


Sensor-based gait training to reduce contact time for runners with exercise-related lower leg pain: a randomised controlled trial

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ABSTRACT

Objectives To assess the effects of a 4-week randomised controlled trial comparing an outdoor gait-training programme to reduce contact time in conjunction with home exercises (contact time gait-training feedback with home exercises (FBHE)) to home exercises (HEs) alone for runners with exercise-related lower leg pain on sensor-derived biomechanics and patient-reported outcomes.

Design Randomised controlled trial.

Setting Laboratory and field-based study.

Participants 20 runners with exercise-related lower leg pain were randomly allocated into FBHE (4 male (M), 6 female (F), 23±4 years, 22.0±4.3 kg/m²) or HE groups (3 M, 7 F, 25±5 years, 23.6±3.9 kg/m²).

Interventions Both groups completed eight sessions of HEs over 4 weeks. The FBHE group received vibrotactile feedback through wearable sensors to reduce contact time during outdoor running.

Primary and secondary outcome measures Patient-reported outcome measures (PROMs) and outdoor gait assessments were conducted for both groups at baseline and 4 weeks. PROMs were repeated at 6 weeks, and feedback retention was assessed at 6 weeks for the FBHE group. Repeated measures analyses of variance were used to assess the influence of group and timepoint on primary outcomes.

Results The FBHE group reported increased function and recovery on PROMs beyond the HE group at 6 weeks ($p<0.001$). There was a significant group by time interaction for Global Rating of Change ($p=0.004$) and contact time ($p=0.002$); the FBHE group reported greater subjective improvement and reduced contact time at 4 and 6 weeks compared with the HE group and compared with baseline. The FBHE group had increased cadence (mean difference: 7 steps/min, $p=0.01$) at 4 weeks during outdoor running compared with baseline.

Conclusion FBHE was more effective than HE alone for runners with exercise-related lower leg pain, manifested with improved PROMs, reduced contact time and increased cadence.

Trial registration number NCT04270565.

INTRODUCTION

Lower limb injuries constitute up to 50% running-related injuries,^{1 2} and recent

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Runners with exercise-related lower leg pain have been found to present with altered gait biomechanics during outdoor running.

WHAT THIS STUDY ADDS

⇒ Outdoor gait training with standard of care home exercises (HEs) was more effective than HEs alone on improving self-reported pain and function and on movement patterns during outdoor running.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Clinicians may consider implementing outdoor-based feedback to improve running biomechanics. Future research is needed to establish the benefit of this modality in a larger, representative sample.

literature has advocated using ‘exercise-related lower leg pain’ as the preferred nomenclature when other injuries can be ruled out with clinical examinations.^{1 3} Given the burden exercise-related lower leg pain imposes on runners, recent research has assessed contributing factors to injury development to guide interventions.⁴ However, the only recommended care for runners with exercise-related lower leg pain is to perform calf stretching.⁵ Rehabilitation is often included in clinical practice and should be considered for exercise-related lower leg pain management, especially as recent work has identified hip and ankle muscle weakness among these patients.⁶ Previous research that incorporated a strengthening programme for injured runners successfully reduced patients’ pain and improved patient-reported outcome measures (PROMs).⁷ These studies may be used as a framework for developing interventions for runners with exercise-related lower leg pain.

In addition to strength and motion deficits, recent laboratory-based gait analyses have identified increased peak rearfoot eversion during stance,^{8 9} longer stride length,¹⁰ and slower cadence among runners with lower extremity injuries or active symptoms.¹⁰ Additionally, runners with a history of lower extremity injuries have been found to present with increased vertical impact peaks and average loading rates.¹¹ Although gait-training programmes targeting these factors have been successful,¹² these interventions have been primarily limited to indoor settings among healthy runners. While several studies have implemented outdoor gait training for healthy runners and runners with tibial stress fractures,^{13 14} more evidence is necessary to support our understanding of treatment success among runners actively experiencing lower limb pain in natural running environments.¹² Outdoor running assessments implementing wearable technology have identified increased and more variable contact time as the key factor differentiating runners with exercise-related lower leg pain from healthy counterparts.^{6 15} While previous work has not identified a difference in contact time between injured and healthy runners,¹⁶ this may be attributed to supervised, indoor running that is distinct from typical bouts of outdoor running. Additionally, while longer contact time without significantly different cadence has been found to be associated with lower peak vertical ground reaction forces and higher duty factors among marathoners compared with a control group,¹⁷ longer contact time with concomitantly slow cadence may be associated with a longer epoch of loading exposure imposed on lower extremity structures.¹⁸ Based on past outdoor assessments, it is surmised that this longer overall loading contributes to the cumulative stress imposed on the lower limb. As such, longer contact time may be a key contributing factor to exercise-related lower pain symptoms and may represent a target for clinical intervention. To date, there are no studies that have explored the effects of gait training to reduce contact time on pain and movement patterns among runners with exercise-related lower leg pain.

The purpose of this study was to assess the effects of 4 weeks of outdoor gait training to reduce contact time gait-training feedback with home exercise (FBHE) compared with home exercises (HEs) alone for runners with exercise-related lower leg pain. The authors compared groups and timepoints on PROMs and sensor-derived running biomechanics over the 4-week intervention period. PROMs were repeated for both groups at 6 weeks, and feedback retention was assessed for the FBHE group alone at 6 weeks. It was hypothesised that the FBHE group would demonstrate reduced pain and increased function at 4 and 6 weeks compared with baseline and the HE group, and decreased sensor-derived contact time, increased cadence and decreased loading at 4 weeks compared with baseline and the HE group. It was also anticipated that the FBHE group would retain sensor-derived biomechanical changes at 6 weeks.

METHODS

The Consolidated Standards of Reporting Trials flow-chart outlining the randomised controlled trial study procedures is presented in [figure 1](#).

Participants

Participants were recruited between February 2020 and May 2021 (end of the academic semester) through our local university and surrounding community. Participants were required to be 18–45 years of age, involved in running at least three times per week for the past 3 months, and report pain between 20 mm and 80 mm on the 100 mm Visual Analogue Scale (VAS) during or following running in the lower leg for ≥ 1 month, confirmed using a clinical assessment.^{19–21} Participants had to score $< 90\%$ on the Exercise-Induced Leg Pain Questionnaire, British Version (EILP-Br).^{3 19 20 22} The Exercise-Induced Leg Pain Questionnaire has been found to have excellent internal consistency (intraclass correlation coefficient (ICC): 0.92–0.94) and test–retest reliability (ICC: 0.987–0.995) across patients with exercise-related lower leg pain.^{3 22} Exclusion criteria included pain over the Achilles tendon, popliteal fossa or the superficial posterior compartment of the lower leg, medical diagnoses of compartment syndrome, tibial or fibular stress or full fractures within 3 months.^{3 22} These injuries were exclusionary as these diagnoses would prohibit individuals from completing running due to bone or neurovascular compromise. Participants additionally could not have other pathologies or surgeries, or known pregnancy. The study was approved by our University's Institutional Review Board for Health Sciences Research (IRB-HSR 22107) and registered as a clinical trial. All participants provided informed consent prior to study procedures.

Sample size estimation

While we originally aimed to recruit 20 participants per group to achieve 80% power and $< 15\%$ attrition, the global pandemic resulted in resource constraints hindering our sample size.²³ Based on our available sample and outcomes from our primary variable of interest, the false-positive risk based on the prior probability of 0.5 was 7%.²⁴

Patient-reported outcome measures

In addition to the 100 mm VAS and EILP-Br questionnaires completed during screening, participants completed a running history questionnaire (weekly mileage, number of running days per week, years of experience and pace), Wisconsin Running Injury and Recovery Index,²⁵ and Lower Extremity Functional Scale (LEFS; [table 1](#)) at baseline. The Global Rating of Change (GROC) scale was used to gauge recovery throughout the programme at study timepoints of 2, 4 and 6 weeks.²⁶ Each questionnaire included in this study have demonstrated fair to excellent construct validity (LEFS: r range=0.73–0.8,²⁷ Wisconsin Index: r range=0.67–0.75,²⁸ or face validity (GROC: r range=0.72–0.90)²⁹ and excellent test–retest

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) study flowchart

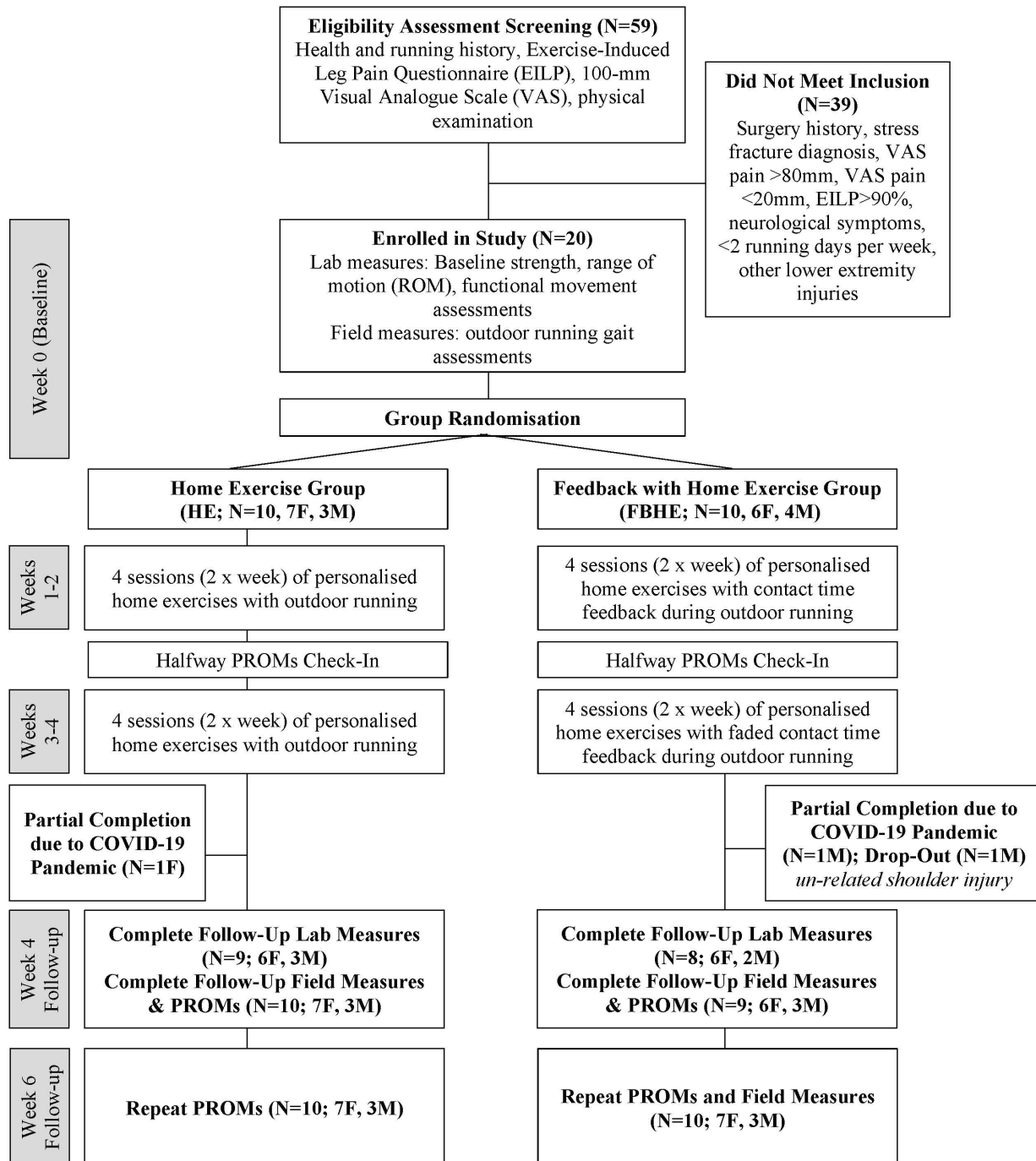


Figure 1 Consolidated Standards of Reporting Trials study flowchart. PROM, patient-reported outcome measure.

reliability (LEFS: $R=0.94$,²⁷ GROC: $ICC=0.90$ ²⁹ and Wisconsin Index: $ICC=0.934$).²⁵

Patient and/or public involvement

Four physical therapists (two dual-credentialed as athletic trainers) that had expertise in treating injured runners were involved in designing the functional movement assessments and rehabilitation plans prior to study initiation.

Procedures

Baseline visit: clinical assessments

Participants reported for a baseline visit at the university research laboratory. Clinical assessments were performed by a blinded athletic trainer with at least 2 years of clinical experience (SLS and XDT) or a trained laboratory assistant with 2 years of laboratory experience (PNF). Lower extremity alignment and range of motion were

Table 1 Participant demographics at baseline for FBHE and HE groups

	FBHE n=9; 3 M, 6 F (mean±SD)	HE n=10; 3 M, 7 F (mean±SD)	P value
Age (years)	23±4	25±5	0.48
Height (cm)	168±12	167±8	0.84
BMI (kg/m ²)	22.0±4.3	23.6±3.9	0.42
Running experience (years)	6±5	5±3	0.68
Weekly mileage (km)	24±18	24±19	0.97
Average running pace (min/km)	5:57±1:07	5:29±0:39	0.75
Shoe mileage	160±135	145±129	0.81
Pain location			

Note: the participant who dropped out of the study was excluded from the FBHE group.

Heat maps generated based on where patients indicated they experienced pain at baseline. Areas with warmer colours indicate higher density of selected problem areas, while cooler colours indicate lower density of selected problem areas.

*Significant at $p \leq 0.05$.

BMI, body mass index; F, female; FBHE, contact time gait-training feedback with home exercise; HE, home exercise; M, male.

measured using a standard goniometer, and strength was assessed using a hand-held dynamometer. All measurements followed standard patient positioning, anatomical landmarks and equipment based on well-established and published procedures (online supplemental file 1).^{30–32}

Participants completed three functional movements: Y-Balance Test reach distances,³³ lateral step-downs from a 15 cm stair,³⁴ and single-leg squats to 45° knee flexion.³⁵ The functional movements were classified by the same blinded assessor into one of the following profiles: (1) medial knee displacement and/or ipsilateral hip drop with or without contralateral trunk lean (valgus), (2) lateral patellar displacement and/or contralateral hip hike with or without ipsilateral trunk lean (varus) and (3) neutral. If participants had one or more movement profile in the valgus or varus groups, they were categorised accordingly. If these adaptations were not present, participants were categorised into the ‘neutral’ group. Clinical measurements and assessment scores were used to delineate specific HE plans, which were developed by an expert panel of physical therapists with expertise in treating injured runners (online supplemental file 2).

Baseline visit: outdoor running

RunScribe Plus sensors (RunScribe Labs, Half Moon Bay, California, USA) consisting of a triaxial accelerometer, magnetometer and gyroscope were used to collect outdoor running biomechanics (contact time, cadence, pace, stride length, shock (composite score combining

impact, or vertical, and braking, or horizontal, force vectors), and pronation excursion and velocity) at a 200 Hz sampling rate, with on-board processing and memory. The sensors have demonstrated fair (pronation excursion ICC: 0.57) to excellent (contact time ICC: 0.93) validity against gold standard three-dimensional motion capture systems.^{36,37}

Participants were issued a set of sensors, instructed on proper usage, and downloaded the associated mobile application. Participants mounted the sensors on their shoelaces and ran on a predetermined 2688 m route for calibration and baseline outdoor running assessment. Participants were asked to run with the sensors two times per week during sustained runs (≥ 2 miles) over 4 weeks and to record their pain level during runs in the mobile application (0–10).

Baseline visit: group allocation

Clinicians blinded to participant group allocation were dismissed. A random-number generator was used by an investigator who was not involved in patient interactions (JH) to determine the randomisation sequence. Group assignments were placed in sealed opaque envelopes and opened following baseline measures by the clinician administering the feedback. Participants allocated to the HE group were provided a list of their specific HEs with video demonstrations to be completed two times per week over the study period (online supplemental file 3).

Participants were instructed to record exercise compliance in their RunScribe mobile applications.

Participants allocated to the FBHE group received the same HE instructions and were additionally issued a Garmin Forerunner 235 wristwatch (FR235; Garmin Corporation, Olathe, Kansas, USA). The wristwatches were solely used to facilitate gait-training feedback and display the contact time metric in real time and were not used for monitoring purposes. The unblinded researcher manually set a 5% reduction of each participant's baseline outdoor run average contact time onto the Garmin wristwatch using custom code. The 5% threshold was determined from previous findings among runners with exercise-related lower leg pain.¹⁵ FBHE participants were oriented to the gait-training procedures on the indoor treadmill; they received a vibration of three quick, successive pulses that were intermittently delivered every 125 ms from the watch if the contact time on the RunScribe sensors exceeded the threshold and were sequentially repeated until the contact time fell below the threshold. FBHE runners were instructed to shorten their contact time to reduce the vibration; however, they were not provided further cues. Once participants indicated they were comfortable with the feedback procedures to be completed two times per week, they were dismissed.

Weekly check-ins

Participants completed virtual weekly check-ins due to the COVID-19 pandemic to determine HE compliance and adjust exercises as needed (see online supplemental file 3 for specific criteria-based progressions). At the 2-week timepoint, all participants completed the Wisconsin Running Injury and Recovery Index²⁵ and the GROC scale,²⁶ and repeated the 100 mm VAS. The feedback programme was faded for the FBHE group by using the feedback for 50% of their runs for the final 2 weeks (ie, 15 min of a 30 min run).

Follow-up procedures

Participants returned to the laboratory at 4 weeks to repeat outdoor gait assessments, which were completed without feedback for the FBHE group. No further instructions were provided to participants to avoid any potential influence on retention outcomes.

Participants were contacted 2 weeks later (6-week timepoint) to repeat all PROM questionnaires. The FBHE group also repeated the outdoor gait assessment without feedback on the calibration route to assess gait-training retention.

Data processing

Outdoor running biomechanics

Sensor-derived biomechanics were calculated on-board through a proprietary software into the specific spatio-temporal (contact time, cadence, stride pace and stride length), kinetic (shock) and kinematic variables (pronation excursion and maximum pronation velocity).^{15 36 37} Operational definitions of all sensor-derived outcomes

have been published elsewhere.¹⁵ Step-by-step data from each run were extracted from the manufacturer's dashboard, and averages were taken per limb for each recorded run. Walking and standing events were visually identified in the datasets from when the flight ratio variable fell to 0 and were removed from analyses.

Statistical analyses

Descriptive analyses were conducted using independent samples t-tests to compare baseline age, height, body mass index, questionnaire scores and running experience between groups. We additionally compared running volume at baseline and cumulative distance accrued during the study time frame. Separate 2×4 repeated measures analyses of variance (RMANOVAs) were used to assess the influence of groups (FBHE, and HE) and timepoints (baseline and 2, 4 and 6 weeks) for PROMs. Additionally, separate discrete measures 2×2 RMANOVAs were used to assess the influence of group (FBHE and HE) and timepoints (baseline and 4 weeks) for sensor-derived outdoor running biomechanics. A one-factor RMANOVA was used to assess gait-training retention for FBHE group across three timepoints (baseline and 4 and 6 weeks). All RMANOVA assessments were conducted in using RStudio V.1.2.1335. Alpha was set a priori to .05 for all analyses, and Tukey's post hoc analyses were used for statistically significant findings.

RESULTS

Groups did not significantly differ at baseline for demographic factors or for cumulative distance accrued across the intervention programme (table 1). One FBHE participant was lost to follow-up due to an unrelated shoulder injury, and there were no adverse events pertaining to this study. Intention-to-treat analyses were not possible as there were no follow-up data. As such, 19 participants (FBHE: 9 and HE: 10) were included in PROM and outdoor gait assessment analyses (figure 1). Compliance with the HE programmes was excellent for both groups (FBHE: 96% and HE: 97%).

PROM results

There were significant time main effects for VAS pain scores. Both groups significantly decreased pain measures at timepoints of 4 and 6 weeks compared with baseline and 2 weeks (table 2). The FBHE group maximum pain change score at 6 weeks was clinically meaningful at -36 mm (CI -55 to -11 mm, $d=1.75$; 66% of patients reached a minimally clinically important difference of 30 mm),³⁸ while the HE group improved by only -10 mm (CI -46 to 6 mm, $d=0.89$; 40% of patients met minimally clinically important difference; table 2).

There were significant group and time main effects for the Wisconsin Running Injury and Recovery Index and EILP-Br and a significant time main effect for the LEFS questionnaire (table 2). There was a significant group by time interaction for the GROC scores (table 2). While both groups reported increased function at follow-ups

Table 2 PROMs between FBHE and HE groups across study timepoints

	Baseline			2 weeks			4 weeks			6 weeks		
	FBHE (n=9)	HE (n=10)	P value	FBHE (n=9)	HE (n=10)	P value	FBHE (n=9)	HE (n=10)	P value	FBHE (n=9)	HE (n=10)	P value
100 mm VAS: maximum pain in the last week	54.8±16.3	41.1±15.3	0.07	42.2±21.2	47.5±13.4	0.51	34.5±21.9*	36.2±17.1*	0.85	19.3±20.5*†	31.3±27.4*†	0.28
100 mm VAS: pain at rest in the last week	7.9±6.1	4.1±3.9	0.11	8.5±11.6	6.1±5.0	0.56	3.5±4.4	4.5±7.6	0.72	1.7±3.8†	3.4±4.1†	0.35
100 mm VAS: pain during typical run in the last week	33.4±18.8	31.4±12.3	0.78	23.7±16.4	25.6±12.7	0.78	20.3±15.4*	21.7±12.1*	0.82	12.5±15.2*	20.5±21.8*	0.35
100 mm VAS: pain following typical run in the last week	24.5±16.8	24.7±13.3	0.98	13.0±8.1	21.1±15.4	0.16	7.4±8.0*	20.2±19.8*	0.07	4.9±6.7*†	11.8±11.7*†	0.12
EILP-Br (%)	76.5±8.3	74.0±13.1	0.62	-	-	-	89.2±8.6*	81.5±15.0*	0.17	94.6±5.3*	80.0±10.2*	<0.001†
LEFS (%)	89.3±9.0	85.4±14.6	0.48	-	-	-	96.5±2.6*	92.6±5.6*	0.06	98.3±2.1*	91.6±4.3*	<0.001†
Wisconsin RRI (%)	58.3±7.6	47.2±16.9	0.08	76.9±10.1	63.1±14.5	0.02‡	85.2±12.0*†	71.6±14.0*†	0.03‡	91.4±7.7*†	74.6±8.5*†	<0.001†
GROC (-7 to 7)	-	-	-	3±2	3±2	0.81	6±1†	5±2†	0.09	6±1†	3±2†	.004‡

*Statistically significant compared with baseline at $p \leq 0.05$.

†Statistically significant compared with 2 weeks at $p \leq 0.05$.

‡Statistically significant differences between groups at $p < 0.05$.

EILP-Br, Exercise-Induced Leg Pain Questionnaire, British Version; FBHE, contact time gait-training feedback with home exercise; HE, home exercise; LEFS, Lower Extremity Functional Scale; PROM, patient-reported outcome measure; RRI, Running Injury and Recovery Index; VAS, Visual Analogue Scale.

of 4 and 6 weeks, the FBHE group reported significantly increased function and recovery than the HE group at 6 weeks and compared with baseline (table 2).

Outdoor running results

There was a significant group by time interaction for contact time, and significant group main effect for cadence at 4 weeks compared with baseline and the HE group (table 3). The FBHE group had significantly decreased contact time from baseline and the HE group, and increased cadence compared with the HE group at 4 weeks. FBHE runners maintained decreased contact time and increased cadence at 6 weeks (table 3).

DISCUSSION

We determined an added benefit of outdoor gait training to reduce contact time for runners with exercise-related lower leg pain for decreasing pain, improving function, and favourably adjusting running biomechanics. Our findings support the usage of this gait-training approach in conjunction with standard of care exercises to improve exercise-related lower leg pain patient management.

Patient-reported outcome measures

Our results support not only that increased contact time is a consequence of exercise-related lower leg pain,¹⁵ but also that it contributes to the overall exercise-related lower leg pain disability model, given that the FBHE intervention led to greater improvements in pain and function over time.¹ This information is important for clinicians treating exercise-related lower leg pain patients, given that these injuries lead to long-term deficits,^{1 39} and an FBHE intervention over 4 weeks demonstrated lasting patient-reported benefits up to 2 weeks after treatment beyond current management approaches.⁴⁰

While patients reported minimal residual pain at 6 weeks, 67% of FBHE patients compared with 40% of HE patients fell below 20 mm on the VAS, which would no longer classify the runners as patients with exercise-related lower leg pain.^{1 22} The FBHE group had higher maximum VAS pain scores at baseline compared with the HE group, yet markedly decreased pain across the study. Furthermore, the GROC scores reflected that the FBHE group had 2.25-fold higher odds of feeling 'a great deal better' at 4 weeks (75% of FBHE patients vs 33% of HE patients) and 5-fold higher odds of feeling a great deal better at 6 weeks (66% of FBHE patients vs 20% of HE patients). Clinicians should consider incorporating a specific, outdoor contact time gait training to treat exercise-related lower leg pain symptoms most effectively.

Outdoor biomechanics

Our objective approach to decrease contact time by 5% of baseline measures was successful for changing outdoor biomechanics.¹⁵ The faded feedback protocol has been recommended for treadmill-based gait-training interventions,^{41 42} and we identified similarly beneficial treatment effects for outdoor gait training. Our faded feedback

Table 3 Sensor-derived biomechanical measures between FBHE and HE groups across study timepoints

	Baseline		4 weeks		6 weeks
	Mean±SD	Between-group P value	Mean±SD	Between-group P value	Mean±SD
Contact time (ms)					
FBHE	292±34	0.75	268±18*	.01†	270±21*
HE	288±24		286±19		–
Cadence (steps/min)					
FBHE	170±9	0.24	182±10*	.01†	178±10
HE	169±10		170±9		–
Pace (m/s)					
FBHE	3.19±0.43	0.76	3.39±0.49	0.83	3.38±0.46
HE	3.25±0.41		3.35±0.45		–
Stride length (m)					
FBHE	2.20±0.34	0.49	2.24±0.36	0.44	2.27±0.33
HE	2.30±0.31		2.37±0.32		–
Shock (g)					
FBHE	13.2±2.1	0.44	13.0±1.7	0.55	13.7±1.90
HE	14.0±2.5		13.6±2.5		–
Pronation excursion (°)					
FBHE	11.7±4.7	0.54	12.7±5.6	0.81	11.8±6.0
HE	10.5±4.3		13.3±5.0		–
Maximum pronation velocity (°/s)					
FBHE	842±288	0.49	855±252	0.37	918±219
HE	757±245		746±264		–
Foot strike type (1–16)					
FBHE	7±2	0.93	8±2	0.83	8±2
HE	7±3		8±4		–

*Statistically significant compared with baseline at $p \leq 0.05$.

†Statistically significant differences between groups at $p \leq 0.05$.

FBHE, contact time gait-training feedback with home exercise; HE, home exercise.

schema slightly differed from previous study designs as we provided 100% feedback over consistent run times and distances, whereas previous studies gradually built the time of interventions up over the first half of the intervention.^{43 44} However, we pre-emptively decided on this schedule due to the field-based nature of the intervention. Our intervention still implemented concepts of motor learning theory in which a stimulus is introduced and then gradually removed over time, and we found this overall model to lead to desirable biomechanical changes. The FBHE group surpassed the prescribed contact time feedback at 4 weeks (8.22%) and retained this change at 6 weeks (–0.69% change from 4 weeks), suggesting that patients were able to effectively incorporate the biomechanical adjustment into their motor learning framework to eliminate the feedback stimulus.⁴⁵ FBHE patients concomitantly increased cadence at 4 and 6 weeks; given that cadence has been identified as a risk factor for RRI in laboratory analyses,^{9 42} targeting contact time may have a desired effect across affected

spatiotemporal parameters for RRI treatment. Given that we only assessed retention for the FBHE group, the long-term effects of the gait-training intervention should be interpreted with some caution as we were unable to repeat these measures and compare against the standard of care patients in the HE group.

Clinical implications and future directions

Our findings support the use of a data-driven, ecological approach to gait training. While clinicians may not have access to extensive gait analysis equipment, commercially-available sensors to prescribe interventions alleviate cost, time, and resource burdens. Future work should seek to replicate this gait-training approach in natural running settings among patients with exercise-related lower leg pain in larger sample sizes. Additionally, future work should consider adopting a specific, evidence-based outdoor gait training programme for patients with other running-related injuries due to mounting accessibility of wearable sensors and growing importance of biometrics

in patient care. Finally, there is a need to compare the efficacy of clinic-based supervised gait-training interventions,¹² field-based supervised gait-training interventions⁴⁶ and unsupervised gait-training interventions to determine what the optimal implementation to elicit desired patient-centred outcomes and biomechanical changes.¹⁴ We hope that this study framework will set the precedent of specific patient care by meeting runners in their training environment and addressing runners' specific RRI deficits.

Limitations

Our overall sample size was small due to limitations of human subjects research during the COVID-19 pandemic. As such, our results should be interpreted with some caution, and future research should seek to replicate these methods in a larger sample. Outdoor gait training limited control over external running factors (ie, running surface and environment); however, external validity of the intervention was increased due to this decision. The feedback intervention is currently not commercially available and requires some technical expertise. HEs were individualised, meaning exercise prescriptions varied by patient. This approach was designed with clinicians currently treating injured runners, which strengthens this decision. There was a relatively short follow-up period, and longer-term follow-ups are needed to assess retention length. Furthermore, we did not compare the FBHE group to the HE group for outdoor biomechanics at 6 weeks, and it is unlikely but theoretically possible that there was a time effect that drove the biomechanical findings. Future work comparing groups for long-term outcomes is warranted.

CONCLUSION

Outdoor gait training along with HEs was more effective than HEs alone for runners with exercise-related lower leg pain by improving PROMs, and influencing contact time and cadence at 4 weeks, and with lasting effects at 6 weeks. Clinicians may consider implementing this gait-training approach for runners with exercise-related lower leg pain to improve clinical management.

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Contributors AFDL: conceptualisation, methodology, validation, formal analysis, investigation, resources, data curation, writing (original draft), visualisation, project administration, and guarantor. SLS, PNF and XT: investigation, data curation and writing (review and editing). JMH and DJH: conceptualisation, methodology, writing (review and editing) and supervision. JSR: conceptualisation, data curation, formal analysis, writing (review and editing) and supervision. JH: conceptualisation, methodology, formal analysis, resources, writing (review and editing) and supervision.

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Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by University of Virginia Institutional Review Board for Human Subjects Research (#22107). The participants gave informed consent to participate in the study before taking part.

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REFERENCES

- 1 Bonasia DE, Rosso F, Cottino U, *et al*. Exercise-Induced leg pain. *Asia Pac J Sports Med Arthrosc Rehabil Technol* 2015;2:73–84.
- 2 Francis P, Whatman C, Sheerin K, *et al*. The proportion of lower limb running injuries by gender, anatomical location and specific pathology: a systematic review. *J Sports Sci Med* 2019;18:21–31.
- 3 Korakakis V, Malliaropoulos N, Baliotis K, *et al*. Cross-cultural adaptation and validation of the exercise-induced leg pain questionnaire for English- and Greek-Speaking individuals. *J Orthop Sports Phys Ther* 2015;45:485–96.
- 4 Bertelsen ML, Hulme A, Petersen J, *et al*. A framework for the etiology of running-related injuries. *Scand J Med Sci Sports* 2017;27:1170–80.
- 5 Arnold MJ, Moody AL. Common running injuries: evaluation and management. *American Family Physician* 2018;97:7.
- 6 Koldenhoven RM, Virostek A, DeJong AF, *et al*. Increased contact time and strength deficits in runners with exercise-related lower leg pain. *J Athl Train* 2020;55:1247–54.
- 7 Esculier J-F, Bouyer LJ, Roy J-S. The effects of a multimodal rehabilitation program on symptoms and ground-reaction forces in runners with Patellofemoral pain syndrome. *J Sport Rehabil* 2016;25:23–30.
- 8 Milner CE, Hamill J, Davis IS. Distinct hip and rearfoot kinematics in female runners with a history of tibial stress fracture. *J Orthop Sports Phys Ther* 2010;40:59–66.
- 9 Yong JR, Silder A, Montgomery KL, *et al*. Acute changes in foot strike pattern and cadence affect running parameters associated with tibial stress fractures. *J Biomech* 2018;76:1–7.
- 10 Schubert AG, Kempf J, Heiderscheidt BC. Influence of stride frequency and length on running mechanics: a systematic review. *Sports Health* 2014;6:210–7.
- 11 Davis IS, Bowser BJ, Mullineaux DR. Greater vertical impact loading in female runners with medically diagnosed injuries: a prospective investigation. *Br J Sports Med* 2016;50:887–92.
- 12 DeJong AF, Hertel J. Gait-training devices in the treatment of lower extremity injuries in sports medicine: current status and future prospects. *Expert Rev Med Devices* 2018;15:891–909.

- 13 Whittier T, Willy RW, Sandri Heidner G, *et al.* The cognitive demands of gait retraining in runners: an EEG study. *J Mot Behav* 2019;1–12.
- 14 Willy RW, Buchenic L, Rogacki K, *et al.* In-field gait retraining and mobile monitoring to address running biomechanics associated with tibial stress fracture. *Scand J Med Sci Sports* 2016;26:197–205.
- 15 DeJong Lempke AF, Hart JM, Hryvniak DJ, *et al.* Use of wearable sensors to identify biomechanical alterations in runners with exercise-related lower leg pain. *J Biomech* 2021;126:110646.
- 16 Messier SP, Martin DF, Mihalko SL, *et al.* A 2-year prospective cohort study of overuse running injuries: the runners and injury longitudinal study (trails). *Am J Sports Med* 2018;46:2211–21.
- 17 Van den Berghe P, Breine B, Haeck E, *et al.* One hundred Marathons in 100 days: unique biomechanical signature and the evolution of force characteristics and bone density. *J Sport Health Sci* 2022;11:347–57.
- 18 Gindre C, Lussiana T, Hebert-Losier K, *et al.* Aerial and terrestrial patterns: a novel approach to analyzing human running. *Int J Sports Med* 2016;37:25–6.
- 19 Reinking MF, Hayes AM. Intrinsic factors associated with exercise-related leg pain in collegiate cross-country runners. *Clin J Sport Med* 2006;16:10–14.
- 20 Willems TM, Witvrouw E, De Cock A, *et al.* Gait-related risk factors for exercise-related lower-leg pain during shod running. *Med Sci Sports Exerc* 2007;39:330–9.
- 21 Winters M, Bakker EWP, Moen MH, *et al.* Medial tibial stress syndrome can be diagnosed reliably using history and physical examination. *Br J Sports Med* 2018;52:1267–72.
- 22 Nauck T, Lohrer H, Padhiar N, *et al.* Development and validation of a questionnaire to measure the severity of functional limitations and reduction of sports ability in German-speaking patients with exercise-induced leg pain. *Br J Sports Med* 2015;49:113–7.
- 23 Lakens D. Sample size Justification. Collabra:Psychology, 32
- 24 Longstaff C, Colquhoun D. False positive risk web calculator. Available: <http://fpr-calc.ucl.ac.uk/> [Accessed 05 Jul 2022].
- 25 Nelson EO, Ryan M, AufderHeide E, *et al.* Development of the University of Wisconsin running injury and recovery index. *J Orthop Sports Phys Ther* 2019;49:751–60.
- 26 Abbott JH, Wright AA. Global rating of change (GROC): the minimally important change at which patients choose to stop seeking treatment. *N Z J Physiother* 2010;38:66.
- 27 Binkley JM, Stratford PW, Lott SA, *et al.* The lower extremity functional scale (LEFS): scale development, measurement properties, and clinical application. North American orthopaedic rehabilitation research network. *Phys Ther* 1999;79:371–83.
- 28 Nelson EO, Kliethermes S, Heiderscheid B. Construct validity and responsiveness of the University of Wisconsin running injury and recovery index. *J Orthop Sports Phys Ther* 2020;50:702–10.
- 29 Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *J Man Manip Ther* 2009;17:163–70.
- 30 Fraser JJ, Koldenhoven RM, Saliba SA, *et al.* Reliability of ankle-foot morphology, mobility, strength, and motor performance measures. *Int J Sports Phys Ther* 2017;12:1134–49.
- 31 Gribble PA, Hertel J. Considerations for normalizing measures of the StAR excursion balance test. *Meas Phys Educ Exerc Sci* 2003;7:89–100.
- 32 Williams DS, McClay IS. Measurements used to characterize the foot and the medial longitudinal arch: reliability and validity. *Phys Ther* 2000;80:864–71.
- 33 Gribble PA, Hertel J, Plisky P. Using the StAR excursion balance test to assess dynamic postural-control deficits and outcomes in lower extremity injury: a literature and systematic review. *J Athl Train* 2012;47:339–57.
- 34 Rabin A, Kozol Z, Moran U, *et al.* Factors associated with visually assessed quality of movement during a lateral step-down test among individuals with patellofemoral pain. *J Orthop Sports Phys Ther* 2014;44:937–46.
- 35 Crossley KM, Zhang W-J, Schache AG, *et al.* Performance on the single-leg squat task indicates hip abductor muscle function. *Am J Sports Med* 2011;39:866–73.
- 36 DeJong AF, Hertel J. Validation of foot-strike assessment using wearable sensors during running. *J Athl Train* 2020;55:1307–10.
- 37 Koldenhoven RM, Hertel J. Validation of a wearable sensor for measuring running biomechanics. *Digit Biomark* 2018;2:74–8.
- 38 Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. *Acad Emerg Med* 2001;8:1153–7.
- 39 Brewer RB, Gregory AJM. Chronic lower leg pain in athletes. *Sports Health* 2012;4:121–7.
- 40 Winters M, Eskes M, Weir A, *et al.* Treatment of medial tibial stress syndrome: a systematic review. *Sports Med* 2013;43:1315–33.
- 41 Agresta C, Brown A. Gait retraining for injured and healthy runners using augmented feedback: a systematic literature review. *J Orthop Sports Phys Ther* 2015;45:576–84.
- 42 Davis IS, Futrell E. Gait retraining: altering the fingerprint of gait. *Phys Med Rehabil Clin N Am* 2016;27:339–55.
- 43 Chan ZYS, Zhang JH, Au IPH, *et al.* Gait retraining for the reduction of injury occurrence in novice distance runners: 1-year follow-up of a randomized controlled trial. *Am J Sports Med* 2018;46:388–95.
- 44 Van den Berghe P, Derie R, Bauwens P, *et al.* Reducing the peak tibial acceleration of running by music-based biofeedback: a quasi-randomized controlled trial. *Scand J Med Sci Sports* 2022;32:698–709.
- 45 Charlton JM, Eng JJ, Li LC, *et al.* Learning gait modifications for musculoskeletal rehabilitation: applying motor learning principles to improve research and clinical implementation. *Phys Ther* 2021;101:pzaa207.
- 46 Derie R, Van den Berghe P, Gerlo J, *et al.* Biomechanical adaptations following a music-based biofeedback gait retraining program to reduce peak tibial accelerations. *Scand J Med Sci Sports* 2022;32:1142–52.