

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of short-term and long-term effects of yoga with music on beta-endorphin, serotonin, body composition, stress and depression of inactive obese women

Protocol summary

Study aim

Simultaneous effect of yoga and music on beta-endorphin and serotonin levels and comparison of short-term and long-term effects of music on these levels in inactive obese women

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 28 patients. Excel software random function was used for randomization.

Settings and conduct

Based on the online call in sports clubs, 28 people will be selected voluntarily and randomly in 3 groups, 8 people and 1 group of 4 people (control) as a statistical sample. The subjects are not aware of randomization and the clinical caregivers, outcome assessors, data analysts, identify the subjects by code, and analyze the subjects in the order of the table numbers through a pre-coded table. 48 Before the start of training, pre-test evaluations were performed, after the first training session, the second blood sample was taken, and finally, the third blood sample was taken to assess the duration after 6 weeks of training (or music) intervention.

Participants/Inclusion and exclusion criteria

Body mass index equal to or greater than 30 kg / m², age group 25-45 years, no regular exercise in the past 6 months, no metabolic diseases and no medication or exercise supplements in the past month.

Intervention groups

48 hours before the start of the exercises, we had pre-test evaluations for all intervention groups (first, second, third, control), immediately after the first yoga practice session with music (first group), yoga practice without music (second group), Listening to music without practicing yoga (group 3) and the control group, we had a second blood sample and finally, after 6 weeks, we had a third blood sample for all intervention groups.

Main outcome variables

Beta-endorphin levels, serotonin levels, body composition, anxiety changes and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220304054178N1**

Registration date: **2022-06-20, 1401/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-20, 1401/03/30**

Update count: **0**

Registration date

2022-06-20, 1401/03/30

Registrant information

Name

Setareh Ghaderi

Name of organization / entity

The University of Kordestan

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-25, 1401/03/04

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

2022-05-25, 1401/03/04

Actual recruitment end date

2022-08-11, 1401/05/20

Trial completion date

2022-08-11, 1401/05/20

Scientific title

Evaluation of short-term and long-term effects of yoga with music on beta-endorphin, serotonin, body composition, stress and depression of inactive obese women

Public title

The effects of yoga and music on beta-endorphin, serotonin, body composition, anxiety and depression in obese obese women

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Obese women with a body mass index equal to or higher than 30 kg per square meter. Age group 25-45 years.

Exclusion criteria:

Not having sufficient BMI of the subjects Lack of interest in yoga and music Lack of motivation of subjects in performing clinical trials Not enough time by the subjects to do the test

Age

From **25 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each participant provides a sample to study.

Actual sample size reached: **28**

More than 1 sample in each individual

Actual sample size in each individual: **1**

Each participant provides a sample to study.

Randomization (investigator's opinion)

Randomized

Randomization description

To perform the simple randomization method, we used the card shuffling method. In this method, a number of cards selected by the researcher from 1 to 28 were written on each card. For example, by removing the cards, we took out a card and registered its number as the first group and took the card out of the basket, this process until we reach a random sequence according to the sample size ($n = 8$) for the group. The first continued. The procedure was the same for all groups. In order to hide the random allocation, we used the central randomization method. In this method, the card numbers were given to two yoga instructors in two separate clubs and they were sampled in these two clubs at the same time based on the order of participants's study, and the researcher contacted the relevant clubs about random allocation. The participant asked a specific group, using

the telephone.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The first and second groups practice yoga in the hall air for 23 to 24 degrees Celsius for 6 weeks and three sessions (60 to 90 minutes) per week (18 sessions). After the pre-test, the Hatayoga training program will be performed. Before starting the exercises, the trainer will devote 15 minutes to general warm-up, then 15 to 30 minutes of asanas (physical exercises), pranayama (breathing exercises) and finally 15 minutes, meditation or shavasana (relaxation). will be.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kurdistan University

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No. 4, Shadab Alley, Sheikh Mazhar St., Shahrak Daneshgah St., Saez, Kurdistan

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Saez,

Province

Kurdistan

Postal code

6681685563

Approval date

2022-01-08, 1400/10/18

Ethics committee reference number

IR.UOK.REC.1400.032

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Beta endorphin

Timepoint

Before the start of the course (48 hours before), 2 days and 42 days after the start of the course

Method of measurement

Human Beta-Endorphin, ELISA Kit

2

Description

Serotonin

Timepoint

Before the start of the course (48 hours before), 2 days and 42 days after the start of the course

Method of measurement

Human Serotonin, ELISA Kit

3

Description

Body composition

Timepoint

Start of study (before training), end of study (after last training session)

Method of measurement

Bioelectric impedance analyzer

4

Description

Changes in anxiety and depression

Timepoint

Start of study (before training), end of study (after last training session)

Method of measurement

Physical, Mental and Social Health Questionnaire, General Health Questionnaire, Eising Self-Esteem Questionnaire, Beck Depression Inventory, Beck Anxiety Inventory.

5

Description

Changes in depression

Timepoint

Start of study (before training), end of study (after last training session)

Method of measurement

Physical, Mental and Social Health Questionnaire, General Health Questionnaire, Eising Self-Esteem Questionnaire, Beck Depression Inventory, Beck Anxiety Inventory

Secondary outcomes

1

Description

Obesity

Timepoint

The first measurement before the first blood draw and the last measurement before the third blood draw

Method of measurement

Use of bioelectric impedance analyzer

Intervention groups

1

Description

The first intervention group: 48 hours before the start of training, pre-test evaluations, immediately after the first session of yoga practice with music, the second blood draw and finally, to evaluate the long-term effects of yoga and music, after 6 weeks of training intervention with We had the music of the third blood draw.

Category

N/A

2

Description

Second intervention group: 48 hours before the start of exercises, pre-test evaluations, immediately after the first session of yoga practice without music, second blood draw and finally, to evaluate the long-term effects of yoga and music, after 6 weeks of practice intervention without We had the music of the third blood draw.

Category

N/A

3

Description

Third intervention group: 48 hours before training, pre-test evaluations, 48 hours after, immediately after listening to music without training intervention, second blood sampling and finally, to evaluate the long-term effects of music after 6 weeks of blood We had the third one.

Category

N/A

4

Description

Control group: 48 Before the start of the course, we had pre-test evaluations. After 48 hours, we performed a second blood sample and evaluation, and finally, after 6 weeks, we performed a third blood sample or evaluation. This group has no sports activities and continued their daily life.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Laboratory

Full name of responsible person

Anwar Bahrami Azar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?

Yes

Title of funding source

The University of Kordestan

Proportion provided by this source

10

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
The University of Kordestan

Full name of responsible person
Stareh Ghaderi
Position
Graduate student
Latest degree
Bachelor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Latest degree

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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

In the form of informed consent, the first paragraph was
about the confidentiality of patients' personal
information.

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

Yes - There is 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

Data on study outcomes can be published after being
unidentifiable.

**When the data will become available and for how
long**

2022/10/22

To whom data/document is available

All researchers have approved proposals for meta-
analysis.

Under which criteria data/document could be used

To conduct meta-analysis studies

From where data/document is obtainable

Address: No. 4, Setareh Ghaderi, Shadab Alley, Sheikh
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Mobile +98 992 772 6504 Email starehartan@gmail.com

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

The request is accompanied by a letter approving the
meta-analysis

Comments