Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 lumber 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

Teharn 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 commeetee 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
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1148965111
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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, Engelab street
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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
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Tehran
Postal code
1148965111
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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
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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
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