain, and LF Power is reported in ms^2.

14

Description

LF/HF Ratio

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

The LF/HF ratio assesses the balance between sympathetic and parasympathetic activity. An increased ratio indicates sympathetic predominance. This ratio is calculated by dividing LF Power by HF Power using the same Holter ECG recordings and frequency-domain analysis.

15

Description

Maximal Oxygen Uptake (VO_2max)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

After baseline measurements, participants are guided to a standard 400-meter track to perform the Cooper test for estimating VO_2max. In this test, participants are instructed to cover the maximum distance possible within 12 minutes. VO_2max is then estimated based on the distance covered using the following formula:VO_2max (ml/kg/min)=(22.351×distance in kilometers)−11.288VO_2max (ml/kg/min)=(22.351×distance in kilometers)−11.288

Secondary outcomes

1

Description

Tumor Necrosis Factor-alpha (TNF-α)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Serum Tumor Necrosis Factor-alpha (TNF-α) levels will be determined using commercially available human ELISA kits (ZellBio, Germany), based on the sandwich enzyme-linked immunosorbent assay (ELISA) method.

2

Description

Cortisol

Timepoint

Primary outcomes will be assessed at two time points: At

baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Salivary cortisol levels are used as a primary biomarker for assessing physiological stress. To ensure consistency and minimize the influence of daily fluctuations, samples are collected every morning at a fixed time, ideally between 7:00 and 9:00 a.m., when cortisol levels naturally peak. After collection, the samples are stored under appropriate temperature conditions and analyzed using enzyme-linked immunosorbent assay (ELISA) techniques.

3

Description

Peripheral blood oxygen saturation (SpO_2)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

In this study, peripheral blood oxygen saturation will be measured noninvasively using a finger pulse oximeter model Beurer PO 45 (Germany). The device measures oxygenated and deoxygenated hemoglobin in capillary blood using two light wavelengths (red and infrared) and calculates the oxygen saturation percentage based on the light absorption ratio. The sensor is placed on the participant's dominant index finger, and once the display stabilizes (usually within 5 to 10 seconds), SpO_2 and heart rate values are read from the digital screen and recorded. Measurements are performed at rest in a quiet environment with room temperature between 22 and 25 degrees Celsius to avoid errors caused by movement, cold, or strong light. Each measurement is repeated twice, and the average is recorded as the final SpO_2 value. The normal SpO_2 range in healthy individuals is 95 to 99 percent; however, in non-athletic smokers, a relative reduction in SpO_2 values is expected due to the presence of carbon monoxide and increased carboxyhemoglobin.

4

Description

Systolic and Diastolic Blood Pressure (SBP, DBP)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Systolic and diastolic blood pressure will be measured from the participant's right arm using a digital blood pressure monitor, Beurer BM20. Before measurement, participants will rest in a seated position for 25 minutes. Blood pressure will be recorded three times at 5-minute intervals, and the average of the three measurements will be considered the final blood pressure value.

5

Description

Body composition indices (height, weight, body fat percentage, and BMI)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Participants' height will be measured using a stadiometer, Seca model 769, made in Germany, with an accuracy of 1 millimeter. Body weight will be recorded using a Camoushita body scale with an accuracy of 0.1 kilograms. Body fat percentage will be determined using a caliper, model SH5020.Calculation of Body Mass Index (BMI)Body Mass Index will be calculated using the following formula: BMI (kg/m2) = weight (kg) / height (m2)

6

Description

24-hour food reminder

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

During the intervention period, participants in the exercise and supplementation groups will maintain their usual diet. Additionally, they will record a three-day non-consecutive dietary log, including one weekend day and two weekdays, during the first and last weeks of the study. Based on these records, total caloric intake and macronutrient composition (protein, fat, and carbohydrates) will be accurately calculated. Participants are also required to refrain from consuming any supplements, medications affecting the dependent variables, or engaging in additional exercise outside the study protocol, and report any deviations to the investigator.

7

Description

International Physical Activity Questionnaire (IPA-Q)

Timepoint

Primary outcomes will be assessed at one time point: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation.

Method of measurement

Physical activity level will be assessed using the Short Form of the International Physical Activity Questionnaire (IPAQ). This questionnaire includes seven items and evaluates light, moderate, and walking activities over the past seven days. According to the scoring protocol, the amount and intensity of physical activity are calculated and classified.

8

Description

Pittsburgh Sleep Quality Questionnaire (PSQI)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

To assess participants' sleep quality, the Persian version of the Pittsburgh Sleep Quality Index (PSQI) will be used. This self-reported questionnaire includes 19 items divided into seven components: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Each component is scored from 0 to 3, and the sum of the seven component scores forms the global PSQI score (0–21). A score of ≤5 indicates good sleep quality, while a score >5 indicates poor sleep quality. This tool provides a comprehensive assessment of sleep quality and its impact on daily functioning, and the Persian version has been validated in Iranian studies.

9

Description

health-related quality of life (HRQOL)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

To assess participants' health-related quality of life (HRQOL), the WHOQOL-BREF questionnaire will be used. It will be administered before the intervention and after the eight-week intervention. The WHOQOL-BREF evaluates four main domains: physical health, social relationships, psychological status, and environment. Scores for each domain include raw and transformed values, reflecting the individual's perception of health-related quality of life. In general, higher scores indicate a better understanding of functional health and overall well-being.

10

Description

Patient Health Questionnaire (PHQ)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

To assess the severity of depression among participants, the Persian version of the PHQ-9 questionnaire will be used. This self-reported questionnaire consists of 9 items evaluating the individual's psychological status over the past two weeks, covering components such as decreased interest in activities, feelings of depression, sleep disturbances, fatigue, appetite changes, guilt, concentration problems, psychomotor agitation or retardation, and suicidal thoughts. Each item is scored on a 0 to 3 scale (0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day), and the sum of the 9 items provides the total PHQ-9 score (0–27). This score reflects depression severity: 0–4 minimal, 5–9 mild, 10–14 moderate, 15–19 severe, and 20–27 very severe. The Persian version has been validated and recommended for use in Iranian studies.

11

Description

Perceived Stress Scale (PSS)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

To assess perceived stress among participants, the Persian version of the Perceived Stress Scale (PSS) will be used. This self-reported questionnaire consists of 14 items evaluating the individual's stress experience over the past month, covering aspects such as sense of control, managing important tasks, dealing with unexpected events, worries, and daily psychological pressure. Each item is scored on a 0 to 4 scale (0 = never, 1 = almost never, 2 = sometimes, 3 = often, 4 = almost always), and positively worded (reverse) items are reversed before calculating the total score. The sum of the 14 items yields the total PSS score (0–56), with higher scores indicating greater perceived stress. The Persian version has been validated and used in the Iranian population.

12

Description

Fagerström Test for Nicotine Dependence (FTND)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or

omega-3 supplementation.

Method of measurement

To assess nicotine dependence, the Fagerström Test for Nicotine Dependence (FTND) questionnaire will be used. This questionnaire consists of six items about cigarette consumption behavior, with total scores ranging from 0 to 10. Based on the total score, nicotine dependence is classified into three levels: low (0–3), moderate (4–6), and high (7–10). The validity and reliability of the Persian version of this questionnaire were confirmed in the study by Sarbandi et al. (2015), with a reported Cronbach's alpha of 0.71.

13

Description

COPD Assessment Test (CAT)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

Participants' symptoms will be recorded using the Chronic Obstructive Pulmonary Disease Assessment Test (CAT). This standard tool includes eight domains, assessing cough, sputum production, chest tightness or heaviness, shortness of breath when climbing stairs or inclines, limitations in daily household activities, sleep quality, and fatigue. The total score reflects the impact of COPD on patients' daily quality of life, with higher scores indicating greater disease impact.

14

Description

Dyspnea Assessment Test

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

The severity of dyspnea in participants will be assessed using the Modified Medical Research Council Dyspnea Scale (mMRC). This scale ranges from 0 to 4 and evaluates the impact of shortness of breath on physical activities in patients with respiratory issues. A score of 0 indicates breathlessness only with strenuous activity, while a score of 4 represents severe breathlessness that prevents leaving the house or performing tasks such as dressing and undressing. Participants will indicate the level of activity at which they experience breathlessness.

15

Description

Resting Heart Rate (RHR)

Timepoint

Primary outcomes will be assessed at two time points: At baseline (pre-test), 24 hours before the initiation of any exercise training or omega-3 supplementation; After eight weeks of intervention (post-test), 48 hours following the completion of the HIIT program and/or omega-3 supplementation.

Method of measurement

The resting heart rate of participants will be measured after 20 minutes of seated rest using a digital heart rate monitor, Polar model, made in Sweden.

Intervention groups

1

Description

Control group: Participants do not perform any HIIT training and receive two placebo capsules daily, similar in appearance and taste to the omega-3 supplement. Placebo capsules contain inactive vegetable oil and no active EPA or DHA. Participants are asked to maintain their usual lifestyle throughout the study period.Intervention group 1 (HIIT + omega-3): Participants follow a 10-week HIIT program with three sessions per week, divided into an introductory phase (weeks 1–2, 70–80% vVO_2max, RPE 9–12) and a main training phase (weeks 3–10, progressive intensity 100–140% vVO_2max, RPE 14–19). Each session includes 10 minutes of warm-up, main exercise, and 10 minutes of cool-down. Simultaneously, participants consume two 1000 mg omega-3 capsules daily (180 mg EPA and 120 mg DHA), one in the morning with breakfast and one in the evening with the main meal.Intervention group 2 (HIIT + placebo): Participants follow the same HIIT training protocol as above, but receive placebo capsules instead of omega-3.Intervention group 3 (omega-3 only): Participants consume two 1000 mg omega-3 capsules daily (180 mg EPA and 120 mg DHA) without performing any HIIT training.All capsules are coded and distributed to ensure a single-blind design, so participants are unaware of the type of supplement they receive. All measurements are conducted both before and after the intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Rizgary Teaching Hospital

Full name of responsible person

Rivan Hermiz

Street address

52RQ+G4M م, Peshawa Qazi, Erbil, Erbil Governorate, Iraq

City

Erbil

Postal code

52RQ+G47

Phone
+964 66 227 1516
Fax
+964 66 227 1516
Email
info@hmu.edu.krd
Web page address
https://ww7.rizgary.org/?usid=104&utid=58fa78d68562ad42f3f091a40a57303d

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rizgary Teaching Hospital
Full name of responsible person
Rivan Hermiz
Street address
52RQ+G4M ڕ, Peshawa Qazi, Erbil, Erbil Governorate, Iraq
City
Erbil
Postal code
52RQ+G4M
Phone
+964 66 227 1516
Fax
+964 66 227 1516
Email
info@hmu.edu.krd
Web page address
https://ww7.rizgary.org/?bpt=345&usid=104&utid=58fa78d68562ad42f3f091a40a57303d&ch=1&rurl=https%3A%2F%2Fww7.rizgary.org%2F%3Fcaf%3D1%26bpt%3D345%26usid%3D104%26utid%3D58fa78d68562ad42f3f091a40a57303d%26query%3D%25D9%2588%25D8%25B1%25D9%2588%25D8%25AF%25DB%258C%2B%25D8%25B3%25DB%258C%25D8%25B3%25D8%25AA%25D9%2585%2B%25D8%25AA%25D8%25A7%25D9%2585%25DB%258C%25D9%2586%2B%25D8%25A7%25D8%25AC%25D8%25AA%25D9%2585%25D8%25A7%25D8%25B9%25DB%258C%26afdToken%3DChMIvL7fwKXPkQMVAXHxAx0gjxCPEm8BIlqpj8b6SN-Nf5F20BMsnWIGVzVgRomKtryRAdYBT0FvY68y3LYzP-eRWpbEI-TtkyVzPureUtJsdEtkPajaOsR9lQaR04PCo04eDz1Qh62WWN9woELwiDwoGN7Ngk5-HwP9y2QLdBwAjUc1cv0gATI1AbFSVKoO0bWmq75yttnjJV1HT0ykZeLwAjGOnEDfd6hrjCYHZeGOfvInTqZJuAJ3qO_qcsU%26pcsa%3Dfalse%26nb%3D0%26nm%3D8%26nx%3D541%26ny%3D79%26is%3D700x373%26clkt%3D110%26ch%3D1
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Spiritual help
Proportion provided by this source
10
Public or private sector
Private
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 Tabriz
Full name of responsible person
Badrkhan Rashwan Ismael
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Sport Medicine
Street address
Department of Exercise Physiology, Faculty of Physical Education and Sport Sciences, University of Tabriz, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5164736931
Phone
+98 935 705 9284
Fax
Email
rashwanismael.b@tabrizu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Tabriz
Full name of responsible person
Elaheh Piralaiy
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Department of Exercise Physiology, Faculty of Physical Education and Sport Sciences, University of Tabriz, Tabriz, Iran
City
Tabriz
Province

East Azarbaijan

Postal code

5164736931

Phone

+98 914 628 5306

Fax

Email

epiralaiy@tabrizu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

University of Tabriz

Full name of responsible person

Badrkhan Rashwan Ismael

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Sport Medicine

Street address

Department of Exercise Physiology, Faculty of Physical Education and Sport Sciences, University of Tabriz, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5164736931

Phone

+98 935 705 9284

Fax

Email

rashwanismael.b@tabrizu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Title: Data and Documentation Related to the Effect of Eight Weeks of HIIT and Omega-3 Supplementation on Inflammatory Variables, Lung Ventilation, and HRV in Young Male Smokers Details: After the completion of the study and de-identification of participants, individual participant data regarding primary and secondary outcomes will be available for sharing. These data include biochemical results (such as IL-6 and hs-CRP), pulmonary and cardiovascular function, heart rate variability, cognitive indices, sleep quality, perceived stress, depression, health-related quality of life, and other variables measured throughout the study. Sensitive personally identifying information, consent forms, and other confidential personal details will not be shared. Additionally, the study protocol, statistical analysis plan, and data dictionary will be provided to facilitate a full understanding of the data structure and collection methods. Access to these data and documents will be available to interested researchers after the publication of the study, under ethical and confidentiality guidelines.

When the data will become available and for how long

The access period for the data and documents will begin six months after the publication of the final article in the relevant scientific journal, and access will be available indefinitely, as long as other researchers are interested in using them.

To whom data/document is available

Access to the study data and related documents will be granted to interested researchers and investigators affiliated with universities, research institutions, and recognized scientific centers worldwide. Researchers working in industry may also request access, provided that their intended use of the data is for legitimate scientific research and publication purposes. All requests must include a clear research proposal and a commitment to maintain confidentiality and adhere to ethical standards.

Under which criteria data/document could be used

The study data and related documents can only be used for scientific research purposes and for publishing results in reputable journals. Their use is subject to the following conditions: The received data and documents must be used solely for scientific analysis related to the study objectives, and any attempt to identify participant identities is strictly prohibited. The requesting researcher must submit a research proposal outlining the study aim, analysis methods, and research design. Results derived from the data must be maintained and reported in accordance with ethical standards and confidentiality requirements. Any redistribution of the data or transfer to third parties without written permission from the study team is prohibited. Permitted analyses include re-evaluation of primary and secondary outcomes, meta-analyses, and secondary investigations consistent with the study protocol. The data cannot be used for commercial, advertising, or other non-scientific purposes. Overall, access to the data and documents is conditional upon adherence to ethical standards, scientific objectives, and protection of participant confidentiality.

From where data/document is obtainable

To request access to the study data and documents, interested parties can contact as follows: Responsible Person: Badrkhan Rashwan Ismael Email: rashwanismael.b@tabrizu.ac.ir Direct Phone Number: +98 9357059284 Position and University: PhD student,

Department of Exercise Physiology, University of Tabriz University Mailing Address: 29 Bahman Boulevard, Tabriz, East Azerbaijan Province, Iran University Phone Number: +98 41 3334 1300 University Website: https://tabrizu.ac.ir/en Applicants should provide their full contact information, affiliated institution, purpose of data use, and type of analysis planned. Access to the data and documents will be granted in accordance with ethical guidelines and confidentiality of participant information.

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

The process for requesting access to the study data or documents is as follows: Submission of a formal request: The applicant must send an official email to rashwanismael.b@tabrizu.ac.ir . This email should include the applicant's full personal and institutional details, the purpose of using the data, the type of analysis or research intended, and a list of the data or documents requested. Initial review by the research team: Upon receiving the request, the research team reviews it for completeness, research purpose, and compliance with ethical principles. This step typically takes 1 to 2 weeks. Signing a data use agreement or ethical compliance agreement: If the request is approved, the applicant must sign an agreement outlining confidentiality obligations, restrictions on the use of the data for unauthorized purposes, and adherence to participant rights. Preparation of data and documents: After signing the agreement, the research team prepares the requested data after de-identification of participants and provides related documents, including the study protocol, statistical analysis plan, and data dictionary. Delivery of data and documents: The data and documents are securely sent to the applicant via encrypted email or a secure platform. The entire process, from submission to final delivery, usually takes 2 to 4 weeks, depending on the volume of data and complexity of the documents. This procedure ensures that access to the data is provided while maintaining ethical standards, confidentiality, and information security.

Comments