Official Title: The Effect of a Gait Modification Training Program on Impact Loading and Running-related Injuries

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Objectives

The purpose of this study is to determine whether a gait modification training program can result in a reduction in impact loading and the incidence of running-related injuries (RRI) among recreational distance runners. Knee angle at initial contact (IC) has been identified in a previous study by the principal investigator (pre-submission stage) as both increasing the average vertical loading rate (AVLR) and the incidence of RRI in the female recreational running population. This variable will be modified to determine the effect on impact loading (AVLR) and incidence of RRI using a repeated measures design.

Background

Numerous studies have shown that individuals can be trained to modify aspects of walking and running[1-18]. Moreover, gait retraining has been shown to be effective in treating overuse injuries in runners[4,7,8,18]. However, since it is unclear what variables independently contribute to the recovery from these injuries and whether these variables can be manipulated prospectively to reduce the risk of injury, optimal prevention and treatment of RRI remains unknown. These studies all included some form of feedback to the subjects, which helped them modify their technique. The feedback methods included verbal instructions and real-time visual[1,3,6,7,9,12,17,18] or auditory information[4,5,8,11,15,16]. Other studies used verbal instructions and videotape reviews[13,14] or an extensive training program[8,19]. Many of these studies have used

overlapping instructions and feedback which make it difficult to infer which factors had a causative effect on changing gait mechanics, muscle activation patterns, and ground reaction forces. Others have used feedback that is difficult to reproduce outside of a lab or clinic environment. Simple cues that produce a specific and intended kinematic or spatiotemporal modification are necessary. Furthermore, these cues need to be consistent and reproducible in multiple training environments in order to be retained as part of the motor program.

Arendse et al[19] reported that 7.5 hours of training over 5 consecutive days was required to learn FF landing, while Dallam et al[20] reported a 1-hour session for 12 weeks was necessary. Diebal et al showed FF landing could be trained in 6 weeks, with training sessions 3 times per week for 45 minutes[8]. An 8-session faded-feedback approach was used by Barrios et al to retrain walkers. This design produced changes in lower extremity biomechanical variables immediately post-intervention as well as at 1-month follow-up [1]. Subjects who receive intermittent feedback have been shown to perform better in the long-term than subjects who receive continuous immediate feedback[21,22]. Removing the feedback is beneficial to motor skill learning because the subjects must rely on internal cues for performing correct motor patterns[23].

Some researchers have suggested that further studies should investigate the effect of gait retraining on injury prevention in runners[8,19]. Changing a runner's gait to reduce the risk of a certain injury, however, may have unintended consequences such as increasing the chance of another kind of injury if other kinematic or spatiotemporal variables are adversely impacted[2,19]. Knowledge of the independent contributions of identified kinematic and spatiotemporal risk factors to impact loading and injury

incidence will allow for targeted modification of these variables so that the risk of negative consequences is limited.

Hypotheses

It is hypothesized that after a 15-week training program, a change in knee flexion at IC will be significant ($p < 0.05$) and will result in decreased impact loading (AVLR) and incidence of RRI.

Outcome Measures

Primary outcome measures:

1) Kinetic outcomes: Average vertical loading rate (Body weights [BW] per second) and vertical impact peak (BWs).
2) Incidence of RRI (calculated as the number of new injuries reported per 100 runners at risk).

Secondary outcome measures:

Secondary outcome measures will be kinematic and/or spatiotemporal correlates of impact loading and incidence of RRI as guided by the literature and determined in previous studies.

1) Knee flexion angle at IC
2) Peak knee flexion angle
3) Angle of the shank at IC

Other outcome measures:

Other outcome measures will be collected to describe and assess the success of the gait modification intervention. These measures include:

1) Participant compliance: Participant compliance with the gait modification intervention will be measured by the number of training sessions attended at Fortius (to a maximum of 8, converted to a percentage) and the number of home training sessions completed (to a maximum of 22, converted to a percentage). Participants will record their home training sessions in their weekly online questionnaire.
2) Adverse events: Adverse events experienced due to the intervention (i.e. increased pain or a new injury) will be recorded in the weekly online questionnaires.
3) Fidelity of training sessions: Assessed by calculating the difference (error, in degrees) between the intended target angle and the actual angle produced during the 10 consecutive stance phases at each of the four time points during each training session (first min, 33%, 66%, and last min) and averaged within the session.
4) Perceived difficulty in achieving targeted modification: Assessed at each training session using an 11-point numerical rating scale (NRS) (0 = "no difficulty", 10 = "unable to perform").
5) Pain: Assessed at each training session using an 11-point NRS (0 = "no pain", 10 = "worst pain imaginable").
6) Rating of Perceived Exertion (RPE): Assessed at each training session using the 15-point Borg RPE scale.

7) Anthropometric and functional measurements: These will include BMI, navicular height, hip internal/external rotation range of motion, Q-angle, and weight-bearing ankle dorsiflexion and knee valgus angle.

Methods

The proposed study is a repeated measures design. A sample size calculation for comparing injury incidence is based on our current injury rate (27.9%) in our previous studies. We calculate that we will require a sample size of 30 to achieve a minimum power of 80% ($\alpha = 0.05$). Thirty uninjured female recreational runners will be recruited through advertisements in Vancouver-area running clinics. Participants must be female between the ages of 18 and 60; have been running for at least three months prior to study commencement; and have experience with running on a treadmill. Participants must not have run more than two half marathons previously. Participants will be excluded if they have experienced a lower extremity injury in the prior three months; have undergone hip, knee, or ankle joint surgery; or currently have pain in their lower back or lower extremities while running.

Eligible participants will first be screened for the biomechanical trait in question (less than 10° of knee flexion at IC). A historical control group from a previous study will be used as a comparison group and a sample that meets the same screening criteria will be matched for age and BMI.

Demographics and a detailed training and injury history will be taken for each subject, which will include information on running experience, previous best times at 5km, 10km, half marathon and marathon distances (if available), and overall number and

type of general musculoskeletal and/or running injuries. Anthropometric and functional measurements (including height, mass, foot length, navicular height, hip internal/external rotation range of motion, Q-angle, and weight-bearing ankle dorsiflexion) will be collected prior to treadmill testing for descriptive purposes and for use as covariates. Participants will wear their regular running shoes.

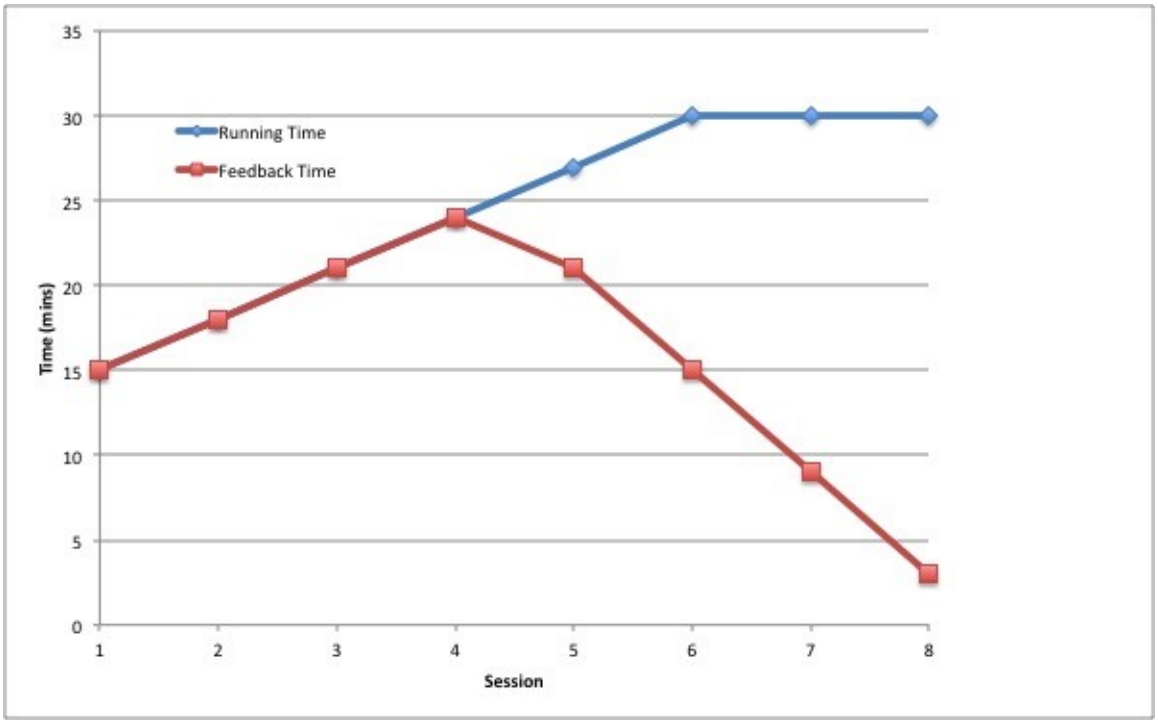
Using an eight-camera passive marker system (Qualisys Motion Capture Corp., Gothenburg, Sweden) and Visual 3D software (C-Motion, Inc., Germantown, MD), participants will undergo a static calibration trial to form a musculoskeletal model. Anthropometric properties of body segments will be scaled to each individual using the subject's height, mass, and segment lengths. Each model segment position will be multiplied by the respective mass; these numbers will then be summed and divided by the total body mass. For bilateral analysis, 19 static/calibration markers and 42 tracking markers (total = 61) will be affixed to each subject. Before data collection, each subject will be allowed 5 minutes to warm-up and determine their speed. Participants will be able to adjust the speed as needed over this period until they identify a speed that is representative of a typical moderate intensity run. Participants will then be asked to identify their rating of perceived exertion (RPE) using Borg's RPE scale [33]. The speed will be adjusted until the participant is at an RPE of 13 ("Somewhat hard" or 70% effort). Three-dimensional kinematic and spatiotemporal data will be collected at this pace over three trials of 15 seconds using the six-camera, three-dimensional motion analysis system. Kinetic data will be collected using an embedded force platform in the instrumented treadmill. All kinetic variables will be normalized to subject body mass. Initial contact and toe-off will be identified by force plate data (using a threshold of 50N).

These data points will be used to determine the stance and swing phases of the gait cycle. All outcome measures will be determined by averaging the first 10 consecutive stance phases within each of the three trials (n = 30 total stance phases). For the purposes of comparison between RF strikers and MF/FF strikers (who may not display a clear VIP), AVLR will be calculated for all individuals as the slope of the vertical GRF–time curve from IC to 13% of stance. This time value has been shown to be the best surrogate for the timing of a missing VIP.

Participants will follow a 15-week half-marathon training program, wearing their regular running shoes throughout the study. During the training program, participants will attend the Fortius Biomechanics Lab on Weeks 1, 2, 4, 6, 8, 10, 12, and 14 (eight sessions in total) for a 15-30 minute gait modification training session following a faded-feedback design (figure 1)[1]. The aim of these sessions will be to modify the angle of knee flexion at IC so that it is greater than 10 degrees. Gait modification will be facilitated through the use of real-time biofeedback of performance[1,24,25] at each training session. The co-investigator, a sport physiotherapist, will also provide standardized verbal instructions to change the desired biomechanical outcome (e.g. “Land with a more bent knee”). For the first four sessions, participants will receive feedback for 100% of the session. By the eighth session, feedback will be provided for just 10% of the session (minutes 1, 15, and 30). All participants will have a total of 60 running sessions (four times per week for 15 weeks). During the weeks in which a lab-based gait modification session is scheduled, participants will have one lab-based biofeedback session and three “regularly scheduled” run sessions in which they will be instructed to focus on the same cues given in the lab during their runs. During the weeks in which no lab-based feedback session is scheduled,

participants will only have the four "regularly scheduled" run sessions in which they will be instructed to focus on the same cues given in the lab during their runs. This will ensure that they do not have any more run sessions than the historical control group.

Figure 1. Faded-feedback design depicting time spent running on the treadmill during each session and time with visual real-time biofeedback for each session. For the first four sessions, participants will receive feedback for 100% of the session. By the eighth session, feedback will be provided for just 10% of the session.



Kinetic, kinematic, and spatiotemporal data will be collected during each session to ensure that the goal of the intervention is being achieved. This will be assessed by calculating the difference (error, in degrees) between the intended target angle and the actual angle produced during the 10 consecutive stance phases at each of four time points during each training session (first min, 33%, 66%, and last min) and averaged within the

session.

Pain, RPE, and perceived difficulty in achieving the targeted modification will be measured in all training sessions using an 11-point NRS (pain and perceived difficulty) and the Borg RPE scale. Adverse events (increased pain or a new injury) and participant compliance with the gait intervention will be assessed in the weekly online questionnaire.

All participants will return to the Fortius Biomechanics Lab at the conclusion of the 15-week half-marathon clinic for retesting. A one-month post-test will also be performed to assess for retention. During both sessions (follow-up and retention), the participants will be asked to run naturally and then with the modified pattern. The natural pattern will be collected to determine whether it has changed since baseline.

The verbal instruction during each training session will be given by the principal investigator (a sport physiotherapist with clinical experience in gait retraining). The therapist will not be involved in data collection, but will process the data. To ensure blinding, data will be collected by an independent lab assistant and coded to blind for participant number for later processing and analysis by the principal investigator. This process will ensure that the principal investigator is unaware of which participant they are analyzing until the conclusion of the study.

Demographic, anthropometric, and functional variables will be analyzed for differences between the intervention group and a historical control group from our previous studies at baseline using 2-tailed t-tests for normally distributed continuous variables. Injury incidence (number of new injuries reported per 100 runners at risk) will be compared between groups using paired t-tests. Differences in outcomes pertaining to the feasibility of the intervention (perceived difficulty, exertion, fidelity, compliance) will

be assessed in the intervention group between session 1 and 8 using paired t-tests. The biomechanical and clinical outcomes from the follow-up and one-month post-intervention modified patterns will be compared to the baseline values using ANOVAs for repeated measures. Planned pairwise comparisons between the visits will be conducted. Differences will be considered statistically significant at $p<0.05$.All statistical analyses will be performed using SPSS version 22.0 (SPSS Inc., Chicago, IL).

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