TITLE: Identification of exercise components of core stability and their effectiveness on foot posture, foot function and lower limb alignment in adults with flexible flat feet

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IREC ETHICAL APPROVAL NUMBER: IREC 2024-257

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DOCUMENT TYPE: Study Protocol

BACKGROUND

Flexible flat feet are a common clinical condition that may influence lower limb alignment and proximal joint biomechanics. Conventional foot-focused exercises are commonly prescribed; however, their effects may be limited. Emerging perspectives suggest that altered foot posture may be influenced by proximal postural and neuromuscular factors, including core musculature function. Therefore, this study aimed to examine the effect of core stability exercises on foot posture and lower limb alignment in individuals with flexible flat feet

Objectives

1. To evaluate the feasibility of core stability training protocol that will be devised in the proposed study.
2. To assess the effect of core stability training on the foot posture in adults with flexible flat feet.
3. To assess the effect of core stability training on lower limb alignment in adults with flexible flat foot.

STUDY DESIGN

- Randomized Controlled Trial
- Allocation: parallel
- Number of groups: 2
- Study duration: December 2024 to January 2026
- Study was conducted at Department of Physical rehabilitation Sciences, International Islamic university of Malaysia, Kuantan, Pahang, Malaysia.

PARTICIPANTS

- **Participants were recruited from general student population around Kuantan with following criteria:**

  - Inclusion Criteria
    - ✓ Subjects of age group 18 to 30 years.
    - ✓ Both males and females.
    - ✓ No recent history of lower limb injuries.
    - ✓ Subjects with bilateral flexible flat feet as per the definition.
    - ✓ Subjects with positive navicular drop test (> 10mm) and positive Jack's test.

  - Exclusion criteria
    - ✓ Rigid flat foot
    - ✓ Subject who are involved in a specific sport at least 2 h /day and 3 times a week regularly.
    - ✓ History of arthritic symptoms of lower limb joints.
    - ✓ History of any ligament or tendon injuries around ankle, knee, or hip joint.
    - ✓ History of any limb surgery or back surgery.
    - ✓ Chronic back pain.
    - ✓ Any history of neurological deficit or diabetic neuropathy.

INTERVENTIONS

Experimental Group

Six-week exercise protocol with progression developed following systematically reviewing bod of evidences and tested for feasibility and acceptability in pilot trial.

Exercises	**Repetitions and phase wise progression**	**Rest period between exercise sets**
Warm up (Back arching and knee rolling)	3 times each exercise	5 sec rest between exercises
Abdominal hollowing	Repeat until the subject learns to contract core muscles.	5 sec rest between each trial
Curl ups with hands behind head	Phase 1:10 rept × 3 times Phase 2: 15 rept × 3 times Phase 3: 20 rept × 3 times	120 sec rest between the sets
Bridges with leg lifts	Phase 1: 15 sec hold × 3 times Phase 2: 20 sec hold × 3 times Phase 3: 25 sec hold × 3 times	120 sec rest between the sets
Side bridges	Phase 1: 15 sec hold × 3 times Phase 2: 20 sec hold × 3 times Phase 3: 25 sec hold × 3 times	120 sec rest between the sets
Planks on feet	Phase 1: 15 sec hold × 3 times Phase 2: 20 sec hold × 3 times Phase 3: 25 sec hold × 3 times	120 sec rest between the sets
Quadripedal stance with contralateral arm and leg raise.	Phase 1: 15 sec hold × 3 times Phase 2: 20 sec hold × 3 times Phase 3: 25 sec hold × 3 times	120 sec rest between the sets
Cool Down	Self-stretching of hamstrings and calf in long sitting position 3 times with 10 sec hold.	

Control Group

Conventional foot exercises for control group (3 times weekly for 6 weeks) adapted from previous studies.

A. ***Warm up:***
   Active ROM exercise (Knee and hip flexion) 10 repetitions × 2 sets)

B. ***Training:***
   - Active dorsiflexion exercises in long sitting (10 sec hold × 15 repetitions ×2 sets)
   - Active plantarflexion exercises in long sitting (10 sec hold × 15 repetitions ×2 sets)
   - Active inversion exercises in long sitting (10 sec hold × 15 repetitions ×2 sets)
   - Active eversion exercises in long sitting (10 sec hold × 15 repetitions ×2 sets)

C. ***Cool down:***
   - Calf stretches in long sitting for 10 seconds hold × 3 sets.

OUTCOME MEASUREMENTS

- **Rearfoot Angle (Right & Left)**
  Rear foot angle was measured by testers using Goniometer in standing position.
- **Staheli Plantar Arch Index (SPAI) (Right & Left)**
  SPAI was measure using footprint method and calculation of arch index
- **Q Angle (Right & Left)**
  Q angle was measure using Goniometer.

ASSESSMENT TIMELINE

- Baseline
- Post Intervention after 6 weeks

SAMPLE SIZE

- Initially Pilot trial started with a sample size of 20 for assessing feasibility
- After completion of protocol, a sample size of 62, determined using G power was recommended.

SAMPLING

- Participants were recruited using convenience sampling and randomly assigned to either the experimental (core stability) group or control (conventional exercises) group. Randomization was performed using a blinded lottery method, in which eligible participants were coded, and the codes were placed in a container. An independent assessor randomly allocated participants to each group using these codes.

BLINDING

- Assessors were blinded to group allocation during the randomization process. Participants and intervention-givers were not blinded due to the nature of the exercise intervention.

STATISTICAL ANALYSIS

- Changes scores (Post mean – Pre mean) were calculated and multivariate analysis was conducted with BMI as a covariate.

ETHICAL CONSIDERATIONS

- Ethics approval was obtained from IREC, Research management centre, International Islamic University of Malaysia with protocol Id -IREC 2024-257
- Written informed consent was obtained from all participants prior to enrolment.

INFORMED CONSENT FORM

INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
KULLIYAH OF ALLIED HEALTH SCIENCES

Informed Consent form for:

This Informed Consent form is for adults aged 18 to 30 years of both genders who we are inviting to participate in research on Bilateral flexible flat feet. The title of our research project is "**Identification of exercise components of core stability and their effectiveness on foot posture, foot function and lower limb alignment in adults with flexible flat feet".**

Name of Principal Investigator: _____

Name of Organization: _____

Name of Sponsor: _____

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you).

- Certificate of Consent (for signatures if you agree to take part).

You will be given a copy of the full Informed Consent Form.

PART I: Information Sheet

Introduction

I am Mr. _____ a PhD student for the International Islamic university of Malaysia. I am doing research to check the efficacy of core stability exercises on the flat feet. I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with, about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information, and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

Purpose of Research

Flexible flat feet are very common and affect other joints of the limbs and low back if not treated on time. We want to find ways to stop this from happening. We want to use special exercises called core stability exercises for the treatment of flexible flat feet. We want to learn whether these exercises will help the people with flat feet in any means.

Type of research intervention

This research will involve exercises for back (core stability exercises) and exercises for foot in a single session as well as four follow-up visits to the clinic.

Participant selection

We are inviting all adults aged between 18 to 30 years with flexible flat feet who attend clinic of Department of physical Rehabilitation Sciences, IIUM Kuantan to participate in the research on the use of core stability exercises on flat feet.

Voluntary participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services, you receive at this Centre will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier.

Information on trial

The exercises used in this research are called core stability exercises and foot muscle exercises. These exercises have been tested before in various other conditions. We want to

test their effect on bilateral flexible flat feet. Some participants will be given core stability exercises, and some will be given foot exercises. There is no risk involved both the sets of exercises.

Procedure and protocol

A. **Description of process**

We are asking you to help us learn more about flexible flat feet. If you accept, you will be asked to visit the clinic at least 3 to 4 times weekly for 45 minutes treatment sessions. In every session you will be performing exercise sessions. Before the sessions start a pretesting of your foot arch, lower limb alignment and foot function will be assessed, and same tests will be repeated after the completion of the treatment sessions.

- **Duration**

  The research takes place over 4 weeks in total. During that time, it will be necessary for you to come to the clinic 3 times weekly, for 1 hour each day.In total, you will be asked to come 12 times to the clinic in 4. At the end of 4 weeks, the research will be finished.

- **Side effects**
  As stated earlier there are no side effects for these exercises. However, you might feel bit tired after doing exercise session and that will recover after taking rest.

- **Risks**
  There are no risks involved with this intervention.

- **Benefits**
  If you participate in this research, you will have the following benefits:
  The treatment for your flexible flat feet will be free of charge. There may not be any benefit for you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

- **Reimbursements**
  You will not be provided any incentive to take part in the research.

- **Confidentiality**
  The information that we collect from this research project will be kept confidential. Information about you that will be collect during the research will be put away and no-one, but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up.

- **Sharing the Results**
  The knowledge that we get from doing this research will be shared with you if you wish so.

- **Right to Refuse or Withdraw**
  You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice, and all your rights will still be respected.

- **Who to Contact**
  If you have any questions, you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:
  Name: Shahid Mohd Dar
  Address: Kulliyah Allied Health Sciences, IIUM Kuantan.
  Telephone number: 0169807816
  E-mail: shahiddar@iium.edu.my

This proposal has been reviewed and approved by IREC, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IREC, contact:

Name:

Address: IIUM Research Ethics Committee (IREC), Research Management Centre (Kuantan) Level 1, Admin Building (OCD). International Islamic University Malaysia Bandar Indera Markota, 25200 Kuantan, Pahang

Telephone number: 09-5704733/4227

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

IF ILLITERATE:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent.

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year