Clinical Study Protocol

Reducing knee pain and loading with a gait retraining program for individuals with knee osteoarthritis: Protocol for a randomized feasibility trial

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SUMMARY

Objective: This study aims to 1) determine the feasibility of conducting a full-scale randomized controlled trial (RCT) evaluating the efficacy of a gait retraining program on decreasing knee pain and impact loading in people with knee osteoarthritis, and 2) provide an estimate of treatment effects for a gait retraining program compared to a traditional walking program.

Methods: Forty individuals with knee osteoarthritis will be enrolled in this randomized, double-blind, feasibility trial with two parallel groups. Participants will be randomly allocated to a gait retraining program aimed to decrease peak axial acceleration of the lower leg (i.e., tibia) by 20% or a traditional walking program. Both programs involve 8 sessions of walking on a treadmill. Feasibility will be assessed with recruitment, enrollment, and retention rates, and number of adverse events and unanticipated problems. Treatment effects will be estimated with measures of knee pain and impact loading collected at baseline, follow-up (<1 week post-intervention), and retention (>1 month post-intervention) visits. Knee pain will be evaluated with the Western Ontario and McMaster Universities Osteoarthritis Index and impact loading will be measured during walking with three-dimensional motion analysis.

Conclusion: Findings of this study will inform the feasibility of a full-scale RCT investigating the efficacy of a gait retraining program for people with knee osteoarthritis.

Trial registration: (NCT04148807).

1. Introduction

Osteoarthritis (OA) is the most common joint disorder in the United States. The knee joint is frequently affected, with approximately 12% of adults over 60 years old having symptomatic knee OA [1] Due to the growing older adult population and obesity epidemic, the prevalence of knee OA and associated healthcare costs are expected to increase over the next 20 years [2,3]. Unfortunately, there is no definitive treatment for managing symptoms of knee OA or slowing the progression of disease. The lack of effective treatment is alarming because knee OA is a leading cause of disability [4] which in turn negatively influences quality of life, participation in life roles, and physical activity levels. Therefore, a critical need exists for developing non-invasive treatments that reduce symptoms of knee OA and slow disease progression.

Many treatments for knee OA primarily target pain and inflammation (e.g., injectable therapies and oral medications). Although pain is the primary symptom of knee OA and an important target of treatment, addressing pain in isolation can be detrimental to joint health. Notably, several studies have demonstrated that analgesics and anti-inflammatories encourage OA progression because their pain reduction effects are associated with increased knee joint loading [5–9]. Since increased knee joint loading is a well-established risk factor for the development and progression of knee OA [10–13], treatments that target loading may be more effective at improving patient outcomes.

Theoretically, there are many different ways to effectively reduce loads. Weight loss programs, orthotics, knee braces, and canes are among
the most commonly reported approaches for reducing loads during walking in individuals with knee OA. Gait retraining is another promising treatment approach, with supportive evidence for reducing impact loading during walking and running [14–19]. Gait retraining uses motor learning principles to teach a new motor behavior in order to reduce a gait parameter that is associated with pain and/or disease progression (in this case, load). The simplicity, cost-effectiveness, and sustainability of gait retraining may provide some key advantages compared to weight loss programs and other treatments. To date, the most common gait retraining techniques for knee OA have focused on increasing lateral trunk lean, toe-in angle, toe-out angle, and medial knee thrust to reduce a surrogate measure of medial tibiofemoral joint load (i.e., knee adduction moment; KAM) [14,16–22]. Although these techniques effectively reduce KAM in the treated leg, they may introduce abnormal gait patterns that increase the risk of secondary injuries [23]. Modifying loads directly, instead of indirectly through changes in joint positions or angles, may reduce concerns regarding secondary injuries and could lead to better long-term outcomes for individuals with knee OA.

While not yet applied to knee OA, gait retraining with feedback on loading has been used to reduce injury risk in runners [24]. Ankle-worn accelerometers provide a simple, clinically-accessible method for monitoring and providing real-time feedback on peak tibial axial acceleration (PTA), which is a valid and reliable measure that has a positive association with peak and average vertical loading rates during walking and running [25–29]. Notably, Crowell and Davis [30] showed that PTA while running can be reduced by 50% (effect sizes ranged from 1.2 to 1.7) in healthy runners who complete a two-week gait retraining program that provides feedback on PTA. However, it is currently unknown if the effects of this gait retraining program are similar for walking in individuals with knee OA, and if older people with knee OA are willing and able to undertake such a program. Therefore, the primary aim of this study is to determine the feasibility of conducting a full-scale randomized controlled trial (RCT) evaluating the efficacy of a gait retraining program on decreasing knee pain and impact loading in people with knee OA. The secondary aim is to provide an estimate of treatment effects for a gait retraining program, compared to a traditional walking program, in people with knee osteoarthritis. We hypothesize that compared to individuals who participate in a traditional walking program, those in a gait retraining program will have greater reductions in 1) knee pain and 2) impact loading (vertical impact peak, average loading rates, and instantaneous loading rates) while walking.

2. Methods

2.1. Study design

This study is a randomized, double-blind, feasibility trial with two parallel groups. It was prospectively registered on clinicaltrials.gov (ID: NCT041488807) and designed to conform to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [31] and 2010 Consolidated Standards of Reporting Trials (CONSORT) statement: extension to randomized pilot and feasibility trials [32]. Participants will be randomly allocated to one of two groups using an a priori computer-generated sequence. The experimental group will receive a gait retraining program, while the control group will receive a traditional walking program. Feasibility measures (primary outcomes) will be collected throughout the trial. Knee pain and impact loading while walking (secondary outcomes) will be collected at three assessment visits: baseline, follow-up (within 1 week of the last intervention session), and retention (1 month after the last intervention session). The study flow is shown in Fig. 1 and data collected at each study visit is presented in Table 1.

2.2. Participants

A total of 40 participants who meet the clinical definition of having knee OA in at least one knee based on the National Institute for Health and Care Excellence (NICE) guidelines [33] will be recruited in Boston, Massachusetts and the local vicinity. Based on previous literature [34, 35], a sample size of 20 participants per group will be adequate for evaluating feasibility and gaining sufficient data to determine if the treatment is worth pursuing in a full-scale RCT. Eligibility criteria are detailed in Table 2. The expected recruitment rate is two participants per month. Methods for recruitment include social media and online postings, postcard mailings, flyers, newspaper ads, local clinicians, word-of-mouth, and snowball sampling.

Initial screening will be performed either over the phone or online. Phone screening will be performed by trained study personnel using an approved script. Online screening will be performed using a secure survey platform (Qualtrics XM, Seattle, WA, USA), and responses will be verified by phone. Screening questions will be answered so that reasons for exclusion can be reported. Individuals who fit the study criteria will be scheduled for a baseline assessment at their earliest convenience. If a baseline assessment occurs longer than a month after the initial screening, the individual will be re-screened to ensure eligibility.

2.3. Feasibility

Recruitment, enrollment, retention, adverse events, and unanticipated problems will be collected and documented throughout the study. Recruitment rate will be measured as the number of individuals screened each month, while enrollment rate will be measured as the number of individuals waitlisted or enrolled each month. Retention will be determined as the percent of enrolled participants who complete all study visits. Lastly, the percent of participants with an adverse event or
### Table 1
Summary of data that will be collected.

| Data                          | Instrument | Timepoints |
|-------------------------------|------------|------------|
|                               |            | Baseline   | Intervention #1 | Intervention #2 | Intervention #3 | Intervention #4 | Intervention #5 | Intervention #6 | Intervention #7 | Intervention #8 | Follow-up | Retention |
| Descriptives                  |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Demographics                  | Survey     | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Medical history               | Survey     | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Physical activity             | PASE       | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| History and characteristics of knee pain | Survey, VAS | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Gait speed determination     | Timing gates | •        | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Anthropometrics               | Stadiometer, digital scale | •    | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Primary Variables of Interest |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Knee pain with activities    | WOMAC-Pain | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Overall knee pain severity   | VAS        | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Impact loading: VIP, VALR, VILR | Force plates | •        | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Secondary Variables of Interest |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Pain sensitization           | Algometry  | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Knee pain while walking      | NPRS       | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| overground                   |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Additional biomechanical      | 3D motion  | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| measures (e.g., joint angles, | capture    | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| moments, powers)             |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Satisfaction, motivation, and perceived improvement | Survey | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Intervention data \(^a\)     |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Tibial acceleration (PTA)    | IMU        | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Knee pain during treadmill walking | NPRS | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Impact loading (VIP, VALR, VILR) | Instrumented treadmill | •    | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| Additional biomechanical      | 3D motion  | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| measures (e.g., joint angles, | capture    | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |
| moments, powers)             |            | •          | •              | •                | •                | •                | •                | •                | •                | •                |            |           |

PASE – Physical Activity Scale for the Elderly; VAS – Visual Analog Scale; WOMAC-Pain – Western Ontario and McMaster Universities Osteoarthritis Index Pain Subscale; VIP – Vertical impact peak; VALR – Vertical average loading rate; VILR – Vertical instantaneous loading rate; NPRS – Numeric Pain Rating Scale; IMU – Inertial Measurement Unit.

\(^a\) Feasibility outcomes will be collected throughout the study.

\(^b\) Data are collected in the last minute of the warm-up and first minute of the cool-down period at each session.
Table 2
Study eligibility criteria.

| Inclusion criteria                  | Exclusion criteria                  |
|-------------------------------------|-------------------------------------|
| ≥45 years old                       | Walks with an assistive device      |
| Knee pain for ≥3 months             | Intra-articular knee injection within 3 months |
| Knee stiffness after periods of inactivity (e.g., sleeping) that lasts <30 min | Disease or condition that affects lower extremity function, besides knee osteoarthritis |
| Knee pain of ≥4 out of 10 while walking* | History of lower extremity surgery |
|                                    | Prescribed opiates or narcotics      |
|                                    | Unwilling to stop other treatments  |
|                                    | Currently pregnant                  |
|                                    | Skin allergy to adhesives           |

* Not part of National Institute for Health and Care Excellence (NICE) guidelines.

unanticipated problem during the study will be determined.

2.4. Randomization and blinding

Participants will be randomly allocated (1:1) to either a gait retraining program (experimental group) or a traditional walking program (control group). The randomization sequence will be computer-generated with blocks of 4, password protected, and inaccessible to the single assessor (JJS) until all assessment visits are completed. Participants will also be blinded throughout the study. Participants will be informed that there are two walking programs, but the study hypotheses and differences between programs will not be disclosed. Study personnel who oversee the intervention sessions will not be blinded to group allocation.

2.5. Baseline assessment

Demographics, past medical history, physical activity level, and participant-reported history and characteristics of knee pain will be collected. Demographics will include age, sex, race, and ethnicity. Past medical history will include questions about rheumatic diseases and orthopedic injuries to the lower body. Physical activity level will be assessed with the Physical Activity Scale for the Elderly (PASE) [36], which is a validated questionnaire for community-dwelling older adults. Participant-reported history and characteristics of knee pain will include duration of symptoms and description of past treatments. Index (i.e. more symptomatic) and non-index (i.e. less symptomatic) knees will be determined with the Visual Analog Scale (VAS) [37]. The knee with the higher VAS score will be defined as the index knee. If VAS scores are equal, the index knee will be defined with the question “Which knee causes you more difficulty when walking?” Participants must choose either their right or left knee for this question.

2.5.1. Knee pain evaluation

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [30,31] and VAS will be completed by each participant to assess knee pain. Scores on the WOMAC pain subscale and VAS will be the primary variables of interest, which quantify knee pain with activities and overall knee pain severity, respectively. The WOMAC pain subscale is composed of five Likert-scale questions that are scored from 0 to 4, with a maximum score of 20 indicating extreme pain. The reliability, validity, and responsiveness of the WOMAC has been extensively reported [38-41] and is recommend for use in clinical trials on knee OA by the Osteoarthritis Research Society International [42]. The VAS is a single question with integer scores ranging from 0 to 100, with 0 indicating no pain and 100 indicating worst pain imaginable. The VAS is a valid and reliable tool that has been widely adopted in adult populations, including those with rheumatic diseases [37,43-46].

Secondary variables of interest for knee pain include measures of pain while walking and measures of local and central sensitization, which will be assessed with mechanical algometry. For evaluating pain while walking, the Numeric Pain Rating Scale (NPRS) [37] will be used during each walking trial during the gait analysis (details below). The NPRS is a verbally-administered measure of pain from 0 to 10, with 0 representing no pain and 10 representing the worst pain imaginable. For evaluating sensitization, an algometer (FPX 50, Wagner Instruments, Greenwich, CT, USA) with a 1 cm² rubber tip will be used to apply force at a rate of 0.5 kg/s to the center of the patella while the participant is seated with their feet resting on the floor and knees flexed to 90°. The participant will be instructed to say “pain” when the stimulus becomes painful. The force recorded at this moment will be recorded as the participant’s pain-pressure threshold. Three trials will be performed on each patella, starting with the non-index knee. Additionally, the posterior aspect of the distal radioulnar joint will be tested on the right arm with similar procedures before testing each patella.

2.5.2. Gait speed determination

Participants will perform five 10-m walk tests at their usual walking speed. The speed of each trial will be measured with timing gates (TCI system, Brower Timing Systems, LLC, Draper, UT) that span the middle 6 m. Average gait speed will be calculated and used throughout the study.

2.5.3. Gait analysis

Participants will be equipped with standardized shoes (Gel-Excite 6, ASICS Corp., Kobe, Japan) and 52 retroreflective markers on their pelvis and lower extremities. The markers will be placed by the single assessor (JJS) throughout the study in the locations shown in Fig. 2. A 10-s static trial will be performed while the participant stands in the anatomical position, with the exception of having arms crossed so that each hand is on the contralateral shoulder. Dynamic hip trials will be performed for each leg by having the participant flex, extend, abduct, and circumduct their hip to approximately 20°. After the static and dynamic hip trials are quality checked, 22 anatomical markers will be removed, leaving 30 tracking markers for walking trials. Tracking markers include one marker on the low back, one marker on each of the 2nd and 5th metatarsal heads, and 25 markers attached to rigid clusters on the pelvis, thighs, shanks, and feet.

Participants will walk along a 15-m walkway for each walking trial.

Fig. 2. Side (A) and posterior (B) views of marker placement for gait analysis.
Three-dimensional (3D) marker trajectories and ground reaction forces (GRFs) will be collected with a 12-camera motion capture system (Qualisys AB, Göteborg, Sweden) and four in-ground force plates (Advanced Mechanical Technology Incorporated, Watertown, MA). Trajectory and GRF data will be sampled at 300 and 1200 Hz, respectively. A minimum of 5 acceptable foot contacts will be collected for each lower extremity. Walking trials will only be acceptable if within 5% of the average gait speed determined during the 10-m walk tests.

Marker and GRF data will be processed with Visual3D software (C-Motion, Inc., Germantown, MD, USA), after each trial is appropriately labeled and trimmed. Joint center positions (i.e., hips, knees, and ankles) and segmental coordinate systems will be defined for each participant with marker data from the static and dynamic hip trials. Geometric and inertial properties of each segment (i.e., pelvis, thighs, shanks, and feet) will be determined with marker data and a measure of body mass [47, 48]. Each joint will have 6-degrees-of-freedom and the subject-specific model will be applied to the walking trials. Marker and GRF data will be low-pass filtered and gait events (e.g., heel-strike, toe-off) will be identified.

The primary variables of interest from the gait analysis are vertical impact peak (VIP), vertical average loading rate (VALR), and peak vertical instantaneous loading rate (VILR) (Fig. 3). VIP will be defined as the first local maxima of the vertical GRF waveform, which represents the maximum amount of force acting on the body during the first half of stance (i.e., impact phase). VALR and VILR will be calculated as the average and peak slope of the vertical GRF waveform in the most linear portion from heel-strike to VIP. Each variable will be determined as an average of five trials for each leg. Validity and reliability of ground reaction forces have been reported in previous literature [49-54].

There are several secondary variables of interest from the gait analysis, including spatiotemporal parameters (e.g., step length, stance time), 3D joint kinematics and kinetics (e.g., hip, knee, and ankle angles and moments), lower extremity energetics (positive and negative hip, knee, and ankle power and work), and estimates of knee joint loads from musculoskeletal modeling. For brevity of the current publication, the details of each secondary variable will be described in future publications.

2.6. Interventions

Both groups will complete an 8-session walking program. At the beginning of each session, body mass will be measured and inertial measurement units (IMU; ImeasureU Ltd., Auckland, New Zealand) will be firmly secured immediately proximal to each medial malleolus. Consistent with methods used in other studies [30,55], care will be taken to ensure the y-axis of the IMUs local coordinate system is aligned with the long axis of the tibia to measure PTA. After providing the same standardized shoes worn during the assessment visits, participants will walk on an instrumented split-belt treadmill (Bertec, Inc., Columbus, OH, USA) for a 3-min warm-up period, an intervention period, and a 3-min cool-down period. At all intervention sessions, the speed of the treadmill will be set to 85% of the average gait speed determined during the baseline overground assessment. The reduction in gait speed for the intervention sessions was chosen because self-selected walking speed is slower for treadmill compared to overground walking, and metabolic cost and perceived exertion are greater on a treadmill, even with a slower gait speed [56]. The intervention period will gradually increase from 10 min at the first session to 30 min at the last session. GRFs, IMU data, and measures of knee pain with the NPRS will be collected bilaterally during the last minute of the warm-up and first minute of the cool-down within each session. To provide additional insights into mechanical changes during extended walking in those with knee OA, 3D marker trajectories will also be collected during the first and eighth session. For these two sessions, the single assessor (JJS) will place the markers before the sessions begin. Technical procedures will mimic those described for the baseline assessment, except walking will take place on an instrumented treadmill with ten complete gait cycles collected bilaterally.

2.6.1. Gait retraining program (experimental group)

Those in the retraining group will walk on the treadmill for 5 min before the first intervention session begins to determine baseline PTA for the index leg. Using a custom-written MATLAB program (MathWorks Inc., Natick, MA, USA), average PTA during the last minute of this warm-up will be calculated. During the retraining sessions, real-time auditory feedback will be given whenever the PTA of the index leg is greater than 80% of the participant’s baseline PTA. Participants will be instructed to “walk as softly as possible to avoid hearing the beeping sound.” Following motor learning principles, biofeedback will be provided continuously during the first four sessions and faded during the last 4 sessions (Table 3).

2.6.2. Traditional walking program (control group)

The control group will follow the same procedures as the experimental group, except auditory feedback will not be provided. Additionally, baseline PTA will not be assessed and no instruction will be provided to “walk softly.” In order to increase the likelihood that participants in the control group will complete the traditional walking program, they will be reminded at each session that walking is recommended for the management of knee OA.

2.7. Follow-up and retention assessment visits

The primary follow-up visit will occur within one week of the last intervention session. At this visit, knee pain and impact loading will be reassessed by the single assessor (JJS) following identical procedures as described for the baseline assessment visit. Since many biomechanical measures are sensitive to changes in walking speed, all walking trials at the follow-up visit will be within 5% of the average gait speed that was determined at the baseline assessment visit. Participants will also be

**Table 3**

| Intervention Session # | 1   | 2   | 3   | 4   | 5   | 6   | 7   | 8   |
|------------------------|-----|-----|-----|-----|-----|-----|-----|-----|
| Walking time (minutes)  | 10  | 12  | 15  | 20  | 24  | 26  | 28  | 30  |
| Biofeedback time (minutes) | 10  | 12  | 15  | 20  | 15  | 15  | 6   | 3   |
| % of session with biofeedback | 100 | 100 | 100 | 60  | 40  | 20  | 10  |

a Biofeedback is provided for the gait retraining (experimental) group only.
asked about their satisfaction, motivation, and perceived improvements. Satisfaction will be rated in integers on a 0 to 10 scale, with 0 indicating “not satisfied” and 10 indicating “very satisfied.” Motivation will be quantified with the Intrinsic Motivation Inventory, which includes 25 Likert-scale questions rated from 1 (not true at all) to 7 (very true) that cover domains of interest/enjoyment, value/usefulness, and perceived choice [57]. Perceived improvement will be measured with a Global Rating of Change scale [58], which is a single Likert-scale question with responses ranging from −5 (very much worse) to +5 (completely recovered).

To determine if changes in knee pain and lower extremity mechanics were retained after the gait retraining program, a retention visit will be performed one month after the last intervention session. All procedures at the retention visit will be identical to the follow-up visit.

2.8. Statistical analysis

2.8.1. Primary outcomes – feasibility

Feasibility measures will be reported with descriptive statistics and critically appraised to determine feasibility of a full-scale RCT. We will categorize a full-scale RCT as ‘feasible’ if all of the following are true: (1) at least 20 people are screened each month, (2) at least 4 people are waitlisted or enrolled each month, (3) 70% of the participants complete the entire study, and (4) less than 15% of the participants have an adverse event or unanticipated problem. If all of these criteria are false, a full-scale RCT will be categorized as ‘not feasible.’ If at least one of the criteria are true, a full-scale RCT will be categorized as ‘feasible with modification.’ In addition to these criteria, an RCT will be ‘not feasible’ if WOMAC pain subscale scores increase for more than 40% of participants in the gait retraining group.

2.8.2. Secondary outcomes – preliminary efficacy

Effects sizes with 95% confidence intervals will be calculated for the knee pain and impact loading outcomes. These estimates will be determined for both programs independently with one-way repeated-measures analysis of variance. Descriptive statistics will be calculated and reported for each outcome, including group means, standard deviations, and between-group differences at each assessment visit. Each analysis will be performed with completers-only and using intention-to-treat.

2.9. Data collection and management

Data will be collected and managed with Research Electronic Data Capture (REDCap), a secure, web-based data management tool [59,60]. Directly in REDCap, participants will complete all participant-reported fields (e.g., demographics and questionnaires) with generated surveys and study personnel will complete all data collection and storage forms. Features such as user rights, branching/skip logic, real-time data validation (e.g., expected responses), and missing data will be implemented throughout the study database to maintain blind and improve overall data fidelity. Quality assurance checks will also be performed monthly by study personnel alongside data backup. Informed consent forms, the randomization scheme, and raw motion capture files will be the only study documents not to be stored in REDCap. Lastly, a separate REDCap database will be used to store the participant identifier codebook (i.e., matches name to study identifier) and participant contact information for scheduling purposes.

2.10. Ethics

The study protocol has been approved by the Institutional Review Board (#18-11-15) at Northeastern University. All study personnel have completed training in the protection of human subjects from the Collaborative Institutional Training Initiative (CITI) online training program for biomedical research. At the baseline assessment visit, written consent will be obtained for all participants after thoroughly disclosing experimental procedures, risks, and benefits. Confidentiality will be maintained throughout the study in accordance with professional standards. Safety of the participants will be ensured by screening for adverse events, serious adverse events, and unanticipated problems at each visit. Adverse events will be defined as any unfavorable or unintended diagnosis, sign, symptom, or disease associated with the study which may or may not be related to the intervention. Knee pain and swelling are expected to fluctuate in persons with knee OA when starting a new treatment. Also, based on previous literature [19,20,22], muscle and joint soreness are expected to increase during the first few sessions of gait retraining and then resolve. Therefore, pain, swelling, and soreness will not constitute an adverse event unless it leads to a serious adverse event (e.g., unplanned knee surgery) or withdrawal from the study. Any identified adverse events or unanticipated problems will be documented and reported to the Data & Safety Monitoring Board and the Institutional Review Board within 48 h by the Principal Investigator (JJS). If deemed necessary, appropriate modifications will be made to the study protocol and reported in future publications.

3. Discussion

The growing prevalence of knee OA necessitates the identification of effective treatments to manage symptoms and slow disease progression. Gait retraining that alters impact loading through tibial acceleration biofeedback may be a promising treatment approach since it has successfully reduced pain and lower extremity loading while running [24]. This approach does not overtly change one’s gait pattern, nor does it require customized wedged shoes or orthotics. However, this method of gait retraining has not been investigated in individuals with knee OA while walking. Since walking is the most common form of physical activity for individuals with knee OA [61] gait retraining for walking may have substantial impact on physical functioning and quality of life. Thus, the current study is significant because it will provide preliminary data on the feasibility and efficacy of a low-cost, clinically-accessible gait retraining technique for treating individuals with knee OA.

Studies involving humans or animals

Clinical trials or other experimentation on humans must be in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Randomized controlled trials should follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines, and be registered in a public trials registry.

Authors’ contributions

All authors made substantial contributions: 1) the conception and design of the study or acquisition of data, or analysis and interpretation of data and 2) drafting the article or revising it critically for important intellectual content and 3) approving the final version of the article. Dr. Stefanik (@stefanik@northeastern.edu) takes full responsibility for the integrity of the work as a whole, from inception to finished article.

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Declaration of competing interest

The authors have no competing interests to declare.

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