

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison between the different type of corrective exercises along with Diet on Anterior Pelvic Tilt in obesity Impacting Low Back Pain Patients

#### Protocol summary

##### Study aim

To find out the evidence about the improvement in body weight and its impact on the biomechanical changes of pelvis and lumbar spine after Dieting alone, Diet +Soft tissue release, Diet +Strength exercise, Diet +Aerobic exercise as well as comparing the biomechanical characteristics between these groups to find out the best method for the management of low back pain.

##### Design

This is a single blind randomized clinical trial study. 80 participants will be randomly allocated into 4 groups and total 6 weeks interventions would be given consisting of 5 sessions per week (30 sessions) for exercises and soft tissue release group along with continuous dieting.

##### Settings and conduct

Data would be collected randomly from Karachi, Pakistan population referred to physiotherapy clinic. Before and after 6 weeks interventions, outcome measurements will be assessed in each group.

##### Participants/Inclusion and exclusion criteria

Non specific low back pain; age between 25 to 40years; Anterior pelvic more than 13.5 degree; Grade I and II obesity without Current dermatological or inflammatory illness,Recent fracture, Congenital lower extremity abnormalities, Breathing difficulties,Cardiovascular, pulmonary, hepatic, renal, and hematological disorders

##### Intervention groups

The participants aged between 25-40 years will be assigned in four groups according to their BMI. A comprehensive Rehabilitation plan would be formulated after assessment, incorporating diet only as control group, diet +soft tissue release, diet +strengthening exercise group and diet +aerobic exercise group, all following 500 kcal diet deficit in their daily caloric requirement.

##### Main outcome variables

Pain; disability; Quality of life; pelvic tilt; body fat percentage; muscle strength; muscle thickness; aerobic fitness,waist hip ratio; muscle length for rectus femoris

and iliopsoas

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130121012210N10**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

##### Registration date

2023-03-14, 1401/12/23

##### Registrant information

##### Name

Azadeh Shadmehr

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7752 8468

##### Email address

shadmehr@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-21, 1402/01/01

##### Expected recruitment end date

2023-06-22, 1402/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparison between the different type of corrective exercises along with Diet on Anterior Pelvic Tilt in obesity Impacting Low Back Pain Patients

## Public title

Comparison between the different corrective exercises along with Diet on improvement of Low Back Pain Patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Subjects with NSLBP Age between 25 to 40years Anterior pelvic tilt more than 13.5 degree Grade I and II obesity

### Exclusion criteria:

Dermatological or inflammatory illness Recent fractures Congenital lower extremity abnormalities Cardiovascular, pulmonary, renal and hematological disorders

## Age

From **25 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Subjects in this study are randomly placed in one of the three study groups based on random number table and receive the intervention related to the same group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

assessor is blind regarding to the groups and interventions.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical sciences

## Street address

Central building of TUMS, Ghods Street, Keshavarz Blvd

## City

Tehran

## Province

Tehran

## Postal code

1417613151

## Approval date

2023-01-18, 1401/10/28

## Ethics committee reference number

IR.TUMS.FNM.REC.1401.144

## Health conditions studied

### 1

#### Description of health condition studied

low back pain

#### ICD-10 code

S30.0

#### ICD-10 code description

Contusion of lower back and pelvis

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

before treatment, at the end of treatment (after the 6th week)

#### Method of measurement

according to the Visual analog scale

### 2

#### Description

Disability

#### Timepoint

before treatment, at the end of treatment (after the 6th week)

#### Method of measurement

Oswestry Disability Index questionnaire

### 3

#### Description

Quality of life

#### Timepoint

before treatment, at the end of treatment (after the 6th week)

#### Method of measurement

SF-36 questionnaire

### 4

#### Description

Pelvic Tilt

#### Timepoint

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

photogrammetry

**5**

**Description**

body composition

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

Bioelectrical impedance analysis

**6**

**Description**

Muscle strength

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

Dynamometer

**7**

**Description**

Muscle thickness

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

Ultrasounography

**8**

**Description**

Aerobic Fitness

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

Bruce Protocol

**9**

**Description**

Waist-Hip Ratio

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

circumference of the waist to that of the hips by tape

**10**

**Description**

muscle length

**Timepoint**

before treatment, at the end of treatment (after the 6th week)

**Method of measurement**

Thomas Test

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Control group: The participants would be assessed by a nutritionist and their basal metabolic rate (BMR) would be calculated and finally Recommended Caloric Requirement (RCR) calculation. In RCR 500 kcal deficit would be given which is equivalent to one pound of fat which contains 3500 kcal in week. The participants will follow the regimen for 6 weeks.

**Category**

Rehabilitation

**2**

**Description**

Intervention group: Diet + Soft tissue release Group, This group would follow the same diet of control group. In Addition soft tissue release for Iliopsoas and Rectus femoris would be given for 6 weeks, 5 times per week (30 sessions)

**Category**

Rehabilitation

**3**

**Description**

Intervention group: Diet + Strengthening exercise Group, The same protocol for diet would be given. In addition strengthening training for Pectoralis major , Lattismus Dorsi , Deltoid , Trapezius , Biceps, Triceps, Quadriceps , Hamstrings, Rectus abdominus , Erector spinae and Gastrocnemius soleus would be formulated and supervised for 6 weeks, 5 sessions per week (30 sessions).

**Category**

Rehabilitation

**4**

**Description**

Intervention group: Diet + Aerobic exercise Group, The same protocol for diet would be given. In addition aerobic training which will be apply by exercise between 70% to 75% of Max Heart Rate for 40 minutes per session for 5 days per week for 6 weeks (30 sessions).

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

School of Rehabilitation  
**Full name of responsible person**  
Azadeh Shadmehr  
**Street address**  
Piche Shemiran, Enghelab Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1148965111  
**Phone**  
+98 21 7752 3939  
**Email**  
shadmehr@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
علی اکبر فتوحی  
**Street address**  
Main Campous, Qods Street, Engelahb street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417613151  
**Phone**  
+98 21 8163 3698  
**Email**  
vcr@tums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**

Muhammad Sarfraz  
**Position**  
Resident  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Piche Shemiran, Enghelab Street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1148965111  
**Phone**  
+98 21 7752 8468  
**Email**  
mohdpk23@hotmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Azadeh Shadmehr  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Piche shemiran, Enghelab street  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1148965111  
**Phone**  
+98 21 7752 8468  
**Email**  
shadmehr@tums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Muhammad Sarfraz  
**Position**  
resident  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
Piche shemiran, Enghelab street

**City**

Tehran

**Province**

Tehran

**Postal code**

1148965111

**Phone**

+98 21 7752 8468

**Email**

mohdpk23@hotmail.com

**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**

No - There is not 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**

No - There is not a plan to make this available