

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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- $\alpha$  and cortisol; SpO<sub>2</sub>; VO<sub>2</sub>max; vVO<sub>2</sub>max; 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

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##### 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 (vVO2max), 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,  $\dot{V}O_2\text{max}$ , 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

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Golasht Street - Tabriz University of Medical Sciences  
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**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**

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**ICD-10 code description**

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**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 (nnd 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) – 11.288  
 $VO_2max$  (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<sub>2</sub>)

#### **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<sub>2</sub> 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<sub>2</sub> value. The normal SpO<sub>2</sub> range in healthy individuals is 95 to 99 percent; however, in non-athletic smokers, a relative reduction in SpO<sub>2</sub> 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:  $BMI (kg/m^2) = weight (kg) / height (m^2)$

### **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  $\leq 5$  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%  $v\text{O}_2\text{max}$ , RPE 9-12) and a main training phase (weeks 3-10, progressive intensity 100-140%  $v\text{O}_2\text{max}$ , 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

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**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**

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**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

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PhD candidate

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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## 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](mailto: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**