Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Influence of adding Breathing Training to Land based Whole body strength training &Aquanatal Exercises on Lumbopelvic Pain, Functional Disability, SFMA Scores, Physiological and gait parameters, and posture during Pregnancy

Protocol summary

Study aim

Determining the effect of adding breathing exercises to land-based whole body training and aquanatal exercises on lumbar-pelvic pain, functional disability, SFMA scores Physiological parameters, gait parameters and posture in pregnant women.

Design

Two arm parallel group randomised trial with blinded interventions and outcome assessment will perform on 60 pregnant women. Randomization conducted using Randomizer.org web site.

Settings and conduct

Mother land clinic" for land-based whole body strength training group, and "Shahid Chamran "Swimming pool for aqua natal exercises. Pregnant patients will be referred from Bazarganan Hospital &Gynecologist office. Double blinded study, in which the participants, the assessors, and the analyzers will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy noly parus women, age 20-35 years old, in the 18-22 weeks of pregnancy with on a history of abortion, normal both pregnancy screening tests, normal blood tests & normal blood pressure, diagnosed with pregnancy related lumbo pelvic pain is approved by a gynecologist, received at least the first dose of Covid -19 vaccine.; Exclusion criteria: Report of lumbopelvic pain current or past, infections, vascular, metabolic, or endocrine problems,any medication or analgesia and treatment to relieve pain,a history of lumbar surgery, vaginal bleeding, and any contraindication to exercise in pregnancy.

Intervention groups

1- Whole body strength training & breathing training; will perform focusing on myofascial lines with TRX,,appropriate dumbbells, and training Sticks. 2- Aquanatal exercises & breathing training; the routine will be included of aerobics, strengthening, flexibility, and balance training in the water.

Main outcome variables

Pain& functional disability primary variables; SFMA, Physiologic & gait parameters, and pasture will be the secondary variables.

General information

Reason for update

Acronym

(Selective Functional Movement Assessment(SFMA)

IRCT registration information

IRCT registration number: **IRCT20220129053870N1**
Registration date: **2022-02-08, 1400/11/19**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Niloufar Farivar

Name of organization / entity

The University of Kharazmi of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8001

Email address

niloufar_farivar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15
Expected recruitment end date
2022-05-05, 1401/02/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Influence of adding Breathing Training to Land based Whole body strength training &Aquanatal Exercises on Lumbopelvic Pain, Functional Disability, SFMA Scores, Physiological and gait parameters, and posture during Pregnancy

Public title
The Influence of Breathing Training and Exercise on Lumbopelvic Pain,Blood factors, gait, and function during Pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy pregnant women in 18 -22 week of pregnancy Age 20-35 years old Nolyparus No history of abortion Normal first & the second pregnancy screening results Received at least the first shot of covid-19 vaccine Being diagnosed with lumbopelvic pain by a gynecologist
Exclusion criteria:
Any spinal phatology Neoplastic process Infections Vascular diseases Endocrine & metabolic diseases Being under treatment & giving pain killers for lumbopelvic pain A history of lumbar spine surgery Uterus & vaginal bleeding Any contraindication of exercise in pregnancy regarding the Royal College of Obstetrician & Gynecologists guidelines
Age
From **20 years** old to **35 years** old
Gender
Female

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
Following the baseline assessments, referring to http://www.randomization.com website, participants who meet the inclusion criteria will be randomly assigned into the Land-based whole body strength training & aqua natal exercises groups.Simple randomization will be used.Allocation concealment,the stage of performing the randomization process, the process of performing random allocation in the study, the person who create the random sequence, the person who consider participants in terms of inclusion and exclusion criteria, and the participants assignment will be specified.Randomization will be performed from a computer-generated sequence, concealed in sequentially numbered, sealed, opaque envelopes, and will be kept by the hospital and motherland clinic . (1 for the land - based whole body strength training & 2 for the aqua natal training group) created before initiation of data collection by a researcher who is not involved in the recruitment or treatment of the patients.Then, the random numerical sequence is placed in the sealed opaque envelops. Another researcher blind to the baseline assessments will open an envelope and will process with treatment according to the group assignment. An independent assessor who is not aware of the study hypothesis and method, will assess the outcome measures before and after 14 weeks interventions, while is blind to the intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study the outcome assessors, data analyzer, and participants will be blinded to the process of randomization and devision of the individuals into two experimental and control groups. In the double-blind study, neither party involved in the trial know which group is receiving the actual treatment. Neither the participant nor the assessor, knows who is receiving what treatment. This method is used to prevent orientation in the results. The research set up double-blind with the main experimenter having a colleague. The main assessor is in the process of testing and launching, but their colleague is not in the process of testing. Since participants do not know which group they belong to, their beliefs about treatment do not affect the outcome. The researchers also do not know which groups are actually receiving treatment, they are unable to influence the treatment process by revealing small clues. A Double- blind study helps to reduce the effects of orientation on research. This orientation can include the unwanted influence of the researcher on the way of collecting information or dividing individuals into groups. Researchers sometimes inadvertently interfere in the research process because of their feelings about the research plan or their personal interest in obtaining a specific result.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sports sciences research institute

Street address
No.3, Fifth Alley, Mir Emaad St, Ostad Motahari Street, Tehran

City
Tehran

Province
Tehran

Postal code
1587958711

Approval date
2022-01-19, 1400/10/29

Ethics committee reference number
IR.SSRC.REC.1400.117

Health conditions studied

1

Description of health condition studied
Pregnancy related lumbo pelvic pain

ICD-10 code
R10.2

ICD-10 code description
Pelvic and perineal pain

2

Description of health condition studied
Functional disability

ICD-10 code
O26.89

ICD-10 code description
Other specified pregnancy related conditions

Primary outcomes

1

Description
Pain; Lumbo pelvic pain

Timepoint
At the baseline (before interventions), weeks 34 & 38 of pregnancy(after interventions & follow up)

Method of measurement
Visual Analogue Scale(VAS)

2

Description
Functional Disability

Timepoint
At the baseline (before interventions), weeks 34 & 38 of pregnancy(after interventions & follow up)

Method of measurement
Oswestry Disability Questionnaire

Secondary outcomes

1

Description
Physiologic Parameters

Timepoint
At the baseline (before interventions), weeks 34& 38 of pregnancy (After interventions & follow up)

Method of measurement
Blood Lab Exams

2

Description
Gait parameters

Timepoint
At the baseline (before interventions), weeks 34 & 38 of pregnancy (After interventions & follow up)

Method of measurement
Kinovea Soft ware

3

Description
Posture

Timepoint
At the baseline (before interventions), weeks 34& 38 of pregnancy (After interventions & follow up)

Method of measurement
Kinovea Soft ware

4

Description
Selective Functional Movement Assessment(SFMA)

Timepoint
At the baseline (before interventions), weeks 34& 38 of pregnancy (After interventions & follow up)

Method of measurement
Regarding to the Selective Functional Movement Assessments (SFMA) scores presented by Gray Cook

Intervention groups

1

Description
Intervention group: Whole Body Strength Training; The exercises include whole body exercises focusing on the myo fascial structures.This can spread the force throughout the body system, while minimizing excessive stress on the joints, allowing the joints to move in all three planes, improving overall body awareness and coordination.The selection of exercises according to previous studies will be done in the same direction. These exercises involve several fascia structures simultaneously. There are various techniques for designing exercises, including TRX exercises, lunges, dumbbell exercises, and squats. The exercises are performed in four fascial lines, including super fascial anterior, super fascial posterior, lateral, and spiral.

Exercises are designed three times a week for 60 minutes (5 to 10 minutes of warm-up, 40 to 45 minutes of exercise routine, and finally 5 to 10 minutes of cool - down), with light to moderate intensity individualized for each subject. The exercises include 3 sets, depending on the ability of the individuals 5 to 10 repetitions, in each set with a break of 20 to 40 seconds between each set. In order to exercise progression principle, if a person is able to perform movements, the exercises will be upgraded to an advanced level.

Category

Rehabilitation

2

Description

Intervention group: Aqua natal exercises; Exercise in the water specifically in this study will be done during 20 to 34 weeks of pregnancy. These exercises are designed for three sessions per week for 14 weeks, each session will last 60 minutes, which will be divided into two parts: 1. Strengthening 2. Balance and aerobics. In the first (strengthening) phase of this exercise routine, which will be performed during the 20-24 weeks of pregnancy, the sessions consist of three stages: warm-up, the main phase, and finally stretching and relaxation. In the second phase of training (balance exercises and aerobics), which will be performed during the 24-34 weeks of pregnancy, the exercises will be organized and performed in pregnant women. The intensity of the exercises will be based on the Borg scale and the target heart rate. Maximum oxygen consumption will be assessed using the Bruce Modified Exercise Test. The reserve heart rate will be calculated from the Karvonen formula (Target heart rate = percentage of exercise intensity multiplied by Maximum heart rate-resting heart rate + resting heart rate) and different intensities of aerobic exercise will also be adjusted. 30 degrees Celsius (86 degrees Fahrenheit) will be set and pregnant women will be immersed in water up to the xiphoid process (pool depth will vary depending on the individuals height).

Category

Rehabilitation

3

Description

Intervention group: Breathing Training added to two interventions in each group;Breathing exercises using a balloon: Breathing exercises are performed in a sitting position with the thigh and knee 90 degrees. In this case, the patient is asked to hold the balloon with one hand and breathe through the nose with the tongue on the roof of the mouth (normal resting position) and then exhale through the mouth into the balloon. 75% of the maximum is usually 3-4 seconds, and a full exhalation usually takes 5-8 seconds and then pauses for 2-3 seconds. This slow breathing is thought to further relax the parasympathetic nervous system / nervous system and generally reduce the tone of resting muscles. Ideally, the patient can breathe again without pressing the balloon with their teeth and lips. This requires maintaining intra-abdominal pressure to allow inhalation through the nose without returning air from the balloon and into the mouth.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bazarganan Haspital

Full name of responsible person

Amir Letafatkar

Street address

Center for Human Movement Scien.ces Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex

City

Tehran

Province

Tehran

Postal code

۴۳۹۸-۱۵۸۷۵

Phone

+98 21 2222 8001

Fax

+98 21 2226 9547

Email

letafatkaramir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Amir Letafatkar

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex

City

Tehran

Province

Tehran

Postal code

۴۳۹۸-۱۵۸۷۵

Phone

+98 21 2222 8001

Fax

+98 21 2226 9547

Email

letafatkaramir@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

This study has bern conducted by the researchers and no organizational fund has been received.

Proportion provided by this source
50

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

2

Sponsor

Name of organization / entity
Kharazmi University

Full name of responsible person
Hamid Rajabi

Street address
No. 43, South Mofateh.Ave., Engelab Ave.,

City
Tehran

Province
Tehran

Postal code
1571914911

Phone
+98 21 8832 9220

Email
info@khu.ac.ir

Web page address
https://pess.khu.ac.ir/cv.php

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
This study has bern conducted by the researchers and no organizational fund has been received.

Proportion provided by this source
50

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
Kharazmi University

Full name of responsible person
Amir Letafatkar

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sports Science

Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex

City
Tehran

Province
Tehran

Postal code
۴۳۹۸-۱۵۸۷۵

Phone
+98 21 2222 8001

Fax
+98 21 2226 9547

Email
letafatkaramir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kharazmi Universityb

Full name of responsible person
Amir Letafatkar

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Sports Science

Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex

City
Tehran

Province
Tehran

Postal code
۴۳۹۸-۱۵۸۷۵

Phone
+98 21 2222 8001

Fax
+98 21 2226 9547

Email
letafatkaramir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kharazmi University

Full name of responsible person
Amir Letafatkar

Position

Assistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Sports Science

Street address

Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport complex

City

Tehran

Province

Tehran

Postal code

۴۳۹۸-۱۵۸۷۵

Phone

+98 21 2222 8001

Fax

+98 21 2226 9547

Email

letafatkaramir@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

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

Title and more details about the data/document

Demographic and outcomes-related data are the files which will be shared.

When the data will become available and for how long

After publishing paper(s) extracted from the study.

To whom data/document is available

The data can be displayed and shared at the reasonable request of the Iranian Clinical Trail Registration center, journals, and University individuals/ researchers who are conducting research and scientific activities related to this field.

Under which criteria data/document could be used

Data analysis and the use of documentation can only be provided which their results are reported in systematic review articles by academic researchers and authors. Requirements for sharing data and documents include: 1. To Send an email (preferably with a valid university address) to one of the study researchers/ authors 2. A brief and logical explanation of how to use the data or documentations. 3.Ensuring That the protocol the protocol for systematic review studies, any accessing request to data or documentations will be recorded.

From where data/document is obtainable

Through asking from authors; Amir Letafatkar, letafatkaramir@yahoo.com NiloufarFarivar, Niloufar_farivar@yahoo.com

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

The applicant can request details from the researchers within 7-10 days by an official message sent via an email.

Comments