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Exercise training on pregnancy gait pattern

Submission date
30/10/2024

Recruitment status
No longer recruiting

Registration date
04/11/2024

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During pregnancy, changes in the body can lead to discomfort and mobility issues, especially in the second and third trimesters. This study aims to see if an eight-week exercise program can help pregnant women maintain better foot pressure, improve ankle flexibility, and stabilize their walking patterns.

Who can participate?
Pregnant women in their second trimester (13-26 weeks) with a single baby, who can join a structured exercise program twice a week for eight weeks. Participants should not have any pre-existing conditions that could interfere with exercise.

What does the study involve?
Participants will first have their health and activity levels assessed. They will then be randomly assigned to either a control group receiving standard care or an exercise group participating in a clinical exercise program twice a week for eight weeks. Both groups will be evaluated before and after the program to measure changes in foot pressure, ankle flexibility, and walking patterns.

What are the possible benefits and risks of participating?
Benefits may include reduced pain, better mobility and balance, and improved fitness, which could positively affect labor and overall health. Risks include muscle soreness, potential injury if exercises are not done correctly, and the possibility of worsening pregnancy-related complications, which will be closely monitored.

Where is the study run from?
The study is conducted at Ege University, using their Gait Laboratory and clinical settings. Participants are recruited from the university's prenatal care clinics and maternity wards (Turkey)

When is the study starting and how long is it expected to run for?
April 2022 to February 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT05481983

Secondary identifying numbers
22-4.1T/36

Study information

Scientific Title
The effect of clinical exercise training on plantar pressure, subtalar joint and gait cycle in pregnant women: randomized clinical trial

Study objectives
H0 (Null Hypothesis): Clinical exercise training has no significant effect on plantar pressure, subtalar joint flexibility, and gait cycle in pregnant women.

H1 (Alternative Hypothesis): Clinical exercise training has a significant effect on plantar pressure, subtalar joint flexibility, and gait cycle in pregnant women.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 21/04/2022, Ege University, Ethics Committee of Ege University Faculty of Medicine (KAZIMDİRİK MAH. NO:9, İzmir, 35100, Türkiye; +90 5529382360; egetaek@gmail.com), ref: 22-4.1T/36

Study design
Single-blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Plantar pressure, subtalar joint flexibility, and gait cycle in pregnant women

Interventions
Control Group; at least 150 minutes of moderate-intensity aerobic exercise program was given as specified in the American College of Obstetricians and Gynecologists (ACOG) guidelines. They walked for 30 minutes a day, five days a week, according to their physical activity level. Exercise intensity was adjusted as 2-3 points according to rate of perceived exertion, (RPE) using the Modified Borg Scale. Participants were called by phone once a week to check whether they were exercising.

Exercise group; a one-on-one clinical exercise program was applied with a physiotherapist for a total of 16 sessions, two days a week for eight weeks. Each session lasted 45 minutes. A clinical exercise program suitable for pregnant women was organized by paying attention to the week of pregnancy. The clinical exercise program included core stabilization exercises, exercises involving the pelvic floor muscles and the muscles surrounding the hip, and therapeutic exercises combined with breathing to strengthen the lower extremity muscles. Each session included warm-up-load-cool-down periods. Free weights, resistance bands, or body weights were preferred for strengthening exercises. According to the recommendations of the American College of Sports Medicine (ACSM), strength training with an elastic band was adjusted according to RPE. According to the modified borg scale, loading exercises were performed with a score of 2-3, corresponding to moderate-intensity exercise.

Sample size, randomization and blinding
In order to find a significant difference between the gait analysis results obtained before and after exercise in the exercise and control groups, power analysis was performed using Gpower

3.1.2 under repeated measurement variance analysis test. In the analysis, α=0.05 and medium effect size f=0.25 were taken with 80% power, and a total of 98 individuals, 49 in each group, were found sufficient. Considering the loss of data in the follow-up, it was decided to recruit 5% more patients. Thus, 104 (52:52) was determined as the final sample size.
The Randomization algorithm (Maximum Allowed % Deviation = 10%) was applied using PASS software 11.0 (NCSS LLC, Kaysville, UT) to generate a randomization list that would allow participants to be assigned to two groups of 52 each.

Intervention Type
Other

Primary outcome measure
1. Age is measured using a questionnaire at baseline and at the end of the eighth week
2. Educational status is measured using a questionnaire at baseline and at the end of the eighth week
3. Dominant side is measured by asking participants to kick a soccer ball and recording the preferred limb at baseline and at the end of the eighth week
4. Height is measured using a stadiometer at baseline and at the end of the eighth week
5. Body weight is measured using a clinical measuring device at baseline and at the end of the eighth week
6. Body Mass Index (BMI) is calculated as body weight in kilograms divided by the square of height in meters at baseline and at the end of the eighth week
7. Gestational week is recorded using medical records at baseline and at the end of the eighth week
8. Number of pregnancies is recorded using medical records at baseline and at the end of the eighth week
9. Physical activity levels are measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF) at baseline and at the end of the eighth week
10. Plantar foot loading pressures are measured using the Materialise Motion Footscan® v9 Scientific at baseline and at the end of the eighth week
11. Subtalar joint flexibility is measured using the Materialise Motion Footscan® v9 Scientific at baseline and at the end of the eighth week
12. Foot full period is measured using the Materialise Motion Footscan® v9 Scientific at baseline and at the end of the eighth week
13. Plantar pressure areas are measured using the Materialise Motion Footscan® v9 Scientific at baseline and at the end of the eighth week
14. Multistep walking speed is measured using the Materialise Motion Footscan® v9 Scientific at baseline and at the end of the eighth week

Secondary outcome measures
Pain presence, location, and intensity are measured using the Visual Analog Scale (VAS) at baseline and at the end of the eighth week

Overall study start date
21/04/2022

Completion date
27/02/2023

Eligibility

Key inclusion criteria
1. Age between 18-40 years
2. No risk of pregnancy-related complications
3. Pregnancy between the 12th and 32nd week of gestation

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
104

Total final enrolment
101

Key exclusion criteria
1. History of the lower extremity, pelvic or spine surgery
2. Pain for more than 6 months
3. Any fetal developmental delay

Date of first enrolment
03/05/2022

Date of final enrolment
02/01/2023

Locations

Countries of recruitment
Türkiye

Study participating centre
Ege University
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Sponsor type
University/education

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the study are presented in article format and have been submitted to a journal, with an editor's response pending.

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
The raw data is held by the researchers and will be shared upon request if deemed appropriate.
Ayşe Kayalı Vatansever, ayse.vatansever@bakircay.edu.tr

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Turkish		31/10/2024	No	Yes
Results article		20/12/2024	05/03/2025	Yes	No