The Possibilities and Acceptability of Applying Gait Modification to the Treatment of Knee Osteoarthritis in Saudi Arabia Based on the Perceptions of Patients and Physiotherapists.

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Study Identification

Unique Protocol ID:	KKUMC
Brief Title:	Using Gait Modification to Treat Knee Osteoarthritis in Saudi Arabia: Possibilities and Acceptability.
Official Title:	The Possibilities and Acceptability of Applying Gait Modification to the Treatment of Knee Osteoarthritis in Saudi Arabia Based on the Perceptions of Patients and Physiotherapists. A Mixed-methods Feasibility Study.
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Study Status

Record Verification:	January 2023
Overall Status:	Completed
Study Start:	April 13, 2022 [Actual]
Primary Completion:	October 15, 2022 [Actual]
Study Completion:	December 30, 2022 [Actual]

Sponsor/Collaborators

Sponsor:	King Khalid University
Responsible Party:	Principal Investigator Investigator: Abdullah Al Assiri [aalassiri] Official Title: Principal Investigator Affiliation: King Khalid University
Collaborators:	University of Nottingham

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: FMHS 448-0122 Board Name: Faculty of Medicine & Health Sciences Research Ethics Committee Board Affiliation: Medical School Phone: +44(0) 115 951 5151 Email: FMHS-ResearchEthics@nottingham.ac.uk Address: Room E41, E Floor, Medical School

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Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: A variety of biomechanical gait modification interventions can elevate knee loading and improve knee symptoms in knee osteoarthritis patients. However, there was a lack of acceptability and adherence regarding modification interventions without any explanation.

Thus, this study investigates the feasibility and acceptability of foot insoles as a gait modification tool among Saudi Arabian knee osteoarthritis patients and physiotherapists.

This study aims to answer the following:

- Which gait modification intervention is most likely to be implemented in Saudi Arabia (SA) clinical practice, taking context, patients' clinical and research evidence into consideration?
- In Saudi Arabia, can this proposed foot-insole intervention be implemented? Is there sufficient experience among physiotherapists regarding gait modification to deliver it, and will patients engage with it? How can KOA rehabilitation outcomes be evaluated in the future?

The participants will be conducted over three phases:

1. The patients' interview and therapists' focus group discussion will be used to examine KOA patients' and clinicians' perspectives on enabling and accepting gait modifications in phase 1.
2. The feasibility study will explore how a small number of KOA patients tolerate gait modifications and consider the most relevant outcome measures, such as pain and function, in phase (2).
3. A small group of knee osteoarthritis patients and their physiotherapists who participated in phase (2) will be asked to participate in a descriptive survey in phase (3). To examine the acceptability and feasibility of the study intervention in phase (2).

Detailed Description: Since several different types of gait modifications have been studied, it has been challenging to determine which are most likely to be used by patients and healthcare professionals.

A notable number of Saudi Arabians suffer from knee osteoarthritis (KOA), which reported a 29.5% prevalence of KOA; another recent study reported a 24.5% prevalence of KOA among the elderly. A 2002 study found that 30.8% of those aged 46-55 and 60.6% aged 66-75 were affected. Thus, KOA is roughly equally distributed between genders and is more prevalent among elderly and overweight individuals, so policymakers should focus on raising awareness to prevent and treat affected individuals. The healthcare system in SA is publicly funded and accessible; 79% of patients use the public system, and the rest obtain private care. In most cases, private patients have insurance coverage. The public healthcare system has three primary, secondary, and tertiary care levels. Rehabilitation and gait modification investigations are not available at the

primary level.

This snapshot of the literary review raises questions about the viability of the long-term use of learned/assistive gait modifications. The studies reported dissatisfaction with the gait modification approach but gave no reasons. Since most studies focus on results in a short time or a specific area, pre-training courses measuring acceptability and commitment can fill the gaps in previous studies. After determining the importance of gait modification, the question becomes, should it be integrated into the therapy strategy or other rehabilitative methods to increase the treatment's clinical efficacy? It is essential to understand the practices, views and expectations of KOA patients and health professionals concerning gait modifications.

Conditions

Conditions: Osteoarthritis, Knee
Pain
Biomechanical Lesion

Keywords: Knee osteoarthritis
Insole
Biomechanical
Saudi Arabia

Study Design

Study Type: Interventional

Primary Purpose: Other

Study Phase: N/A

Interventional Study Model: Single Group Assignment
A gait modification (Lateral wedge insole) program will be conducted over 4 to 6 weeks in the physiotherapy gym or adjusted treadmill and outside the clinic during the day (at least 8 hours per day).

- During the session, the researcher will observe participants inside the clinic and ensure that the modified gait application is applied, and outside the clinic will be followed by telephone.
- Participants will walk on the gym floor or an adjusted treadmill for at least 15 to 20 minutes during each session. Participants will be instructed to use the mirror for feedback and achieve the target modified gait procedure. However, it will be emphasised gait modification procedures exhibited at baseline pain and function, and then at the end of the trial, it will focus on subjects' acceptability.

Number of Arms: 1

Masking: None (Open Label)

Allocation: N/A

Enrollment: 17 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Feasibility intervention The intervention will be foot insole (lateral wedge) insole, which has already been delivered in routine UK NHS and SA environments by at least one physiotherapist. Clinical testing will be done with 15-25 knee osteoarthritis subjects. These individuals will be assigned to a single intervention group for 4-6 weeks of re-gait training intervention. It involves a personalised gait retraining programme (sizable insole) for the KOA subjects to evaluate the impact on knee pain and improve function. It is set within 4-6 weeks of VAS and the WOMAC tools for knee pain & function outcome.	Device: Lateral Wedge insole Insoles with lateral wedges are placed in patients' shoes to control biomechanical knee loading on the medial side of the knee. Insoles with lateral wedges are designed to be thinner on the inside (medially of the foot) and thicker on the outside (laterally of the foot) to relieve knee biomechanical loading parameters. Other Names: • Footwear insole • Ankle foot orthoses

Outcome Measures

Primary Outcome Measure:

1. Pain level
   The change from baseline pain intensity level at 6-weeks, based on the nine points of a visual analogue scale, where 0 represents (no pain) and 9 represents (worst pain).

   [Time Frame: 6 weeks post-intervention.]
2. Western Ontario and McMaster Universities Arthritis Index-total
   The change from baseline pain, stiffness and physical activity levels at 6-weeks.

   Each question is scored from 0 to 4, which are: None (0), Mild (1), Moderate (2), Severe (3), and Extreme (4).

   Scores are summed for each subscale, ranging from 0-20 for pain, 0-8 for stiffness, and 0-68 for Physical Function.

   A higher WOMAC score indicates worse pain, stiffness, and functional limitations.

   [Time Frame: 6 weeks post-intervention.]
3. Likert scale
   Measuring knee osteoarthritic subjects' satisfaction based on the 5 point Likert scale survey.

   [Time Frame: 6 weeks post-intervention.]
4. Likert scale
   Measuring therapists' agreement based on the 5-point Likert scale survey.

   [Time Frame: 6 weeks post-intervention supervision.]

Eligibility

Minimum Age:	45 Years
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria: KOA Patient participants: • Adults aged above 45 years old. • Both Male & Female.

- Radiographically or KOA participants meet any diagnostic classification guidelines/criteria (American College of Rheumatology classification criteria) or any eligible diagnostic guidelines.
- Typical knee pain while walking > 3 on an 11-point scale (0-10) in at least one knee pain or tenderness, primarily in the medial knee.

Exclusion Criteria:

- Severe KOA subjects (on the waiting list for knee arthroplasty).
- Knee post-operation or corticosteroid intra-articular injection last 6 months.
- Inability to walk for longer than 20 minutes without experiencing severe pain.
- Painful treadmill walking or unable to walk without heavy assistance, such as a lifting belt or walker frame.
- Significant knee effusion, musculoskeletal or neurological diseases that influence gait parameters.
- It is presently undergoing physiotherapy treatment.
- Rheumatoid Arthritis (RA), gout, one or both knees replaced, low back pain, hip OA, any serious knee or lower limb injuries in the past 24 months.

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IPDSharing

Plan to Share IPD: No

References

Citations: **[Study Results]** Al-Arfaj A, Al-Boukai AA. Prevalence of radiographic knee osteoarthritis in Saudi Arabia. Clin Rheumatol. 2002 May;21(2):142-5. doi: 10.1007/s10067-002-8273-8. PubMed 12086165

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Links:

Available IPD/Information:

Documents

Study Protocol
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