

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of anti-inflammatory compared with the low-calorie diet on anthropometric indecies, anxiety, depression, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese women with knee osteoarthritis

Protocol summary

Study aim

Determining the effect of anti-inflammatory in comparison with low caloric diet on anthropometric indices, anxiety, depression, functional status, pain and quality of life, and serum inflammatory and oxidative stress indices in overweight and obese women with knee osteoarthritis

Design

The method of project implementation is randomized clinical trial. The target population in this study was female patients referring to the physical medicine clinic of Imam Reza Hospital in Tabriz with diagnosis of knee osteoarthritis. The final sample size was 60 (30 persons per group).

Settings and conduct

The target population in this study were female patients referring to the physical medicine and rehabilitation clinic of Imam Reza Hospital in Tabriz, with the diagnosis of knee osteoarthritis. Subjects randomly assigned to two groups and then receive the appropriate dietary intervention. Subjects are unaware of the allocation of people to two types of diet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of knee osteoarthritis (mild, moderate), Age 50 and older, BMI 41-27, have cognitive ability to complete nutritional forms Exit criteria: Receiving less than 800 and more than 4200 calories daily calories, intra-articular injection drug use 3 months ago, oral administration (non-steroid anti-inflammatory drugs) one week before entering the study, those who cannot, for any reason. Use of dietary supplements during the intervention period, participation in sports programs or changes in physical activity, illness and the use of drugs that affect weight, do physical therapy in the past 3 months, aggravation of symptoms and pain

Intervention groups

Intervention 1: Balanced dietary intervention (A)

Intervention 2: Anti-inflammatory Diet Intervention (B)

Main outcome variables

Quality of Life, Pain, Depression, Stress Oxidation, Inflammatory Indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N2**

Registration date: **2018-04-23, 1397/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-23, 1397/02/03**

Update count: **0**

Registration date

2018-04-23, 1397/02/03

Registrant information

Name

Neda Dolatkah

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 1928

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dolatkahn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-11-12, 1397/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of anti-inflammatory compared with the low-calorie diet on anthropometric indecies, anxiety, depression, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese women with knee osteoarthritis

Public title

The effect of anti-inflammatory compared with the low-calorie diet on anthropometric indecies, anxiety, depression, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese women with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of knee osteoarthritis by physicians (mild, moderate) Age 50 and older BMI 41-27 Has the cognitive ability to complete the learned forms of food The desire to participate in the study

Exclusion criteria:

Get daily calories less than 800 and more than 4200 kcal Follow a special food pattern for medical reasons or other reasons Infection with other inflammatory diseases, such as rheumatoid arthritis Diabetes Other musculoskeletal problems, including back pain Having a history of radiotherapy Intra-articular intra-articular injection 3 months ago Oral use (nonsteroidal anti-inflammatory drugs) from a week before entering the study Depression (gaining a score of more than 5 from the Geriatric Depression Scale, GDS-15) History of neurological diseases or drug use People who for any reason are not able to cooperate in completing questionnaires and plans Use of dietary supplements, diuretics or laxatives during the intervention period Participate in sports programs or change physical activity Performing physiotherapy in the last 3 months Use of nonsteroidal anti-inflammatory drugs during the study

Age

From 50 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization to a low-calorie diet or an anti-inflammatory diet was done by an allocation sequence specified by computerized random-number generation (Blockrand in R version 3.4.0; R Project for Statistical Computing) by a statistician not included in intervention delivery or data collection

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants did not learn of their diet group assignment

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgshest St, Azadi St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.TBZMED.REC.1396.1117

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

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes**1****Description**

Functional status and pain associated with osteoarthritis in the lower extremities

Timepoint

Before and after the intervention

Method of measurement

Western Ontario and McMaster (WOMAC)

2**Description**

BMI

Timepoint

The beginning and the end of the study

Method of measurement

The result of dividing the weight into kilograms by squared height in meters

3**Description**

Waist

Timepoint

The beginning and the end of the study

Method of measurement

Strip meter

4**Description**

Hip circumference

Timepoint

The beginning and the end of the study

Method of measurement

Strip meter

5**Description**

Severity of anxiety

Timepoint

The beginning and the end of the study

Method of measurement

Two-part questionnaire of Spielberger's apparent and hidden anxiety

6**Description**

Depression rate

Timepoint

The beginning and the end of the study

Method of measurement

Beck Depression Inventory

7**Description**

The amount of pain

Timepoint

The beginning and the end of the study

Method of measurement

VAS (Visual Analogue Scale)

8**Description**

Quality of Life

Timepoint

The beginning and the end of the study

Method of measurement

SF-36 quality of life questionnaire

9**Description**

Biochemical analysis of blood samples

Timepoint

The beginning and the end of the study

Method of measurement

Biochemical analysis of blood samples

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Balanced diet (A) intervention to reduce the weight of half a kilogram a week will be deducted from the average 3-day energy received by the individual 500 kilocalories and the diet will be designed with the following distribution: Fat: Less than 30% calories, Carbohydrates: 60-55 Percentage of calories and protein: 10-15% calories.

Category

Treatment - Other

2**Description**

Intervention group 2: Anti-inflammatory Diet Intervention (B)The anti-inflammatory diet on fresh fruits and vegetables is the largest portion of the diet that should be eaten in large amounts and in each meal, in different types and colors (two-thirds of dietary calories).

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences Physical and Rehabilitation Sciences Research Center

Full name of responsible person

Neda Dolatkah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Neda Dolatkah
Position
Assistant Professor
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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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