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A 6-week program designed to help people with knee osteoarthritis walk better using biofeedback (a technique that uses sensors to provide information about how the body is moving)

Submission date
07/03/2023

Recruitment status
No longer recruiting

Registration date
07/03/2023

Overall study status
Completed

Last Edited
05/12/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Gait retraining is a way to slow down the progression of knee osteoarthritis without invasive procedures by changing how you walk. This can be done by adjusting things like how wide you step or the angle of your foot. Biofeedback is a way to give you immediate feedback about your body's movements so you can adjust them. However, we don't know which type of biofeedback is most effective, or if it has long-term benefits beyond just walking. This study will test a 6-week biofeedback program to see if it can reduce knee loading and pain in people with knee osteoarthritis. We will compare different types of biofeedback and see how they affect participants' walking patterns. We will also look at how the program changes muscle coordination strategies during walking. The results will help us find the best ways to retrain walking patterns and reduce knee pain for people with knee osteoarthritis.

Who can participate?
Patients aged between 45 and 69 years, with OA.

What does the study involve?
Participants will be randomly allocated into the knee moment biofeedback group, gait pattern biofeedback group, and control group. Supervised training sessions will be conducted once a week for six continuous weeks, with real-time biofeedback produced using marker-based motion capture and an instrumented treadmill. Participants in the biofeedback groups will be encouraged to maintain the altered gait pattern outside of the laboratory. Baseline, post-intervention and one month follow-up assessments will be performed to measure knee loading, muscle activation, gait parameters, knee pain level and functional ability.

What are the possible benefits and risks of participating?
By identifying and practicing the optimal gait pattern identified in this trial, there will be physical

benefits such as pain reduction, reduced knee loading, improved quality of life and reduced KOA progression for people with KOA. Besides, we offer travel expenses and parking permits for taking part in this study. There is a small risk of falling if a participant loses balance when conducting movement tasks, but the risks of falling during the trial is considered very low and certainly no greater than when conducting these daily activities outside the laboratory.

Where is the study run from?
University of Bath (UK)

When is the study starting and how long is it expected to run for?
July 2022 to October 2024

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305860

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52744, EP/T022523/1, IRAS 305860

Study information

Scientific Title
A 6-week knee moment and gait pattern biofeedback gait retraining programme in people with knee osteoarthritis and its translation into daily life

Study objectives
Gait retraining with knee moment and gait pattern biofeedback can significantly reduce knee loading and knee pain, improve knee function and quality of life in people with knee osteoarthritis. In addition, one of these biofeedback will have a better effect regarding to reduce knee loading and knee pain compared to the other biofeedback group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/06/2022, South West - Central Bristol REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8258; centralbristol@hra.nhs.uk), ref: 22/SW/0063

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
EXPERIMENT SETTING
All data collection sessions will be conducted in the Applied Biomechanics Suite at the University of Bath. During gait retraining, participants will walk on an instrumented treadmill. During baseline, post-intervention and follow-up assessment, participants will conduct overground walking, sit-to-stand and stair climbing on embedded force platforms in the floor and a portable embedded force platform on stairs. During each session, a fifteen camera, three-dimensional (3D) optoelectronic camera system (Oqus, Qualisys, Sweden) will be used to collect motion capture data. Reflective markers will be placed on the body for static and dynamic measures. Markers will be placed on both legs at the distal phalanx of the first toe, metacarpal phalangeal joints 1 and 5, calcaneus, medial and lateral malleolus of the ankle, medial and lateral joint centre of rotation of the knee, left and right anterior superior iliac spine (ASIS) and posterior superior iliac spine (PSIS), left and right iliac crest, vertebrae C7,

suprasternal notch of the manubrium and on the acromion process of the left and right shoulders. Clusters of 4 marker on rigid plates will be placed on the lateral side of the shank and thigh of each leg midway between joints using Velcro straps. At baseline assessment (Week 0), post-training assessment (Week 6) and 1-month follow-up assessment, surface electromyography (EMG) data will be collected from lower limb muscles using surface electrodes, including the following muscles spanning the knee: Vastus lateralis, vastus medialis, rectus femoris, long head of biceps femoris, medial and lateral gastrocnemius, and tibialis anterior. Before placement, electrode locations on each participant's affected leg will be palpated, shaved, lightly abraded, and cleaned with an alcohol swab. A reference electrode will be placed over the head of the fibula.

PROCEDURE

Participants will be asked to record a one-week activity log prior to starting the training programme, which will measure their normal amount of activity before intervention. Participants will attend the lab a total of nine times. Firstly, they will be invited to the lab for a baseline qualitative assessment session (Week 0a). After all participants completing the baseline qualitative assessment session, a randomisation procedure will be conducted by a researcher who is not involved in any aspect of data collection or training. The randomisation and group allocation will be determined prior to the gait retraining programme commencement. Participants will be randomly allocated to knee moment biofeedback group, gait pattern biofeedback group and control group.

Then, participants will attend a baseline quantitative assessment session (Week 0b) after the group allocation. For participants who are allocated to knee moment biofeedback group and gait pattern biofeedback group, there will be a gait retraining biofeedback identification section within the baseline quantitative session (Week 0b), while participants in the control group will have a treadmill walking familiarisation session (Week 0b) with the same amount of time as the intervention groups. Sessions 3-8 (Week 1-6) will involve performing the gait retraining using the randomised biofeedback for the two intervention groups, while only treadmill walking without any instruction and feedback for the control group. Session 8 (Week 6) will finish with the post training assessment. Finally, session 9 will be a retention assessment (Week 10).

Baseline and Biofeedback identification

Qualitative assessment (Week 0a)

During the baseline qualitative session, demographic and somatometry information (e. g. age, sex, height, weight), Oxford knee score, WOMAC questionnaire will be collected.

Quantitative assessment (Week 0b)

After the baseline qualitative assessment session and group allocation, there will be a baseline quantitative assessment session, which will involve collection of baseline biomechanical data (e. g. KAM, KFM, EMG data, FPA, step width, step length, walking velocity) and numeric rating scale (NRS) knee pain during three daily activities. Participants will be asked to perform walking and sit-to-stand on the overground forceplates, and stair climbing on a portable embedded forceplate on the stair. For the two intervention groups, each activity will need to be performed under four foot conditions, which are 10° toe-out, 10° toe-in, neutral (0°) and preferred foot positions. For the control group, each activity will need to be performed only under preferred condition. Under the toe-out, toe-in and neutral conditions, researcher will instruct participants to correct foot orientation using the angle of foot (defined as a 6DOF rigid body) to the global coordinate system in Qualisys Track Manager (QTM). Participants will then be asked to maintain this foot angle and will receive oral feedback from the researcher whilst they are getting used to the foot orientation. The angle will inevitably vary from the starting angle, but as long as the measured angle from the trial is between ± 5° of the intended orientation, it will be accepted. All foot conditions will be completed in a randomised order, except that preferred condition will

always be conducted first. Each condition in each activity will be repeated until five successful trials are obtained. At the end of the final trial of each condition, participants will be asked to report their perceived knee joint pain using NRS. This protocol has already been approved previously (IRAS ID: 280287).
To reduce the burden placed on the participants who are in the intervention groups, if they have already completed the study stated above (IRAS ID: 280287), they will only need to perform the preferred condition during each activity to ensure that their walking mechanics have not changed since they performed the previous study. Each activity will be repeated five times. At the end of the final trial of each activity, participants will be asked to report their perceived knee joint pain using NRS.

Biofeedback Identification (Week 0b)
This section will only be conducted in the two intervention groups. After the three activities assessment, participants will be instructed to walk on the instrumented treadmill and to try various gait patterns (FPA, step width and step length) to identify a new gait that reduces KAM and KFM in a symmetric, pain free and sustainable method. The FPA, step width and step length that most effectively reduces KAM and KFM for each individual will be identified and recorded for the following week.
For control group, there will be a treadmill walking familiarisation session (Week 0b) instead. They will be instructed to walk on the instrumented treadmill for the same amount time as the intervention group.

Gait retraining programme
Participants will come back to the lab to begin their 6-week gait retraining programme (Week 1 to Week 6) from the following week (Week 1). For the two intervention groups, participants will start to learn and practice the new gait pattern identified in Week 0b by either knee moment feedback or gait pattern feedback (FPA, step width and step length). The frequency for the lab-based training session will be once a week, and the length of each treadmill walking retraining will gradually increase from 15 minutes in Week 1 to 30 minutes in Week 6. The length of feedback time will go up by the same amount (three minutes) each week until Week 4. From Week 5 onwards, feedback time will remain the same (24 minutes) while walking time will increase to 30 minutes in Week 6. The frequency and length of training session will be identical for the control group. Outside the lab, participants in the intervention groups will be asked to practice walking with the altered gait pattern on their own at least 10 min per day as well as try to maintain this pattern during the rest of their daily walking. All participants will be given weekly activity logs to record the time of day and amount practiced each day during the 6 weeks of gait retraining. Participants will also be provided with accelerometers throughout the study, which are movement monitors worn on the wrist to measure the overall physical activity level.

Knee moment biofeedback gait retraining group
Participants will be asked to walk on an instrumented treadmill at constant self-selected speed. Real-time feedback of their live KAM and KFM through Visual 3D (C-Motion, Inc.) will be provided on the screen in front of the treadmill. They will be instructed on how to reduce KAM by modifying their gait patterns (FPA, step width and step length) with a target of minimum 10% reduction of KAM and a target of no increase in KFM (Richards et al., 2018; Ulrich et al., 2020). The baseline KAM value will be presented as a doted red line for reference. The optimal gait pattern may change over the six weeks in this group.

Gait pattern biofeedback gait retraining group
Participants will be asked to walk on the same instrumented treadmill at constant self-selected speed. The feedback of both target and real-time gait parameters including FPA, step width and step length will be visualised and presented on the screen in front of the treadmill through

motion capture system and Visual 3D. The individualised magnitude of modification (the degree of foot internal rotation and the distance of step width) in the target feedback will depend on the baseline outcome measures, and it will be presented symmetrically for both legs consistently over the six weeks. Participants will be told to match the target as much as possible. No further verbal instruction will be provided. The training time and feedback time per session will be identical to that of the knee moment biofeedback group.

Control group
Participants in the control group will be asked to walk on the same instrumented treadmill at a self-selected speed without any guidance or feedback. The frequency and length of training session will be identical to that of the intervention groups. However, no feedback will be given about their joint mechanics and motion capture during the walking training. In addition, participants will be given no instructions for out-of-lab activities.

Dual-task
From week 1 to week 6, walking with dual-task will be performed on the same instrumented treadmill in the end of each session. After completing the gait retraining on the treadmill during these sessions, participants will be asked to rest for 5 minutes and then return to walking on the treadmill for 1-2 minutes while performing the dual task. Participants will perform the Visual Stroop test for the dual-task. Words that describe a colour (e.g. red, blue) will display on the screen in front of the participants at 2 second intervals, in different colour text (e.g. the word red will be display in blue text). Participants will need to response with the colour of the text while maintaining the modified gait pattern during treadmill walking.

Post-training assessment
Post-training assessment will be conducted at the end of this training programme, which will be the end of the Session 6 (Week 6). Participants will need to complete WOMAC questionnaire in the beginning of the assessment. Then, they will be asked to conduct overground walking, sit-to-stand and stair climbing on the overground forceplates and a portable embedded forceplate on the stair. Reflective markers will stay on participants' body, while EMG electrodes will be added on the lower limb muscles to measure the muscle activation during these activities. All activities will be performed under their preferred condition. Each activity will be repeated five times. At the end of the final trial of each activity, participants will be asked to report their perceived knee joint pain using NRS.

Follow-up retention assessment
There will be a follow-up retention assessment session one month after the completion of the training programme (Week 10). During the follow-up assessment session, participants will be asked complete the WOMAC questionnaire first. Then, they will be asked to conduct overground walking, sit-to-stand and stair climbing on the overground forceplates and a portable embedded forceplate on the stair. Reflective markers and EMG electrodes will be attached on participants' body to capture the movement and measure the muscle activation. All activities will be performed under their preferred condition. Each activity will be repeated five times. At the end of the final trial of each activity, participants will be asked to report their perceived knee joint pain using NRS.
Between the post-training assessment session and follow-up assessment session, there will be no training or instructions of any kind being provided. Each assessment sessions will collect the same outcome measures, completed in the same order by the same assessor.

Delayed control intervention
For control group, while participants may have a strong preference to receive the intervention, they will be offered a delayed control intervention after they finish the study (Week 10). It will

involve a biofeedback identification session and six in-person biofeedback gait retraining sessions. There will be no assessment session in this delayed control intervention programme.

Intervention Type
Behavioural

Primary outcome measure
1. Knee loading parameters (e. g. KAM, KFM and KAM impulse) are measured using the forceplates and motion capture system at all assessment session(week 0, week 6 and week 10), and all training sessions (week 1-6) in the intervention groups.
2. Gait pattern parameters (e. g. foot progression angle, step width, step length) are measured using motion capture system at all assessment session(week 0, week 6 and week 10), and all training sessions (week 1-6) in the intervention groups.
3. Knee pain is measured using Numeric Rating Scale (NRS) at all assessment sessions (week 0, week 6 and week 10).
4. Functional ability is measured using WOMAC questionnaire at all assessment sessions (week 0, week 6 and week 10).

Secondary outcome measures
1. Muscle activation data is measured using surface electromyography (EMG) at all assessment sessions (week 0, week 6 and week 10) and first and last training sessions (week 1 and week 6).
2. Knee osteoarthritis severity is measured using Oxford Knee Score at baseline assessment session (week 0).
3. Free-living energy expenditure is measured using a wrist-mounted physical activity monitor (GENEA Active) and weekly activity logs from week 0 to week 5.

Overall study start date
01/07/2022

Completion date
23/10/2024

Eligibility

Key inclusion criteria
1. Clinical diagnosis of knee OA
2. Aged between 45 and 69 years
3. BMI <=40.0 kg/m²
4. Current knee pain (minimum VAS score 2)
5. Oxford Knee Score 20 ~ 35 for index knee
6. Able to walk without an assistive device for at least 15 consecutive minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
45 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
50

Key exclusion criteria
1. Body mass index (BMI) >40.0 kg/m²
2. History of knee joint replacement or tibial osteotomy
3. Conditions other than knee OA that could affect walking (e.g. amputation, severe back pain, severe peripheral vascular or heart disease and neurological or developmental disease including multiple sclerosis, Parkinson's disease, myositis, rickets, or lower limb musculoskeletal surgery within the past 6 months)
4. Inability to adopt an altered gait due to previous injury or surgery on the lower extremities
5. Use of any orthotic equipment
6. Corticosteroid injection within the previous 6 weeks
7. Participation in a new structured exercise program within the past 3 months, or planning to commence exercise or other treatment for knee OA in the next 3 months

Date of first enrolment
01/08/2022

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
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ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Research council

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of this study will be disseminated in different formats including peer-reviewed journal articles, conference presentations and internet media, to a wide audience including clinicians, physiotherapists, researchers and individuals with KOA.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication. The data collected by motion capture system will be marker-based model which is not identifiable. Each participant will be assigned a unique project code and their personal information will never be identifiable in published research or conference presentations. An Excel data sheet maintained on a University X: Drive (password protected) will be used to record participant information and only the research team will have access to this information. Signed consent form will be stored in a locked cupboard and kept for 10 years to evidence the consent process.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 9	25/08/2022	07/03/2023	No	Yes
HRA research summary			28/06/2023	No	No
Protocol article		19/12/2023	08/01/2024	Yes	No