Wearable Sensors for In-Field Running Gait Analysis and Intervention

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APPROVAL OF THE DISSERTAION

This dissertation, “Wearable Sensors for In-Field Running Gait Analysis & Intervention”, has been approved by the Graduate Faculty of the Curry School of Education and Human Development in partial fulfillment of the requirements for the degree of Master of Education.

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ABSTRACT

Running-related injuries are extremely prevalent among recreational and competitive runners alike. Exercise-related lower leg pain (ERLLP) remains among the most prevalent running-related injuries, and while there is information on biomechanical contributors to injury progression in controlled laboratory environments, little is known about injured runners' biomechanics during outdoor running. Biomechanical features identified in ERLLP runners in natural settings may be used to drive objective gait-training interventions to advance clinical management. Outdoor assessments using wearable sensors and wellness screening can additionally be used to prospectively investigate contributing factors to running-related injuries.

The purpose of manuscript 1 was to utilize a machine learning feature extraction analysis to identify biomechanical features among runners with ERLLP compared to healthy runners during outdoor running using wearable sensors. We identified that runners with ERLLP had increased and more variable contact time, and that contact time differences between groups was dependent upon pace, signifying that subsequent gait-training interventions should be individualized for each patient.

The purpose of manuscript 2 was to was to assess the effects of randomized control trial assessing the effects of a 4-week outdoor gait-training intervention using wearable sensors to reduce contact time in conjunction with a home exercise program (FBHE) compared to home exercises alone (HE) for runners with ERLLP on patient-reported pain, function, and outdoor running biomechanics. We identified that the FBHE intervention was superior to HE alone for improving patients' pain and function, reducing

contact time, and increasing cadence at follow-up timepoints compared to baseline and compared to the HE group.

The purpose of manuscript 3 was to prospectively assess gait biomechanics and wellness among Division-1 cross-country athletes over the course of a single competitive season. We identified that stride length, impact, pace, contact time, mileage, and running a meet the prior day were all significantly associated with athletes' perceived exertion, and that contact time and braking forces were related to athlete wellness. Stride length, loading, cadence, contact time, and pronation velocity were found to differ among injured athletes in the two recorded days leading up to injury compared to healthy teammates.

Implementing wearable sensors into gait assessments allowed us to quantify biomechanical deficiencies in runners' natural settings. Using this data, we were able to design an objective, data-driven gait-training program that appeared to be superior to traditional clinical management techniques. We were additionally able to identify several biomechanical factors that were evident among runners that developed running-related injuries over time, that serves as a foundation for future hypothesis-driven assessments to aid in injury assessments and interventions.

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USE OF WEARABLE SENSORS TO IDENTIFY BIOMECHANICAL ALTERATIONS IN RUNNERS WITH EXERCISE-RELATED LOWER LEG PAIN

ABSTRACT

Background: Exercise-related lower leg pain (ERLLP) is one of the most prevalent running-related injuries, however little is known about injured runners' mechanics during outdoor running. Establishing thresholds of key biomechanical alterations among runners with ERLLP would help guide clinical interventions. **Purpose:** To a) identify defining biomechanical features among runners with ERLLP compared to healthy runners during bouts of typical outdoor running, and b) identify biomechanical thresholds to generate objective recommendations for impairment-based gait-training interventions. **Methods:** Thirty-two runners with ERLLP (13 M, age: 21± 5 years, BMI: 22.69±2.25 kg/m^2) and 32 healthy runners (13 M, age: 23± 6 years, BMI: 22.33±3.20 kg/m^2) were assessed using wearable biomechanical sensors during one week of typical outdoor training. Step-by-step data from all sustained outdoor running activities were extracted to assess kinetic (impact g, braking g), kinematic (pronation excursion, maximum pronation velocity), and spatiotemporal (stride length, cadence, contact time, stride pace) measures. Preliminary feature extraction analyses were conducted to determine key biomechanical differences between healthy and ERLLP groups. Analyses of covariance (ANCOVA) and variability assessments were used to subsequently compare groups on the key features from the preliminary analyses. Participants were split into 3 pace bands, and mean differences across ERLLP and healthy groups were calculated to establish biomechanical thresholds. **Results:** Contact time was identified as the key defining feature differentiating healthy and ERRLP groups. ANCOVA assessments reflected that the ERLLP group had increased contact time (Mean Difference [95% Confidence Interval] =8 ms [6.9,9.1], $p<.001$), and approximate entropy analyses reflected greater variability in contact time

across runs. Contact time differences were largely dependent upon running pace, with larger between group differences being exhibited at faster paces. **Conclusions:** Runners with ERLLP demonstrated substantially longer contact time than healthy runners during outdoor training. Clinicians and researchers should consider contact time as a key parameter when assessing and treating runners with ERLLP.

Word Count: 304

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Introduction

Running for exercise is one of the most popular forms of physical activity worldwide, and distance running events attracted over 107.9 million runners across 70,000 scheduled running events in 2019.[1] Despite the increasing popularity of running over the past decade, lower extremity pathologies are extremely prevalent among distance runners regardless of participation level. Epidemiological research reflects that 42-53% of running-related injuries are localized to the shank,[2] and recent literature has advocated using "exercise-related lower leg pain" (ERLLP) as the preferred nomenclature for pathologies to this anatomical region when fractures and other specific soft-tissue injuries can be ruled out with clinical examinations.[3,4] ERLLP is described as pain in the region spanning between the tibial plateau and the malleoli, experienced during or immediately following running that occurs in the anterior or medial aspect of the leg.[3] Up to 75% of ERLLP cases are reported as recurrent injuries,[5] and subsequently present a substantial health burden for patients and clinicians. Therefore, there has been an increased push to evaluate factors contributing to the development and exacerbation of symptoms among runners with ERLLP.

Researchers have explored biomechanical factors associated with ERLLP patients, particularly as pain is known to occur during or immediately following bouts of running. Laboratory-based gait analyses using gold standard instrumented treadmills and motion capture technology have consistently identified increased peak rearfoot eversion during stance,[6,7] vertical ground reaction forces,[8] stride length,[9] and slower cadence among ERLLP runners.[9] Although these factors are important to consider for patient evaluations and interventions, these findings have been limited to assessing a finite

number of steps in indoor environments with tight experimental control and direct clinician supervision. Interventional studies targeting these reported deficits have also solely focused on uninjured runners to elicit biomechanical changes,[10–12] so it remains unclear how manipulating these factors would improve pain and other key patient-reported markers of recovery. Further, the majority of intervention studies have used arbitrary cut-off values to administer gait-training interventions which is not representative of impairment-based clinical practice in which clinical care is tailored to the specific patient deficits related to their injury sequalae. As such, focusing on the aforementioned biomechanical factors for clinical assessment may not fully transfer to over-ground outdoor running biomechanics, and may not alleviate patient symptomology and injury progression.

The advent of wearable technology has begun to revolutionize gait analysis capabilities, as there is now the opportunity to monitor multiple gait parameters during sustained outdoor running.[13] Wearable sensors to assess running biomechanics consisting of accelerometers, gyroscopes, and magnetometers overcome the cumbersome and expensive aspects of traditional gait laboratory technology, and can reliably measure biomechanics during running over thousands of steps.[14–16] A recent, albeit small, study using wearable technology in the field in an ERLLP group that found increased ground contact time between injured and healthy runners.[17] Therefore, targeting contact time during prolonged running may be a preferable gait-training objective to best influence running during typical outdoor training. However, specific biomechanical thresholds among injured runners have not yet been determined to inform patient-specific gait-training interventions. Further, traditional statistical analyses collapse all steps in a run

into a single mean to compare group-level outcomes, which overlooks stride variability and fluctuations throughout sustained runs inherent in time-series data. Advanced time-series analyses as opposed to collapsed group-level comparisons have not yet been conducted to elucidate more intricacies in runners' biomechanical data in relation to injury status.[18] These assessments are necessary to measure outdoor running biomechanics, and to focus future gait-training interventions to maximize runners' responses to treatment as opposed to one-size-fits-all approaches with arbitrary biomechanical thresholds.[19]

The primary purpose of this study was to identify defining biomechanical features in runners with ERLLP compared to a healthy comparison group during bouts of typical outdoor running. Based on previously published work on runners with ERLLP,[17] we anticipate contact time to be the defining feature of ERLLP patients compared to healthy runners during outdoor running, such that ERLLP runners will present with greater contact time. The secondary purpose of this study was to identify thresholds of biomechanical alterations in runners with ERLLP compared to a healthy comparison group to generate objective recommendations for impairment-based gait-training interventions. We anticipate that target thresholds will be in part dependent upon running pace, given the influence of running speed on spatiotemporal parameters.[17]

Methods

Participants

This study was an extension on a previous assessment of ERLLP patients in the field.[17] Potential participants were recruited from local community running clubs using email

list-servs and fliers. All participants were required to be between 18-45 years of age, and involved in running training at least three times per week for the past three months. Participants were included in the ERLLP group were included if they had current pain between 20 and 80 mm on the 100-mm Visual Analog Scale (VAS) during or following bouts of running in the anteromedial or anterolateral aspect of the leg for at least the past month, which was confirmed using a structured clinical assessment.[5,20] Participants were also required to score less than 90% on the Exercise-Induced Leg Pain Questionnaire – British Version (EILP).[3,20] Individuals were excluded if they experienced pain over the Achilles tendon, popliteal fossa, or the posterior compartment of the lower leg, or any medical diagnoses of compartment syndrome, tibial or fibular stress or full fractures within the past 3 months.[3,21] Potential participants in both the ERLLP and healthy comparison groups were excluded if they ran in minimalist shoes, reported any other current lower extremity or spinal injuries, previous lower extremity surgery, neuromuscular impairments or diseases, or known pregnancy. All participants provided informed consent prior to study procedures, and the study was approved by our University's Institutional Review Board for Health Sciences Research (IRB-HSR ######).

Sixty-four runners qualified for participation (32 ERLLP, 32 Healthy; 26 M, 38 F) and were prospectively followed over the course of one week of typical running training. Participants completed baseline questionnaires, including the 100-mm Visual Analog Pain Scale (VAS), Exercise-Induced Leg Pain Questionnaire – British Version (EILP), lower extremity functional scale (LEFS), Godin Leisure Time Questionnaire, and a

running and health history questionnaire. Participant demographic information is presented in Table 1.

Instrumentation

RunScribe™ Plus wearable sensors (RunScribe Labs, Half Moon Bay, CA, USA) were used for all outdoor running assessments. Each sensor consisted of a triaxial accelerometer and gyroscope to collect spatiotemporal, kinetic, and kinematic data sampled at 200Hz, with on-board processing and memory capabilities. All participants downloaded the associated RunScribe mobile application to upload all running activities to a linked research account.

Procedures

Participants reported to a university research laboratory for a single initial visit where they were issued a set of sensors. The sensors were heel-mounted on each of their regular running shoes, and the athletes completed a predetermined 2688-meter outdoor running route to calibrate the sensors. Participants were instructed to wear the sensors on their shoes each time they ran for one week. On each day that participants ran with the sensors, they were instructed to keep a running log detailing the date, duration, distance, pertinent running details, and VAS pain levels before, during, and following running.

Data Processing

All biomechanical measures obtained from the sensors were calculated through a proprietary software (RunScribe, Inc.) where raw accelerometer, magnetometer, and gyroscope data were processed on-board into the specific spatiotemporal, kinetic, and kinematic variables. Definitions for each of the sensor-derived metrics are provided in Additional Results Table D1.1. Sensor-derived data from each run were accessed and

extracted from the sensor manufacturer's online dashboard to obtain step-by-step datasheets for analysis. Walking and standing events were visually identified in the datasets from when the flight ratio variable fell to zero, and were removed from analyses.

Preliminary Analyses and Results

To address the primary aim of this study, a preliminary exploratory analysis utilizing a subset of the complete dataset was conducted to extract features from the sensor data that differentiated the two groups using the TSFresh Python program.[22] This program compresses multivariate time series data from a long sequence of values to a set of features that no longer exhibit time dependence. This set of features includes standard summary statistics of input variables (i.e. standard deviation, range, slope of the input variable). This approach was used to elucidate the key defining features of the ERLLP group compared to the healthy comparison group for the input variables of stride length, contact time, cadence, flight ratio, shock, impact g, braking g, pronation excursion, and maximum pronation velocity. Operational definitions of these sensor-derived metrics can be found in Additional Methods Table 1.

The TSFresh feature extraction analysis reflected that the top ten defining features differentiating the ERLLP group from the healthy comparison group were all variations of the contact time outcome ($p<.001$). Specifically, the results demonstrated that the mean and standard deviation of contact time were significantly higher for the ERLLP group compared to the healthy group, regardless of the length of the run segment assessed (Additional Results Table D1.2). Therefore, contact time was the key feature used for all subsequent analyses.

Statistical Analyses

Descriptive analyses were conducted using independent samples t-tests to compare participants' age, height, body mass index (BMI), EILP and LEFS questionnaire scores, running experience, and weekly mileage between the ERLLP and healthy groups, with alpha set *a priori* to .05. Group median and 95% confidence intervals were calculated for all sensor-derived biomechanical measures.

Based on the preliminary statistical analyses, follow-up analyses were conducted on contact time, excluding sensor artifact in the data (contact time <100ms and >400ms). To determine the magnitude of difference between the groups, a one-factor analysis of covariance (ANCOVA) was conducted treating stride pace as a covariate. Further, variability assessments were conducted to assess both the fluctuations and the complexity of the contact time across the time series dataset for all participants. Overall contact time variability of each quarter of each participant's runs was assessed using the coefficient of variation (COV), in which a larger COV value represents higher variability in the outcome measure (Equation 1). Contact time variability across the time-series within each run was assessed using approximate entropy analyses and calculated for each quarter of each participant's runs (Equation 2).

Equation 1: $Coefficient\ of\ Variation = \left(\frac{Standard\ Deviation\ of\ Outcome\ Measure}{Mean\ of\ Outcome\ Measure}\right) * 100$

Equation 2:[23,24] $Approximate\ Entropy(m, r, N) = \frac{1}{N-m}\sum_{i=1}^{N-m} -log\frac{A_i(r)}{B_i(r)}$

In Equation 2, $A_i(r)$ is the number of times a sequence of m+1 data points in the time series matches the m+1 data points in the time series starting at index i. Likewise, $B_i(r)$ is the same but matches on m data points. In this manuscript, m is set to 2, and two sequences "match" if their Euclidean distance is smaller than r, here taken to be 0.1 SD. N is the total number of data points in the time series. If the data are highly predictable

and not varied, *Approximate Entropy* will be close to zero indicating there is no stride-to-stride change. When the data is unpredictable, *Approximate Entropy* will be much greater than zero.[23,24]

COV and approximate entropy were compared between groups and across quarters of runs using a repeated measures ANCOVA, treating stride rate as a covariate. Alpha was set *a priori* to .05 for all assessments, and Tukey's post-hoc assessments were conducted for significant findings.

To address the secondary aim, descriptive analyses were used to determine group-level threshold values based on contact time across all steady runs (runs consisting of interval work-outs were excluded). Analyses were further broken down to assess contact time differences across three different running pace bands based upon patients' self-reported speed, given the influence of pace on biomechanics. The pace bands were categorized as follows: Fastest (<8min/mile, N=10), Medium (8-8.5min/mile, N=30), and Slowest (>8.5min/mile, N=26). Three pace bands were selected based upon the distribution in the data of self-reported comfortable running paces, while maintaining a sample size of at least ten participants or more per group. Thresholds for the ERLLP group were based off of the healthy comparison group's median contact time.

Results

Group-level demographics, running, and health history questionnaire responses can be found in Table 1, and responses were comparable across groups for anthropometrics and running experience. The ERLLP group presented with significantly higher VAS scores indicative of more lower leg pain ($p<.001$), and significantly lower LEFS and EILP scores indicative of decreased self-reported function compared to the

healthy group (p<.001). A total of 192 runs were included in all analyses across an average of approximately 15,000 steps per participant (Table 1). Group mean and 95% confidence intervals for all sensor-derived biomechanical measures can be found in Additional Results Table D1.3.

When comparing contact time across steps and runs between groups, the ANOCVA analysis reflected that on average, the ERLLP group presented with 8-ms (Difference of the Mean =8ms; 95% Confidence Interval [CI]= 6.9, 9.1) longer contact time than the healthy group when controlling for stride pace (Figure 1A&B; F=59,711.25, p<.001).

Contact Time Target Values

Descriptive assessments comparing contact time across pace bands for the average contact time measures across steps for each participant across recorded runs can be found in Figure 3. Compared to the ERLLP group, the healthy group had 8ms lower contact time in the Fastest pace band (median contact time: 276 vs. 284ms; difference between groups= 8ms; CI=6.9, 9.1), 11ms lower in the Medium pace band (median contact time: 288 vs. 299ms; difference between groups = 11ms; CI=9.9, 12.1), and 2ms lower in the Slowest pace band (median contact time: 294 vs. 296ms; difference between groups = 2ms; CI=0.9, 3.1).

Contact Time Variability

There was not a statistically significant difference between the ERLLP and healthy running groups across and within all runs for contact time COVs (Figure 2A; MD= 12%; CI= -50%, 73%; F=0.48; p=.49). However, the results from the approximate entropy analysis reflected that when accounting for the time-series component of the dataset, the ERLLP group presented with higher contact time approximate entropy,

reflective of increased variability, than the healthy group (MD=0.10; CI= 0.07, 0.13; F=6.29, p=.01), and the ERLLP group had significantly differences in contact time approximate entropy within runs (F=4.50, p=.004). Post-hoc testing reflected that the 4th quarter of the ERLLP group runs were associated with higher contact time approximate entropy compared to the 1st quarter (Figure 2B; MD=.08; CI= 0.05, 0.11; p=.002).

Discussion

The overall results of this study suggest that prolonged contact time is a significant biomechanical feature that defines runners with ERLLP compared to healthy runners when assessed during routine outdoor running. Approximate entropy data analyses reflected that runners with ERLLP had more variable contact time measures, indicating that sequential steps were less consistent when compared with the healthy comparison group. Additionally, ERLLP runners had increased contact time overall, particularly when running at faster paces. Although previous studies have assessed running-related risk factors associated with injury in laboratory settings, this study is the first to assess runners actively experiencing pain during outdoor running. The increased and more variable contact time findings should be considered clinically when designing gait-training intervention programs for runners actively experiencing ERLLP symptoms.

Contact Time and ERLLP

The findings of the current study expand upon the preliminary field-based assessments of runners with ERLLP, and provide further evidence in a larger sample size that contact time continues to be a key defining biomechanical feature of runners actively experiencing pain.[17] Increased time spent in stance phase of running gait is indicative of more total loading exposure through loading response to propulsion, which coincides

with laboratory-based findings of increased average vertical loading rates in injury risk factor groups.[8] Our findings align with past assessments that have identified slower cadence in ERLLP risk factor groups,[10] as contact time and cadence have been found to be highly correlated. Our study helps to bridge the knowledge between running patterns identified during treadmill-based assessments to biomechanical adaptations during outdoor running. Interestingly, cadence did not emerge as the primary defining feature of ERLLP runners in our current study, although cadence did appear to be a lesser contributor to differentiating the injured to the healthy group as cadence magnitude was in the top fifty features extracted from the TSFresh analysis (Additional Results Table D1.2). These findings may be attributed to the nuanced factors associated with contact time, including the increased contact time variability during outdoor running. Differences in contact time may not have been apparent in previous laboratory-based findings given that treadmill belt speeds are held constant and cannot effectively mimic instantaneous variability that occurs during outdoor running.[25] Furthermore, contact time measures may be influenced by running topography that are not possible to effectively simulate in laboratory environments. Our findings suggest that assessing and targeting contact time in runners with active ERLLP symptoms during bouts of outdoor training should be considered in clinical practice.

It was somewhat surprising that runners with ERLLP had more variable contact time compared to the healthy runner group as assessed with approximate entropy but not COV analyses. Although both approximate entropy and COV assess variability, there are key practical differences between the analyses that provide insights into running behaviors between the groups. COV analyses are based on standard deviation, and in this

context, assessed the average contact time deviation of each step compared to the average contact time across entire runs. Conversely, approximate entropy analyses are based on the variability measures in consecutive steps, and in this context, assessed how each step's contant time varied in the time series data throughout runs. Given that runners with ERLLP had significantly increased approximate entropy measures without significant differences in COV, this indicates that runners remain within a comparable range of contact time measures throughout their runs, yet stride-to-stride variability is increased compared to healthy runners.

Based on the dynamic systems theory that has been applied in other chronic lower extremity injury conditions, researchers have theorized that lower extremity injuries result in increased organismic constraints, thereby affecting movement pattern variability.[26] These applications in running assessments have been largely focused on joint coupling variability, and have identified increased joint coupling variability with slower cadence among healthy runners,[27] and in runners with patellofemoral pain.[28] Our results corroborate with this evidence and suggest that runners adopt a more variable running pattern in the presence of pain.

The greater approximate entropy for contact time noted within in the ERLLP group is suggestive of poorer movement control during sustained running,[18] and these findings relate to previously identified alterations in running biomechanics during ground contact associated with reduced running economy and injury risk.[29] This notion of reduced running efficiency was further supported in that there was increased contact time variability from the first to the fourth quarter of their running segments overall, which we hypothesized was related to a fatigue effect over sustained runs.[30] Given that ERLLP

runners had a greater magnitude of variability increased over time, these findings lend important insights into injured runners' movement characteristics that clinicians can target during gait-training interventions. Providing feedback on contact time during running should be explored as it relates to reducing overall contact time magnitude and variability in this population.

Gait-Training Implications

Developing gait-training interventions in a clinical setting can become overwhelming as there are numerous published approaches to manipulating running mechanics using a one-size-fits-all approach to intervention that have mixed outcomes.[31–33] However, many of the previous gait-training interventions have been based upon a large range of biomechanical thresholds (i.e. increase cadence by 5-15% or decrease loading by 20-50%) that hinder the transference from research to clinical applications. The secondary aim of our study was to identify gait-training thresholds that can be subsequently used for clinical interventions. We performed these assessments so that future ERLLP interventions can be tailored to specific gait alterations observed in the field, and provide an objective means to address patient impairments.

Our findings suggest that contact time measures are dependent upon running pace, and as such, gait-training interventions aimed at altering contact time should be specific to a runner's habitual running speed. Specifically, ERLLP runners that maintained a pace at or below 8:30 minute per mile pace had significantly longer contact time compared to healthy runners in the same pace bands. However, runners that maintained a running pace slower than 8:30 minute per mile pace had comparable contact time to healthy comparison groups. When more closely assessing the runners' demographics within the

Slowest pace band group, these runners had the overall least amount of running experience, and this was the only group that had runners involved in the university's Reserve Officers' Training Corps (ROTC) program. Both novice and ROTC runners have previously been identified to have higher lower limb incidence rates associated with biomechanical running factors,[34–38] and therefore the comparable contact time may be indicative of an averse running pattern that may lead to future injury with increased running exposure. Although we do not have prospective data to support this hypothesis, our findings suggest that runners that are involved from recreational to competitive levels may respond more advantageously to contact time gait-training interventions. Future research should focus on prospective assessments during outdoor training to elucidate biomechanical factors contributing to chronic lower extremity injuries. Clinicians should be aware of the influence runner demographics and training factors when devising interventional programs.

Previous gait-training interventions cueing runners to increase cadence, decrease contact time, shift to a forefoot strike pattern, or a combination of these factors have had promising results in other lower extremity injury populations to reduce pain and improve running patterns in patellofemoral pain[39] and chronic exertional compartment syndrome patients.[40] There have also been promising results of sensor-based gait-training in the field among runners with lower extremity injury risk factors in which runners were successfully able to adopt an increased cadence during outdoor and indoor training.[10] These results suggest that applying contact time interventions would be successful in shifting gait patterns towards a move favorable movement pattern. Future studies exploring the effects of outdoor gait training on an ERLLP population in regards to not

only movement patterns, but also on patient-reported pain and disability, are necessary next steps.[13]

Limitations

This was a cross-sectional assessment of runners with ERLLP, and therefore we cannot determine from this study if increased and more variable contact time is associated with injury risk or injury exacerbation. Future research should prospectively assess runners in the field to determine the relationship between contact time and ERLLP development. Runs recorded in this study were all performed outdoors during runners' habitual training, thus limiting the amount of control we had over their running duration, pace, terrain, and other environmental factors. However, the goal of this assessment was to obtain information on running mechanics during typical bouts of training to reflect running patterns as they would occur in the field. We accounted for these concerns by only assessing sustained runs, and covarying for pace for all analyses. The majority of runners included in this study had bilateral symptoms, which is the most common patient presentation.[41] We performed within group comparisons to assess the influence of limb differences, however there were no notable findings suggesting that the pooled analysis approach was appropriate.

Conclusions

Runners with ERLLP were found to have increased and more variable contact time when compared with a group of healthy runners during outdoor running training. Contact time was dependent upon speed, with larger expected contact time deviations for moderate to faster ERLLP runner groups. Clinicians and researchers should consider

contact time magnitude and variability when designing field-based intervention programs.

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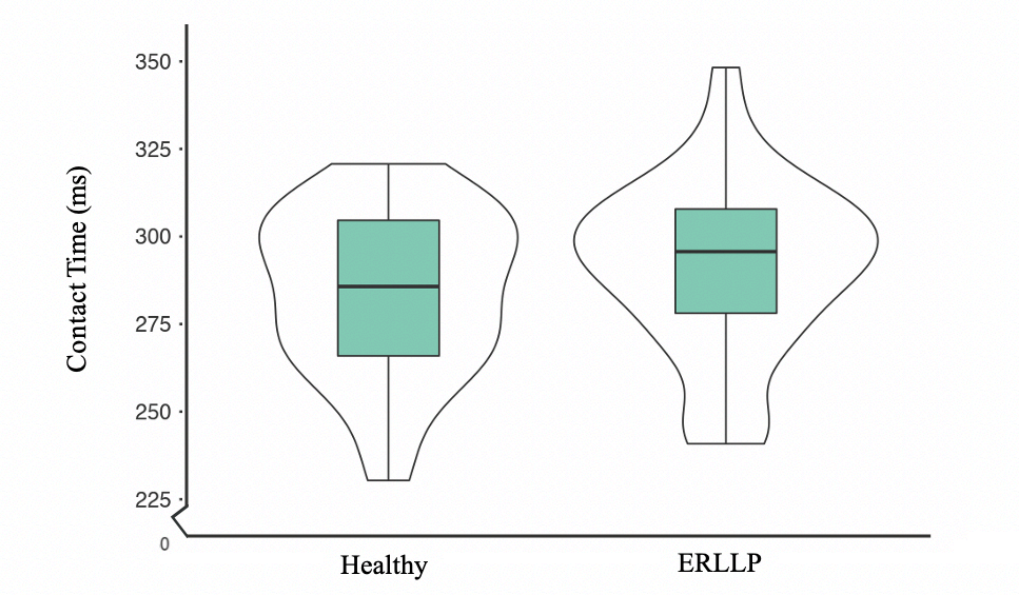
Table 1.1 Participant demographics for Healthy and Exercise-Related Lower Leg Pain Participants.

	Healthy N=32; 13M, 19F (Mean ± SD)	ERLLP N=32; 13M, 19F (Mean ± SD)	P-Value
Age (years)	23.13 ± 5.75	21.22 ± 4.70	.15
Height (cm)	173.24 ± 10.19	170.76 ± 1.42	.28
BMI (kg/m^2)	22.33 ± 3.20	22.69 ± 2.25	.61
Godin	91.66 ± 49.04	75.38 ± 18.15	.08
EILPQ-Br (%)	99.3 ± 1.39	75.68 ± 8.43	<.001*
LEFS (%)	99.26 ± 0.25	87.66 ± 1.00	<.001*
Running experience (years)	5.38 ± 5.26	5.28 ± 3.04	.92
Weekly mileage (km)	41.3 ± 37.6	30.3 ± 19.7	.53
Number of Included Runs Per Participant	3±1	3±1	1.0
Average Distance Per Run (km)	7.1 ± 3.9	6.5 ± 3.3	0.17
Average Steps Per Participant	15,217 ± 7,295	14,547 ± 7,978	0.31
100mm VAS highest pain in the last week	0 ± 0	46.97 ± 15.37	<.001

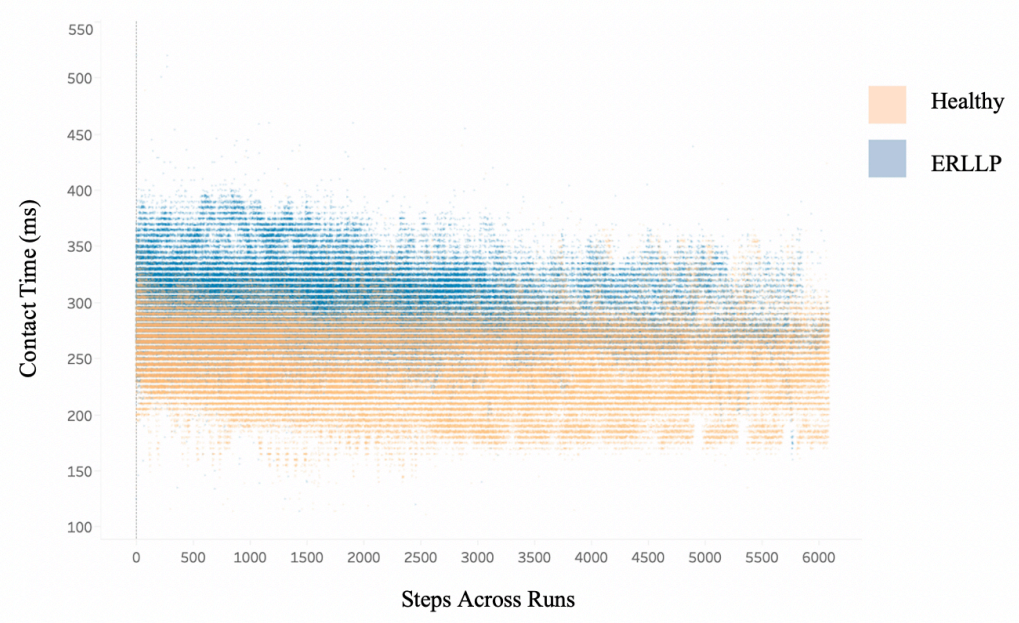
*Significant at $p \leq 0.05$

Abbreviations: cm, centimeters; kg, kilograms; BMI, body mass index; m, meters; Godin, Godin Leisure-Time Exercise Questionnaire; EILP-Br, Exercise-Induced Leg Pain Questionnaire – British version; LEFS, Lower Extremity Functional Scale; km, kilometers; 100mm VAS, 100-millimeter Visual Analog Scale.

Figure 1.1. (a) Distribution plots comparing contact time across groups, and (b) step-by-step contact time measures across runs between groups.



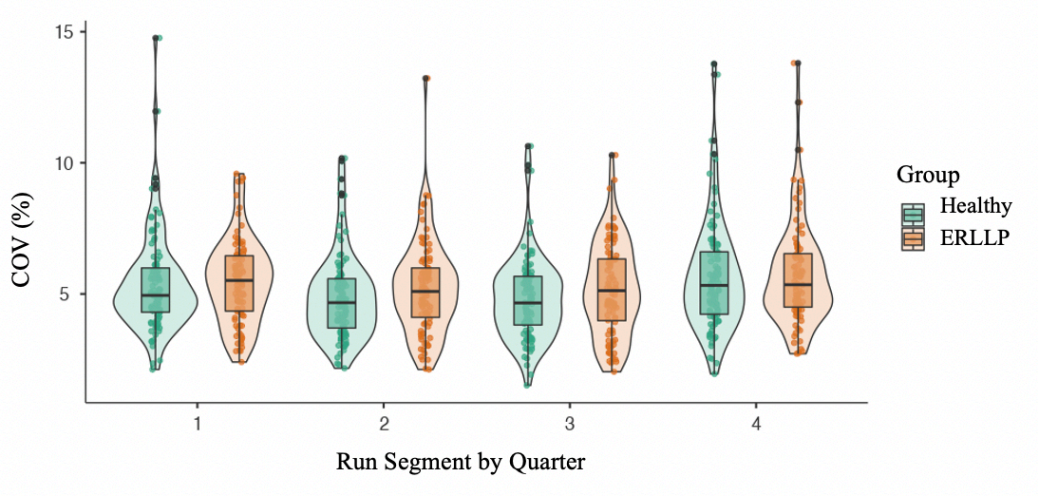
a.



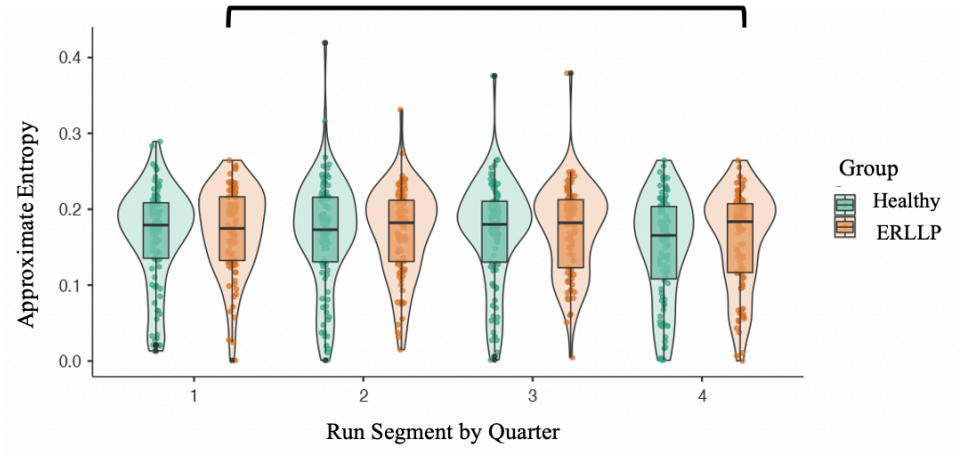
b.

Abbreviations: ERLLP, Exercise-related lower leg pain; ms, milliseconds.

Figure 1.2 (a) Coefficient of variation and (b) approximate entropy outcomes between groups by quarter running segments.



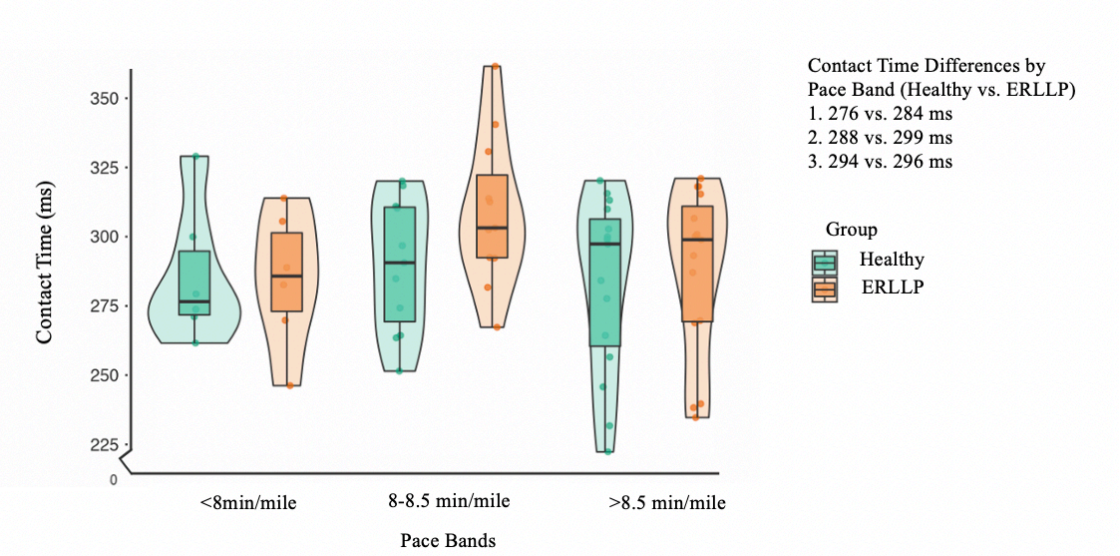
a.



b.

Abbreviations: ERLLP, Exercise-related lower leg pain; COV, coefficient of variation.

Figure 1.3 Contact time measures between groups by pace bands.



Caption: Contact time violin plots with overlaid box plots broken up into Fastest (<8min/mile), Medium (8-8.5 min/mile), and Slowest (>8.5 min/mile) pace bands. *Abbreviations: ERLLP, exercise-related lower leg pain; min, minute.*

SECTION II: MANUSCRIPT II

SENSOR-BASED GAIT-TRAINING TO REDUCE CONTACT TIME FOR RUNNERS WITH EXERCISE-RELATED LOWER LEG PAIN: A RANDOMIZED CONTROL TRIAL

ABSTRACT

Background: Runners with exercise-related lower leg pain (ERLLP) have exhibited increased ground contact time during outdoor running compared to healthy runners. However, it is currently unclear if incorporating contact time feedback during habitual outdoor running for runners with ERLLP improves biomechanics, decreases pain, and increases function above standard of care stretching and strengthening exercises. **Purpose:** The purpose of this study was to assess the effects of a 4-week outdoor gait-training intervention to reduce contact time in conjunction with a home exercise program (FBHE) compared to home exercises alone (HE) for runners with ERLLP. **Methods:** 18 runners with ERLLP were randomly allocated into FBHE or HE groups (FBHE group: 3 males, 6 females, 23±4 years, 22.0 ± 4.3 kg/m^2; HE: 4 males, 5 females, 25±5 years, 23.6±3.9 kg/m^2). Both groups completed 8 sessions of lower extremity stretching and strengthening home exercises over 4 weeks. The FBHE group additionally received vibrotactile feedback using a faded feedback design to reduce contact time during outdoor running, facilitated between wearable sensors and a paired wristwatch. Clinical laboratory measures, and indoor and outdoor gait assessments were completed at baseline and 4 weeks for both groups, and patient-reported outcome measures (PROMs) were collected at baseline, 2 weeks, 4 weeks, and 6 weeks for both groups. The FBHE group repeated an outdoor gait analysis at 6 weeks to assess feedback retention. Separate repeated measures analyses of variance (RMANOVAs) were used to assess the influence of group and timepoint on PROMs, sensor-derived biomechanical measures, and clinical laboratory measures. Statistical parametric mapping RMANOVAs were used to assess indoor running kinematics and lower extremity muscle activation. **Results:** While both

groups reported increased function through to the 6-week follow-up (p=.01), the FBHE group reported significantly increased function and recovery beyond the HE group at the 6-week timepoint across several questionnaires (Running Injury and Recovery Index: Mean Difference [MD]= 15%, p=.02; Exercise-Induced Leg Pain Questionnaire: MD=13.3%, p=.04; Global Rating of Change: MD=3; p=.03). The FBHE group presented with significantly decreased contact time and cadence measures at 4-weeks compared to baseline (MD: -19ms, p=.002), and compared to the HE group (MD: -18ms, p=.01). Contact time changes were retained at the 6-week follow-up. Several strength measures about the foot, ankle, and knee were increased at 4-weeks for both groups (p<.05). All other outcomes were comparable across groups and timepoints.

Conclusions: FBHE was more effective than HE alone for runners with ERLLP manifested with improved PROMs and outdoor gait biomechanics at 4- and 6-week timepoints. Clinicians should consider implementing this ecological gait-training intervention among ERLLP runners to improve clinical management of this prevalent running-related injury.

Word Count: 429

Keywords: biofeedback, running, rehabilitation, shin splints, running-related injury

Introduction

Distance runners of all ability levels are susceptible to sustaining lower extremity injuries resulting in pain and decreased self-reported function, which pose a considerable health burden on the running community.[1–3] Epidemiological studies have identified that pain and dysfunction localized to the lower leg constitute up to 50% running-related injuries.[2,4,5] Although there are several terms, such as medial tibial stress syndrome and shin splints, that have been used to describe pain in this region when fractures and other specific soft-tissue injuries can be ruled out with imaging and physical examinations respectively, recent literature has advocated using "exercise-related lower leg pain" (ERLLP) as the preferred nomenclature.[5,6] ERLLP injuries are particularly recalcitrant to manage clinically given that this is often a diagnosis of exclusion,[5,6] and presents with a wide range of injury etiologies.[7] Further, up to 75% of ERLLP cases have been identified as recurrent conditions which necessitates considerable time and resources to treat these patients.[5,8] Given the burden ERLLP injuries impose on runners, recent research has sought to identify contributing factors to the overall running-related injury model proposed by Bertelsen and colleagues in 2017 to guide evidence-based approaches to treatment.[7]

There have been several studies to date that have explicitly explored treatment options to address anthropometric contributors to ERLLP development. Based on the literature, the current recommended care is to prescribe calf stretching given the association between tight posterior chain musculature and ERLLP development.[9] The remaining evidence has been limited to isolated findings without any controlled research interventions to address ERLLP, and therefore there are no current guidelines delineating

the most effective rehabilitation approaches. However, such programs are often included in clinical practice and should be considered in patient pain management, especially as recent work has identified hip and surrounding ankle muscle weakness among ERLLP patients.[10] Previous strengthening programs targeting lower extremity musculature across a variety of injured runner groups have demonstrated success in reducing pain and improving patient-reported outcomes (PROMs).[11,12] While these studies may be used as a framework for ERLLP interventions, it is important to note that strengthening to address muscle weaknesses would only account for the personal attributes component of the running-related injury model, and not address biomechanical contributors to injury.[7] Furthermore, past clinical management efforts for ERLLP patients have proven ineffective given the limited available evidence and perpetually high injury rates.[2,9] Therefore, clinicians and researchers have turned to running gait evaluations to assess movement deficits that may contribute to this chronic condition.

There is substantial evidence suggesting there are key biomechanical characteristics differentiating ERLLP runners from their healthy counterparts.[10,13–15] Laboratory-based gait analyses have consistently identified increased peak rearfoot eversion during stance,[16,17] higher vertical ground reaction forces,[18] longer stride length,[19] and slower cadence among ERLLP runners.[19] As such, intervention studies have targeted these factors either in isolation or through multimodal gait modification approaches with demonstrative success.[20,21] However, previous gait-training interventions have been primarily employed for healthy runners exhibiting injury risk factors, thus hindering our understanding of treatment success among runners actively experiencing pain.[20] Furthermore, these interventions have primarily been conducted in controlled laboratory

settings, which may not translate to habitual outdoor running.[20,21] The clinical feasibility of indoor gait analyses and subsequent interventions have also been called into question as these techniques require extensive time and equipment resources that hinders implementation into routine patient care.[22–24] While laboratory-based gait assessments should not be discounted given that this approach remains the gold standard to assessment and can capture a wider range of outcomes, there are distinct advantages to moving outside of the laboratory setting for running analyses. As such, recent work has shifted to incorporate outdoor running analyses through implementing lightweight wearable technology, with the goal of obtaining a representative biomechanical assessment among ERLLP patients to guide gait-training programs (Manuscript 1).[10]

Previous outdoor evaluations of ERLLP patients have determined that across sensor-derived biomechanical measures, increased and more variable contact time emerged as the key factor differentiating ERLLP runners from healthy counterparts (Manuscript 1).[10] Based on this evidence, focusing on decreasing contact time during outdoor running may be an effective approach to gait-training for runners with ERLLP. Previous outdoor gait-training interventions among healthy runners with risk factors of lower extremity stress reactions have implemented vibrotactile feedback through accelerometers and linked wristwatches among healthy runners with promising outcomes, and supports an ecological approach to clinical intervention.[23,25] However, to date there are no studies that have explored the clinical benefits of incorporating gait-training biofeedback during outdoor running on specific impairments among runners actively experiencing ERLLP symptoms. Evaluating gait-training applications for runners with ERLLP is a necessary step to determine if there is an added benefit to patient

management beyond typical stretching and strengthening not only to adjust biomechanical gait parameters, but more importantly to improve pain and self-reported function.

Therefore, the purpose of this study was to assess the effects of incorporating a 4-week rehabilitation program including outdoor gait-training biofeedback to reduce contact time in conjunction with a home exercises (FBHE) compared to home exercises alone (HE) for runners with ERLLP. Specifically, we sought compare the effects of FBHE compared to HE and compared to baseline measures on 1) PROMs, particularly centered around pain and function outcomes, 2) contact time and other sensor-derived biomechanical measures during outdoor running, 3) kinematics and muscle activation during indoor treadmill running, and 4) clinical strength and alignment measures. We hypothesized that the FBHE group would demonstrate 1) reduced pain and increased function beyond the HE group and compared to baseline measures, 2) decreased contact time, increased cadence, and decreased loading during outdoor running, 3) decreased sagittal and frontal plane hip motion along with decreased sagittal plane knee and ankle motion during indoor running, and 4) both groups would increase lower extremity strength and increase range of motion given that all participants would receive standard home exercises and stretching.

Methods

Participants

Potential participants were recruited through our local University and surrounding community, including local running clubs and races using email list-servs and fliers. All participants were required to be between 18-45 years of age and involved in running

training at least three times per week for the past three months. Participants had to report pain between 20 and 80 mm on the 100-mm Visual Analog Scale (VAS) during or following bouts of running in the anteromedial, anterolateral, or posteromedial aspect of the leg for at least the past month, which was confirmed using a structured clinical assessment (Additional Methods Table C4b).[26–28] Participants were also required to score less than 90% on the Exercise-Induced Leg Pain Questionnaire – British Version (EILP).[6,27–29] Individuals were excluded if they experienced pain over the Achilles tendon, popliteal fossa, or the superficial posterior compartment of the lower leg, or any current medical diagnoses of compartment syndrome, tibial or fibular stress or full fractures within the past 3 months.[6,29] Participants could not have any other lower extremity or spinal injuries, past lower extremity surgery, neuromuscular impairments or diseases, 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 (NCT #04270565).

Prior to reporting to the laboratory for initial testing, participants completed additional PROMs including a running history questionnaire, the Wisconsin Running Injury and Recovery Index (RRI),[1] and the lower extremity functional scale (LEFS). Participant's demographic information is presented in Table 2.1.

Instrumentation – Gait Assessments

RunScribe™ Plus wearable sensors (RunScribe Labs, Half Moon Bay, CA, USA) were used for all recorded outdoor runs. Each sensor consisted of a triaxial accelerometer, magnetometer, and gyroscope to collect kinematic and kinetic data at a 200 Hz sampling rate, with on-board processing and memory capabilities. Garmin

Forerunner 235 wristwatches (FR235, Garmin Corporation, Olathe, KS, USA) were used to facilitate outdoor gait-training feedback.

Indoor gait assessments were completed on a dual-belt instrumented treadmill with embedded force plates (Bertec Corporation, Columbus, OH, USA) using a 1000 Hz sampling rate and a threshold of 20N to identify initial contact and toe-off. A 12-camera Vicon Motion Capture System (Vicon Motion Systems, Inc., Lake Forest, CA, USA) sampled at 250 Hz was used to assess participants' movement using the plug-in gait model to digitize participants. Lower extremity kinematics and surface electromyography (sEMG) data were recorded using MotionMonitor™ software (Innovative SportsTraining, Chicago, IL, USA). Wireless rectangular 27 × 37 × 13 mm Ag/AgCl Trigno sEMG electrodes (Delsys, Boston, MA, USA: 80 dB common mode rejection rate) with an 11-mV signal input range were used to collect gluteus medius, tibialis anterior, peroneus longus, and medial gastrocnemius muscle activation data at a 2000 Hz sampling rate.[30]

Instrumentation – Clinical Assessments

The Foot Posture 6-item assessment tool (FPI-6) and Arch Height Index Measurement System (JAKTOOL Corporation, Cranberry, NJ) were used to assess foot morphology. A clear plastic 12-inch goniometer and standard tape measure were used to assess range of motion and lower extremity alignment. A MicroFET2 digital handheld dynamometer (Hoggan Health Industries, West Jordan, UT) was used to assess lower extremity strength. A standard Y-balance test (YBT) set-up[31] was used to complete a dynamic postural control assessment.

Procedures

Baseline Visit - Clinical and Functional Movement Assessments

All participants reported for a single baseline visit at the university research laboratory. The first visit began with a battery of clinical assessments performed by either an athletic trainer (SLS, XT) or trained laboratory assistant (PNF) blinded to questionnaire responses and group allocation. The clinical assessment consisted of lower extremity alignment measures including the arch height index, foot posture index, and leg length using previously described methods.[32–34] Foot posture measures obtained from the Arch Height Index Measurement System were used to calculate the unloaded arch height (Equation 2.1), loaded arch height (Equation 2.2), arch rigidity indices (Equation 2.3), and arch drop (Equation 2.4).[33]

Equation 2.1:[33] $Unloaded\ Arch\ Height\ Index = \frac{Unloaded\ Arch\ (mm)}{Unloaded\ Truncated\ Foot\ Length\ (mm)}$

Equation 2.2:[33] $Loaded\ Arch\ Height\ Index = \frac{Loaded\ Arch\ (mm)}{Loaded\ Truncated\ Foot\ Length\ (mm)}$

Equation 2.3:[33] $Arch\ Rigidity\ Index = \frac{Loaded\ Arch\ Height\ Index}{Unloaded\ Arch\ Height\ Index}$

Equation 2.4:[33] $Arch\ Drop\ (mm) = Unloaded\ Arch\ (mm) - Loaded\ Arch\ (mm)$

Range of motion and strength measures were obtained for the following lower extremity joints: 1st metatarsophalangeal ([MTP], flexion, extension),[32] ankle (plantarflexion, dorsiflexion, inversion, eversion),[32] knee (flexion, extension),[35] and hip (flexion, extension).[35] All strength measures were normalized to participants' body mass.

Following clinical assessments, participants completed three functional movement assessments including the YBT,[31] three sets of lateral step-downs from a 15-cm stair,[36] and three sets of single-leg squats to 45° knee flexion.[37] These movement assessments were decided upon following a focus-group with an expert panel of four physical

therapists, two of whom were dual-credentialed as athletic trainers, that had expertise in treating injured runners. YBT reach distances for each reach direction were normalized to participants' leg length to determine dynamic balance performance.[34] The lateral step-down and single-leg squat assessments were scored by the same blinded assessor, and noted if participants demonstrated one of the following movement profiles: 1) medial knee displacement over the first ray of the foot/ipsilateral hip drop/contralateral trunk lean (valgus); 2) lateral patellar displacement over the first ray of the foot/contralateral hip hike/ipsilateral trunk lean (varus); 3) neutral impression. The scoring on the assessments were subsequently used to generate specific home-exercise plans (Additional Methods Table C9b).

Baseline Visit - Indoor Gait Assessment

Following clinical and functional movement assessments, participants were prepared for instrumented indoor treadmill running assessments. Their skin was shaved, debrided and cleaned with isopropyl alcohol, and sEMG electrodes were placed over the gluteus medius, tibialis anterior, peroneus longus, and medial gastrocnemius muscle bellies parallel to the muscle fibers. Electrode placement was determined by manual palpation during a voluntary muscle contraction.[30] Eight clusters containing 34 retroreflective markers were then placed bilaterally on the subjects' foot dorsum, lateral calf, lateral thigh, and on the sacrum and upper back. An examiner used a stylus to indicate bony landmarks for joint center identification using the Bell method in MotionMonitor™ to digitize participants for gait analysis.[38] Following a 10-second static recording, all participants completed a 5-minute warm-up on the treadmill at a self-selected comfortable running pace. Three 30-second trials of motion capture data were

then recorded at the same comfortable self-select running pace. Next, the treadmill speed was set to a standardized 2.68 m/s running speed, and participants were given a one-minute adjustment period so their running patterns could stabilize in response to the new pace. Three additional 30-second data recordings were obtained at the standard speed.

Baseline Visit - Outdoor Running Assessment

All participants were issued a set of wearable sensors and downloaded the associated application onto their cellphones. The sensors were lace-mounted on participants' shoes, and following usage instructions (Additional Methods Table C7d), participants ran on a pre-determined 2688-meter route to calibrate the sensors and serve as a baseline outdoor running assessment. Participants were instructed to wear the sensors on the laces of their shoes twice per week during sustained runs of at least 2 miles over the 4-week study period. Within the RunScribe mobile applications, participants were asked to keep a note about how much lower leg pain they experienced during each of their runs (0 to 10). Participants were also prescribed home exercises and stretches to be completed twice per week over the study period, and were instructed to record exercise compliance in their RunScribe mobile applications. Participants were provided resistance bands as necessary and were emailed the list of exercises and video files with exercise demonstrations.

Baseline Visit - Group Allocation

At this timepoint, the assessing clinicians who were blinded to participant group allocation were dismissed. A random-number generator was used by an investigator who was not involved in participant screening, outcomes measurement, or intervention administration (J.H.) to determine the randomization sequence for participants. Group

assignments were placed in sealed envelopes to ensure concealed allocations, and opened following baseline measures by the clinician administering the feedback procedures. If participants were allocated to the HE group, they were dismissed. If participants were allocated to the FBHE, a 5% reduction of the baseline outdoor run average contact time was manually loaded onto a Garmin wristwatch using custom code as the feedback threshold for gait-training (Manuscript 1). Participants were oriented to the contact time gait-training on the indoor treadmill at their preferred running speed. If a participant's contact time on the RunScribe sensors exceeded the threshold, they received a tactile feedback vibration on their wrist via the wristwatch. The feedback was delivered as three quick pulses, and delivered every 125 milliseconds that they were over the prescribed threshold. Runners were instructed to adjust their running patterns by shortening their contact time to reduce the vibration. After approximately five minutes, or once a participant indicated they were comfortable with the feedback procedures to be completed during two of their regularly-scheduled sustained runs (i.e. non-interval activities) per week, they were dismissed.

Weekly Check-Ins

Throughout the 4-week study period, all participants completed virtual weekly check-ins through email correspondence to determine compliance with the home exercise program, and to adjust the exercises as needed. While in-person check-ins were originally planned, in-person visits were limited to solely baseline and follow-up timepoints due to the severe acute respiratory syndrome coronavirus 2 (COVID-19) pandemic. Participants in the FBHE group performed weekly check-ins to ensure that the sensors were working properly, and to determine if the feedback program needed to be adjusted. At the 2-week

timepoint, all participants completed the Wisconsin RRI,[1] the Global Rating of Change (GROC) scale,[39] and repeated the 100-mm VAS scales. Participants in the FBHE group were instructed to utilize the feedback for 50% of their runs for the remainder of the study period (i.e., 1.5 miles of a 3-mile run, or 15 minutes of a 30-minute run).

Follow-Up Procedures

At the 4-week timepoint, participants in both groups returned to the laboratory to repeat all questionnaires, baseline clinical and functional movement assessments by the same blinded assessor, and indoor and outdoor gait assessments using the same baseline procedures. The outdoor gait assessments were completed without feedback for the FBHE group. Participants were emailed 2 weeks later (6-week timepoint) to repeat all PROM questionnaires, and participants in the FBHE group repeated the outdoor gait assessment without feedback using the same RunScribe Plus sensors on the calibration run route to assess gait-training retention. Following this assessment, all study procedures were complete.

Data Processing

Sensor-Derived Biomechanics Processing

All biomechanical measures obtained from the sensors were calculated through a proprietary software (RunScribe, Inc.) where raw accelerometer, magnetometer, and gyroscope data were processed on-board into the specific spatiotemporal, kinetic, and kinematic variables. Definitions for each of the sensor-derived metrics are provided in Additional Results Table D1a. Sensor-derived data from each run were accessed and extracted from the sensor manufacturer's online dashboard to obtain step-by-step data for

analysis. Walking and standing events were visually identified in the datasets from when the flight ratio variable fell to zero and were removed from analyses.

Indoor Gait Assessment Kinematics and sEMG Processing

Ten consecutive strides from all indoor running trials at self-selected and standard speeds were included for analyses. Sagittal plane ankle, knee, hip, and trunk, and frontal plane hip and trunk joint angles were obtained from the Motion Monitor software and smoothed using a 4th order Butterworth filter. Kinematic data during the running trials were normalized to the mean of the 10-second quiet standing epoch. The raw sEMG data were filtered using a 10-500Hz bandpass filter, a 60 Hz notch filter and 50-sample window, moving average, root mean square algorithm. Gluteus medius, peroneus longus, tibialis anterior, and medial gastrocnemius sEMG data were normalized to average quiet standing signals.[40] Data from each stride were reduced to 101 data point, representing 0-100% of the running gait cycle.

Statistical Analyses

Descriptive analyses were conducting using independent samples t-tests to compare age, height, body mass index (BMI), EILP, LEFS, 100-mm VAS, and Wisconsin RRI questionnaire scores, running experience, pace, and weekly mileage at baseline between the feedback and control groups.

Patient-Reported Outcome Measures Analyses

A multivariate analysis of variance (MANOVA) was initially conducted to assess if there were broad differences in PROMs across groups and timepoints. Subsequent 2x4 repeated measures analyses of variance (RMANOVAs) were used to assess the influence of group (FBHE, HE) and timepoint (baseline, 2 weeks, 4 weeks, 6 weeks) for each

PROM measure, including the EILP, LEFS, 100-mm VAS, and the Wisconsin RRI. Separate 2x3 ANOVAs were used to compare the influence of group (FBHE, HE) and timepoint (2 weeks, 4 weeks, 6 weeks) for patient's GROC scores.

Outdoor Running Analyses

A preliminary MANOVA was conducted to assess if there were broad differences in sensor-derived measures across groups and timepoints. Separate 2x2 RMANOVAs were then used to assess the influence of group (FBHE, HE) and timepoint (baseline, 4 weeks) for all mean sensor-derived biomechanical measures. In order to assess the effects of the feedback gait-training over the course of the study, descriptive analyses were used to compare mean sensor-derived measures and pain measures for the eight recorded runs over the intervention period for both groups. Feedback compliance was assessed by calculating the percentage of steps that had contact time values below the target threshold over the entire run for the FBHE group. Separate RMANOVAs were additionally used to compare sensor-derived measures across baseline, 4-week, and 6-week timepoints for the FBHE group to assess feedback retention.

Indoor Running Analyses

Kinematics and sEMG from the indoor gait assessment assessments were analyzed using the spm1d Version 0.4 for one-dimensional statistical parametric mapping (SPM) package for Matlab (MathWorks, Inc., Natick, MA, USA).[41,42] A 2x2 group (FBHE, HE) by time (baseline, 4 weeks) SPM RMANOVA ($SPM_{RMANOVA}$) and post-hoc SPM t-tests (SPM) were used to compare running gait biomechanics.

Clinical Measures Analyses

For clinical measures, a MANOVA was first used to assess if there were broad differences across the laboratory measures across groups and timepoints. Separate 2x2 RMANOVAs were next used to assess the influence of group (FBHE, HE) and timepoint (baseline, 4 weeks) for strength, ROM, and alignment measures.

Across all statistical analyses, alpha was set *a priori* to .05, and Tukey's post-hoc analyses were used for RMANOVA assessments in the event of statistically significant findings. Mean differences and Cohen's d effect sizes were calculated to determine the magnitude of differences. Analyses were conducted in Excel (Microsoft ®, 2016, Version 16.44, Microsoft Corporation), Jamovi (The Jamovi Project, 2020, Version 1.2), R (RStudio Inc., v1.2.1335), and Matlab (MathWorks, Inc., Natick, MA, USA).

Results

Both groups were similar at baseline for key demographic factors (see Table 2.1).

Patient-Reported Outcome Measures Results

The primary MANOVA analysis reflected that there were significant differences across PROM responses across study timepoints and between groups (λ=3.13, p<.001). Subsequent RMANOVA analyses reflected that there was a time main effect across VAS pain scores, such that both groups significantly decreased maximum pain, pain during runs, and pain following runs at the 2-week and 4-week timepoints compared to baseline measures (Table 2.2; Figures 2.1a-d). Pain at rest was comparable between groups and across study timepoints (Table 2.2).

There was a significant time main effect for EILP, LEFS and Wisconsin RRI questionnaires as both groups reported increased scores at 4 weeks compared to baseline (EILP: F=1.54, p<.001; LEFS: F=8.89, p=.01; RRI: F=42.06, p<.001; Table 2.2, Figures

2.2a-c). Although not statistically significant, the FBHE group presented with an average of 11% higher Wisconsin RRI scores at 4-weeks as compared to the HE group (Mean Difference [MD] with 95% Confidence Interval [CI]= 11% [-3%, 24%]; d=0.82), indicative of increased recovery (F=3.85, p=.07). Finally, there was a significant group by time interaction for GROC scores. While both groups reported improvements from 2-weeks to 4-weeks, the FBHE group increased to a greater extent (MD: 1.82 [0.33, 3.67], d=1.24, p=.01, Table 2.2, Figure 2.2d).

At the point of data analysis, 7 FBHE participants and 7 HE participants had completed the study through the 6-week timepoint, and thus 3 participants were excluded for the follow-up analysis. The MANOVA analyses across all timepoints reflected there were still time main effects for pain, such that both groups reported decreased pain from baseline across study timepoints for maximum pain (p<.001), pain during runs (p=.01), pain post-runs (p<.001), and for pain during rest (p=.05; Table 2.3; Figures 2.3a-d). Although not statistically significant, the group mean change in maximum pain from baseline to the 6-week timepoint for the FBHE group was a clinically-meaningful shift at -33mm (CI: [-55mm, -11mm], d=1.75), while the HE group improved by -20mm (CI: [-46mm, 6mm], d=0.89, Table 2.3; Figure 2.3a). There were significant group and time main effects for the Wisconsin RRI, EILP, and GROC questionnaires, and a significant time main effect for the LEFS questionnaire (LEFS: F=5.57, p=.01; Table 2.3; Figures 2.4a-d). Post-hoc analyses reflected that while both groups reported increased function through to the 6-week follow-up (RRI: F= 25.41, p<.001; EILP: F=5.21, p=.01; GROC: F= 6.37, p=.01; Table 2.3; Figure 2.4a-d), the FBHE group reported significantly increased function and recovery than the HE group at the 6-week timepoint (RRI: MD=

15% [4.6%, 25.6%], d=1.68, p=.02; EILP: MD=13.3% [3.7%, 22.9%], d=1.61, p=.04; GROC: MD=3 [0,6],d=1.34, p=.03; Table 2.3; Figure 2.4a-d).

Outdoor Running Results

The overall MANOVA analysis for sensor-derived measures reflected that there was a significant group main effect, supporting subsequent RMANOVA analyses (λ =3.24, p=.03). For contact time, there was a significant group by time interaction, such that the FBHE group presented with significantly decreased contact time measures at 4-weeks compared to their baseline (MD: -19ms [-37ms, -1ms], d=1.12, p=.002, Table 2.4, Figure 2.5a), and decreased contact time at 4-weeks compared to the HE group (MD: -18ms [-37ms, -1ms], d=0.97, p=.01, Table 2.4, Figure 2.5a). Additionally, there was a significant group by time interaction for cadence, in which the FBHE group had significantly increased cadence at 4-weeks compared to baseline (MD: 7 steps/min [-3steps/min, 17steps/min], d=0.74, p=.01, Table 2.4, Figure 2.5b), and compared to the HE group at 4-weeks (MD: 11 steps/min [1steps/min, 21steps/min], d=1.16 p=.02, Table 2.4, Figure 2.5b). All other sensor-derived measures were comparable across groups and timepoints (Table 2.4, Additional Results Figures D3.1a-f).

Eight participants from the FBHE group had completed all study timepoints at the point of statistical analysis, and thus one participant was excluded for the gait-training retention assessment. However, the results of the RMANOVA reflected that the runners maintained a decreased contact time at the 6-week timepoint compared to baseline (MD: -14ms [-60ms, 32ms], d=0.4, p=.01), yet was similar to the 4-week timepoint measures (MD: +2ms [-38ms, 42ms], d=0.06, p=.39, Table 2.4, Figure 2.6).

Indoor Running Results

There were no statistically significant differences across any kinematic, kinetic, or sEMG measures between groups, nor across timepoints (Additional Results Figures 2.2a-t).

Clinical Assessment Results

There were significant group differences for alignment and ROM (λ =16.4, p=.02), and significant time differences for strength (λ =2.79, .04), and therefore separate RMANOVAs were conducted for each measure. There was a significant group main effect for weight-bearing dorsiflexion (F=7.91, p=.02) and for the arch rigidity index (F=16.49, p=.001), with post-hoc analyses reflecting that the HE group had increased ROM compared to the FBHE group, and that the FBHE group had higher arch rigidity indices (Additional Results Table D2.1). All other ROM and alignment measures were comparable across groups and timepoints (Additional Results Table D2.1).

There were significant group and time main effects for MTP flexion and knee extension strength measures. While both groups demonstrated increased strength at 4-weeks compared to baseline (MTP flexion: p=.01; Knee extension: p=.05), the HE group had greater strength measures compared to the FBHE group at both timepoints (MTP flexion strength: p=.02; Knee extension strength: p=.03). The HE group additionally had greater plantarflexion strength at baseline compared to the FBHE group (p=.01). Finally, there were significant time main effects for ankle dorsiflexion, inversion, and eversion strength measures, with both groups demonstrating increased strength at 4-weeks compared to baseline (Dorsiflexion strength: F=7.82, p=.02; Inversion strength: F=7.56, p=.02; Eversion strength: F=8.02, p=.01; Additional Results Table D2.1). All other

strength measures were comparable between groups and timepoints (Additional Results D2.1).

Discussion

Through this study, we sought to determine if there was an added benefit of incorporating a specific gait-training intervention facilitated through lightweight wearable technology to moderately reduce contact time during outdoor running for runners with ERLLP on pain and function, outdoor and indoor gait biomechanics, and clinical measures. Overall, our primary study hypotheses were supported. While both the FBHE and HE interventions led to improvements in pain, function, and recovery from baseline to the 2- and 4-week timepoints, the FBHE intervention led to maintained increased function and recovery beyond HE at the 6-week timepoint. The FBHE intervention was also successful in reducing contact time with a concomitant increase in cadence from baseline and compared to HE alone, yet without significantly shifting other sensor-derived gait outcomes. Contrary to our anticipated indoor gait analysis hypothesis, neither intervention significantly shifted kinematic, kinetic, nor muscle activity measures from baseline to follow-up, nor were the two interventions significantly different from one another for these measures. Finally, both the FBHE and HE interventions resulted in increased strength about the foot and ankle complex and for knee extension strength following interventions, which was expected given that both groups completed home exercise programs. These findings support the usage of outdoor gait-training interventions for contact time in conjunction with standard of care exercises to improve patient function and biomechanics beyond the current standard of treatment for runners with ERLLP.

Patient-Reported Outcome Measures

The findings from this study augment our knowledge of ERLLP and best treatment approaches for these injured running patients to disrupt the pain cycle and increase patients' self-reported function. Previous outdoor analyses demonstrating increased contact time among ERLLP runners that were experiencing symptoms served for the basis of this intervention, and results of our study support that increased contact time contributes to the overall disability model given that the FBHE intervention led to greater improvements in function over time.[5] This information is important for clinicians treating ERLLP patients given that these injuries lead to long-term patient-reported deficits,[5,8] and a FBHE intervention over 4-weeks demonstrated lasting patient self-reported benefits following treatment beyond current recommended management approaches.[43]

While patients did report that some pain was still present at the 6-week timepoint, 57% of FBHE patients and 55% of HE patients fell below 20mm on the VAS scale, which would no longer classify the runners as ERLLP patients.[5,29] It is important to note that the FBHE group had higher maximum VAS pain scores at baseline compared to the HE group, yet markedly reported decreased pain across the study timeframe. While the study was underpowered from the initial sample size estimation due to limitations in data collection procedures during the COVID-19 pandemic, there was a clinically meaningful decrement in pain from baseline to the 6-week follow-up for the FBHE group (MD: -33mm [-55mm, -11mm]) compared to the HE group (MD: -20mm [-46mm, 6mm]).[44] These effects of improved function were most evident in the FBHE GROC questionnaire scores; the FBHE had 2.25-fold higher odds of feeling "a great deal better" than the HE

group at 4-weeks (75% of FBHE patients vs. 33% of HE patients), and 5-fold higher odds of reporting feeling "a great deal better" than the HE group at 6-weeks (71% of FBHE patients vs. 14% of HE patients). Clinicians should consider incorporating a specific, outdoor contact time gait-training intervention for ERLLP runners to most effectively treat patient symptoms.

Outdoor Running Gait Biomechanics

The feedback prescription to reduce contact time by 5% of baseline measures during outdoor running using the faded feedback design over 4-weeks was effective for treating gait deficits in the FBHE group compared to baseline, and compared to the HE group. The faded feedback protocol has been recommended for treadmill-based gait-training interventions,[45,46] and we identified similarly beneficial treatment effects for outdoor gait-training. The FBHE group marginally surpassed the prescribed contact time feedback at 4-weeks (6.56% reduction in contact time from baseline), suggesting that patients were able to effectively incorporate the adjusted biomechanical pattern to eliminate the feedback stimulus. Furthermore, the runners were able to maintain the new gait pattern at the 6-week retention timepoint with minimal regression to previous gait patterns (-0.70% change from 4-weeks in the subset sample). The FBHE prescription not only served to reduce the targeted contact time measure, but additionally resulted in a concomitant increase in cadence at 4- and 6-weeks (+4.21% increased cadence at 4-weeks, +3.28% increased cadence from baseline to 6-weeks, -0.56% change from 4- to 6-weeks). This outcome was anticipated as contact time and cadence measures have been found to be highly correlated (Manuscript 1). Given that cadence has been identified as a risk factor for lower limb injury development in previous laboratory analyses,[17,46] these

findings suggest that targeting contact time specifically may have a desired effect across affected spatiotemporal parameters.

Based on the previous outdoor gait analyses for runners with ERLLP, we determined that gait-training interventions should be specific to each runner given the influence of speed on spatiotemporal gait measures (Manuscript 1). This data-driven approach was successful in tailoring the gait-training intervention to the patient to avoid a one-size-fits-all approach.[46] The impairment-based model utilized in this study sought to mirror clinical practice, in which assessments drive treatment. While the current feedback prescription was manually adjusted per participant and the feedback program is not commercially available across devices, advancements in the intervention prescription application may be adapted across clinical sites in future work.

Indoor Gait Assessments

Contrary to our hypotheses, we found no differences across timepoints nor between groups for any indoor running gait biomechanics measure. We believed based on past gait-training intervention studies that manipulating spatiotemporal measures would lead to adjustments throughout the kinetic chain to adapt to the manipulated running pattern.[25,46] We surmise that kinematic and kinetic measures were not significantly affected by the gait-training program given the modest adjustment in the contact time measure. Past studies targeting cadence in the field have reported significant reductions in hip adduction and vertical ground reaction forces; however, cadence adjustments were targeted 7.5% and therefore may have led to greater shifts in gait biomechanics.[25] While we did not identify changes in these previously noted biomechanical risk factors, the contact time manipulation also did not lead to unwanted

changes in running form that are associated with other lower extremity overuse injuries, such as increased vertical ground reaction forces nor decreased knee or ankle flexion.[47–49] Previous indoor gait-training study found that the effects of treadmill interventions do not full transfer to outdoor running assessments.[50] Our results further support that feedback prescription and delivery should be conducted in runners' habitual training settings. Therefore, clinicians may consider the FBHE approach as an advantageous management option for runners that opt to train in outdoor environments.

Our findings regarding the null effects of exercises on gait biomechanics align with previous rehabilitative approaches among patients with other chronic lower limb pathologies, namely patellofemoral pain.[46,51,52] While both groups in our study increased lower limb strength from baseline to follow-up, lower extremity biomechanics did not significantly change. It is noteworthy that we did not specifically assess for excessive eversion at the ankle, which has previously been identified as a risk factor for ERLLP development. Additionally, we did not note significant increases in hip abduction strength, however strengthening programs that have targeted gluteal strength have not identified clinically meaningful changes in hip biomechanics.[51] Finally, we were underpowered to adequately compare biomechanical measures, especially sEMG measures given the extent of signal noise. Future work is needed to determine if there are treatment effects of outdoor gait-training on these parameters in a larger, representative sample.

Clinical Measures

Both groups increased strength about the foot and ankle, and increased knee extension following the 4-week intervention period, which align with our hypotheses

given that exercises were prescribed based on specific deficits noted at baseline for both groups. Despite adequate adherence to the prescribed home exercises (FBHE compliance: 96%; HE compliance: 97%) that incorporated exercises targeting intrinsic foot muscle and hip strengthening and stretches targeting lower quarter flexibility, neither group had significantly improved foot posture, gluteus medius strength measures, nor flexibility at 4-weeks compared to baseline. These findings may be due to the nature of the home exercise programs as seen with previous studies,[53] where there was not direct clinician supervision overseeing the quality of the exercises and relied on patient self-report and home exercise videos demonstrating appropriate from to facilitate the intervention. Due to the COVID-19 pandemic, many health care providers had to adapt to clinic closures and implement home care procedures and home-exercise protocols. While our approach has these limitations, we believe this may be reflective of current practice during this unprecedented time. Overwhelmingly, the results of our study suggest that previous stretching and strengthening programs alone may have been ineffective in improving patient overall outcomes, lending to the perpetual long-term deficits seen in this patient population.

Clinical Implications and Future Directions

Our findings support the use of an ecological approach to gait-training using a data-driven method to prescribe interventions for clinical usage. As reflected in our study, ERLLP patients not only benefit by adjusting their gait patterns, but also reported better improvements in function beyond standard of care exercises. Addressing each component of the running-related injury model is key,[7] and implementing a multimodal approach to care was found to be the best management option. Our gait-training approach provides

clinicians with another tool in their clinical toolbox to treat runners with ERLLP. We additionally believe that this impairment-based assessment to gait-training approach in natural running settings should and will be adopted for other running-related injuries due to the mounting accessibility of wearable sensors and the growing importance of biometrics in patient care. While not all patient populations will necessarily present with contact time deficits, we hope that the framework of this study will set the precedent of more specific patient care by meeting them in their training environment, and measuring and addressing runners' gait deficits that are present with common chronic pathologies to mitigate the running-related injury burden.

Limitations

There were several limitations to this study. As previously noted, our study was underpowered based on our initial sample size calculation due to the COVID-19 pandemic, which may have influenced several of the assessment outcomes. The outdoor gait-training approach to the intervention limited the control we had over external factors such as running environment, surface, terrain, and time of day; however, we believe the external validity of the intervention is increased due to this decision. The feedback intervention is currently not commercially-available, and requires some technical expertise to implement with side-loading the application onto watches; however, we hope to make this more clinically accessible in the future. Home exercises were utilized as the treatment approach for the standard clinical care, and were individualized to patient needs, meaning that exercise prescriptions varied by patient. This was the first study to implement any strengthening intervention in this population, and was designed with clinicians currently treating injured runners, which we believe strengthens our approach.

While ERLLP runners may seek treatment under clinical supervision in clinics, this was not feasible under our study conditions. There was a relatively short retention follow-up period included in this study, and therefore it is currently unknown about how long the effects of intervention would last for ERLLP patients. Future work is necessary to conclude if longer-term outcomes are evident using this intervention approach.

Conclusions

Overall, contact time gait-training feedback during outdoor running facilitated with wearable sensors along with home exercises was more effective than home exercises alone for runners with ERLLP by improving PROMs and influencing contact time and cadence measures during outdoor running throughout a 4-week intervention, and with lasting effects at a 6-week follow-up timepoint. Clinicians should consider implementing this ecological gait-training intervention among ERLLP runners to improve clinical management of this prevalent running-related injury.

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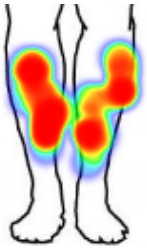
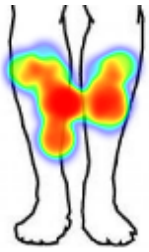
Table 2.1 Participant Demographics for FBHE and HE groups.

	FBHE N=9; 3M, 6F (Mean ± SD)	HE N=9; 4M, 5F (Mean ± SD)	p-Value
Age (years)	23 ± 4	25 ± 5	.48
Height (cm)	168 ± 12	167 ± 8	.84
BMI (kg/m^2)	22.0 ± 4.3	23.6 ± 3.9	.42
Running experience (years)	6 ± 5	5 ± 3	.68
Weekly mileage (km)	24 ± 18	24 ± 19	.97
Average Running Pace (min/km)	5:57 ± 1:07	5:29 ± 0:39	.75
Shoe Mileage	160 ± 135	145 ± 129	.81
Pain Location			

*Significant at p≤0.05
Heat maps generated based upon where patients indicated they experienced pain at baseline. Areas with warmer colors indicate higher density of selected problem areas, while cooler colors indicate lower density of selected problem areas.
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; cm, centimeters; kg, kilograms; BMI, body mass index; km, kilometers.

Table 2.2 PROMs between FBHE and HE groups across baseline, 2-week, and 4-week timepoints.

	Baseline			2-Weeks			4-Weeks		
	FBHE (N=8)	HE (N=9)	p	FBHE (N=8)	HE (N=9)	p	FBHE (N=8)	HE (N=9)	p
100mm VAS – maximum pain in the last week	56±15	41±16	.06	44±24	45±11	.90	38±24	32±13	.57
100mm VAS – pain at rest in the last week	9±7	5±4	.15	11±12	6±5	.32	4±4	4±8	.98
100mm VAS – pain during typical run in the last week	33±20	30±12	.72	23±18	23±10	.93	20±17	19±7	.85
100mm VAS – pain following typical run in the last week	23±16	24±14	.94	13±8	18±12	.37	7±8[a]	18±20	.18
EILP-Br (%)	78.1±6.7	73.1±13.5	.21	-	-	-	91.3±6.9[a]	83.6±14.9	.35
LEFS (%)	88.4±10.0	83.5±14.9	.14	-	-	-	96.3±2.6[a]	91.7±7.9	.44
Wisconsin RRI (%)	58.0±8.3	47.8±17.8	.16	75.7±10.8[a]	63.0±15	.07	84.2±12.7[a]	73.4±13.6	.11
GROC (-7 – 7)	-	-	-	4±2	3±2	.83	6±1[a]	4±2	.02*

[a]Statistically significant compared to baseline at p≤.05

*Statistically significant differences between groups at p≤0.05

Abbreviations: PROMs, Patient-Reported Outcome Measures; FBHE, contact time gait-training feedback with home exercise; HE, home exercise; 100mm VAS, 100-millimeter Visual Analog Scale; EILP-Br, Exercise-Induced Leg Pain Questionnaire – British version; LEFS, Lower Extremity Functional Scale; Wisconsin RRI, Wisconsin Running Injury and Recovery Index.

Table 2.3 PROMs between FBHE and HE groups across baseline, 2-week, 4-week, and 6-week timepoints.

	Baseline			2-Weeks			4-Weeks			6-Weeks		
	FBHE (N=7)	HE (N=7)	p	FBHE (N=7)	HE (N=7)	p	FBHE (N=7)	HE (N=7)	p	FBHE (N=7)	HE (N=7)	p
100mm VAS – maximum pain in the last week	58±15	42±18	.11	47±24	46±11	.97	42±21	29±11	.18	25±22	22±26	.87
100mm VAS – pain at rest in the last week	9±7	4±4	.11	11±13	6±5	.35	5±4	5±9	.97	2±4	3±4	.90
100mm VAS – pain during typical run in the last week	32±21	31±14	.87	25±19	26±8	.97	22±18	20±7	.83	16±17	17±21	.91
100mm VAS – pain following typical run in the last week	25±15	24±15	.88	12±8	19±14	.27	6±8[a]	17±20	.20	7±7	6±7	.85
EILP-Br (%)	78.1±6.7	75.0±14.8	.60	-	-	-	91.3±6.9[a]	82.1±16.1	.17	93.3±5.8	80.0±10.1	.01*
LEFS (%)	88.4±9.8	83.0±17.2	.46	-	-	-	96.3±2.6[a]	92.3±6.5	.14	97.5±2.2	92.0±4.9	.02*
Wisconsin RRI (%)	58.3±8.9	44.8±18.3	.11	77.0±12.6[a]	61.9±16.4	.07	85.9±12.6[a]	73.0±15.3	.11	90.5±8.3[a,b]	75.4±9.6	.01*
GROC (-7 – 7)	-	-	-	4±2	3±2		6±1[a]	4±2		6±1[a]	3±3	.03*

[a]Statistically significant compared to baseline at p≤.05
[b]Statistically significant compared to 2-weeks at p≤.05

*Statistically significant differences between groups at $p \leq 0.05$

Abbreviations: PROMS, Patient-reported outcome measures; 100mm VAS, 100 millimeter Visual Analog Scale; EILP-Br, Exercise-Induced Leg Pain Questionnaire – British version; LEFS, Lower Extremity Functional Scale; Wisconsin RRI, Wisconsin Running Injury and Recovery Index.

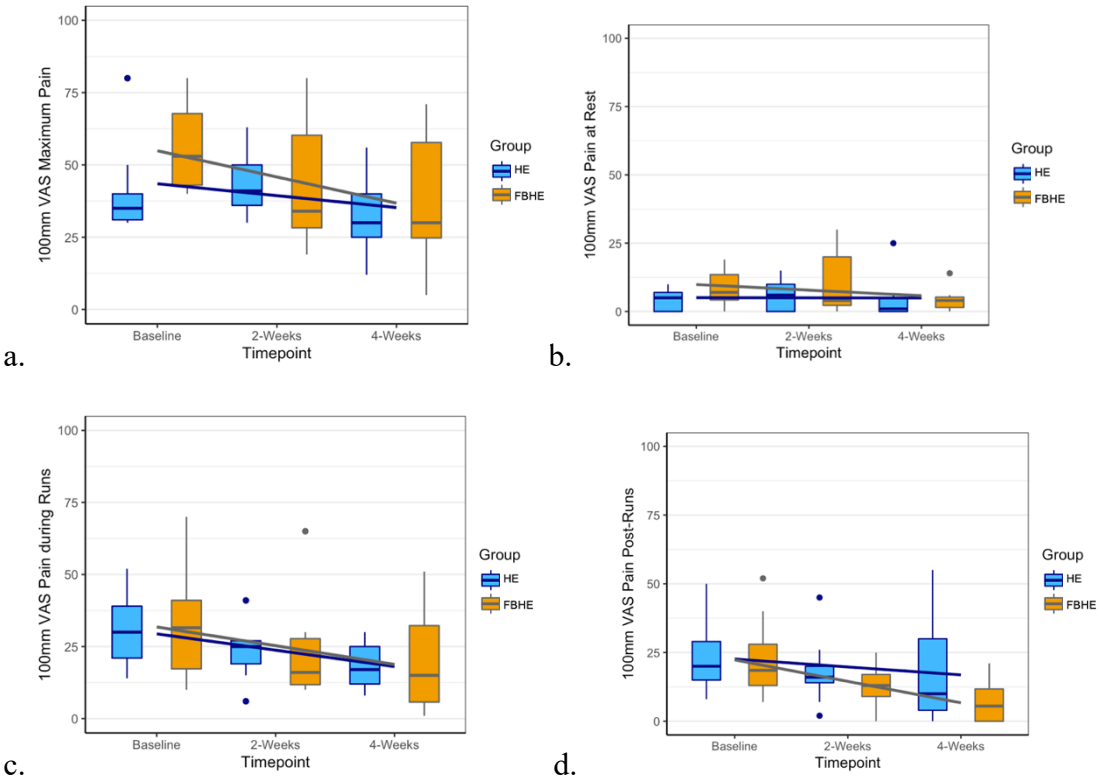
Table 2.4 Sensor-derived biomechanical measures between FBHE and HE groups across baseline, 2-week, and 4-week timepoints.

	Baseline			4-Weeks		
	FBHE	HE	p	FBHE	HE	p
Contact Time (ms)	287±16	288±16	.96	268±18[a]	286±19	.01
Cadence (steps/min)	175±9	170±10	.29	182±10[a]	171±9	.03
Pace (m/s)	3.25±0.41	3.27±0.44	.95	3.38±0.46	3.46±0.47	.70
Stride Length (m)	2.24±0.33	2.31±0.32	.65	2.29±0.36	2.38±0.35	.59
Shock (g)	13.4±1.8	13.9±2.6	.66	13.3±1.5	13.5±2.7	.97
Pronation Excursion (°)	12.5±4.8	11.2±3.8	.54	12.9±5.9	13.9±4.9	.72
Maximum Pronation Velocity (°/s)	906±289	731±246	.20	863±268	732±276	.34
Foot Strike Type (1-16)	8±2	7±3	.68	8±2	8±4	.97

[a]Statistically significant compared to baseline at p≤.05
*Statistically significant differences between groups at p≤0.05

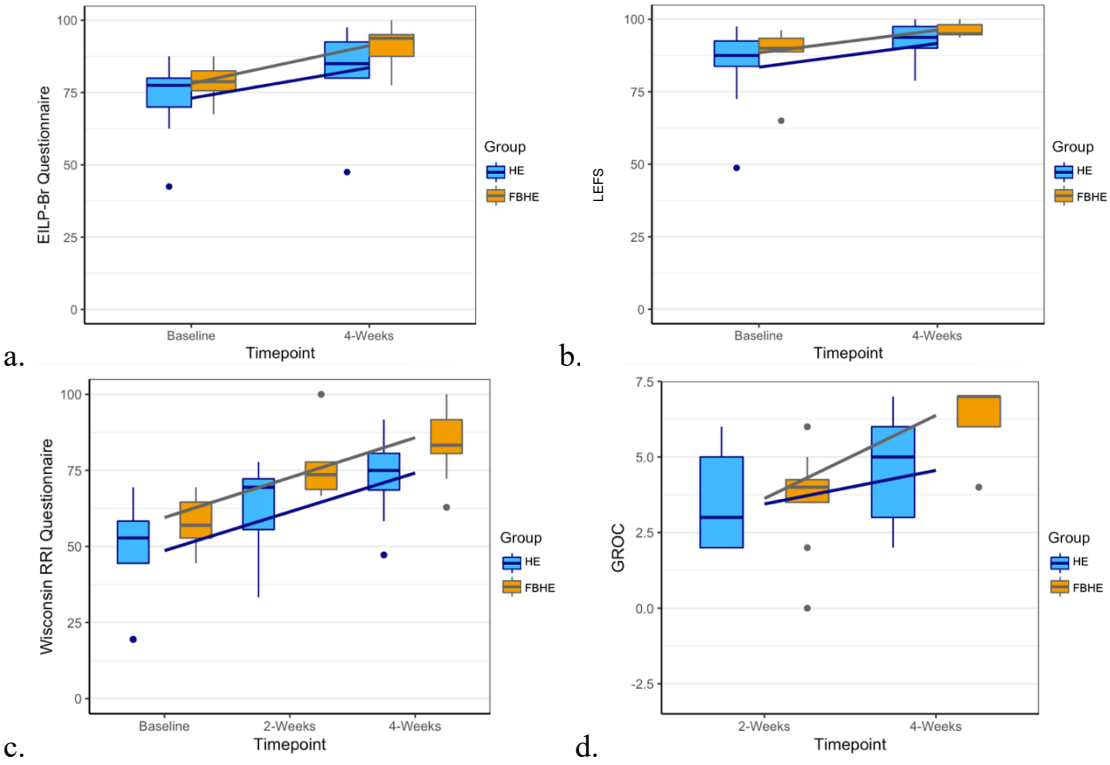
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise.

Figure 2.1. 100mm VAS (a) maximum pain, (b) pain at rest, (c) pain during runs, and (d) pain post-runs from baseline, 2-, to 4-weeks.



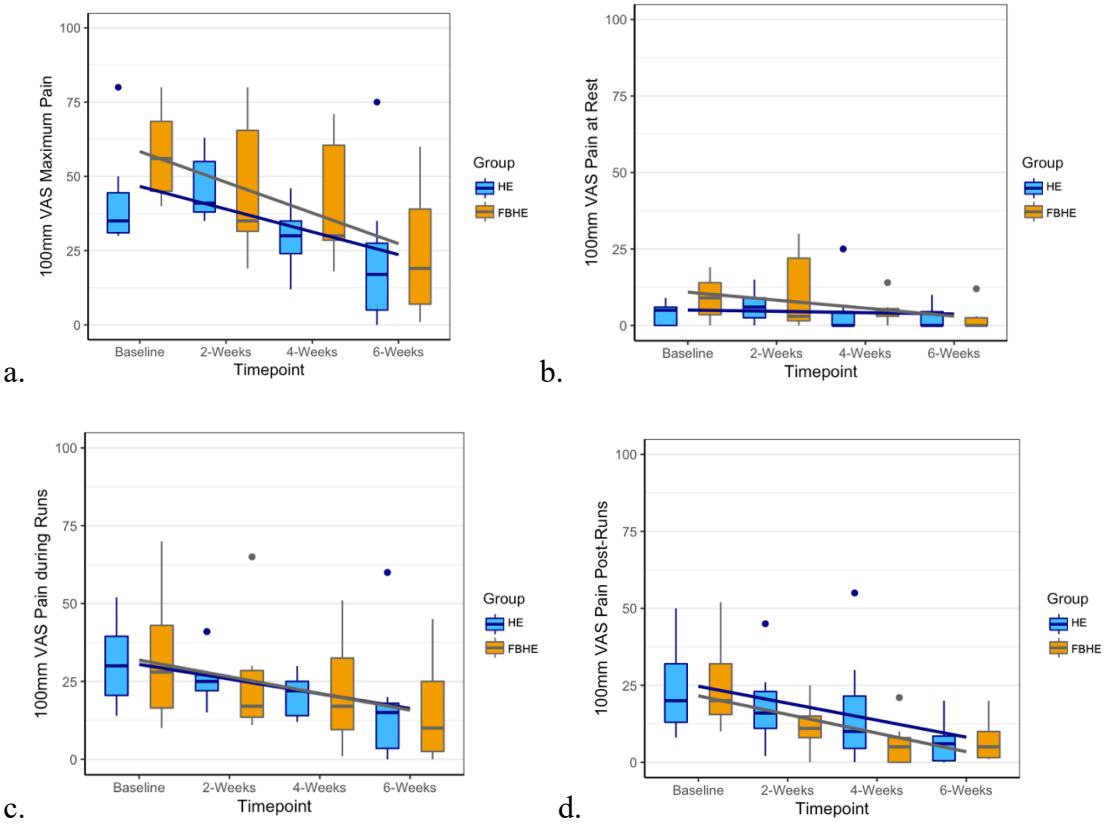
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; 100mm VAS, 100-millimeter Visual Analog Scale

Figure 2.2. PROM scale responses from (a-b) baseline to 4-weeks, (c) baseline, 2-, and 4-weeks, and (d) 2- and 4-weeks.



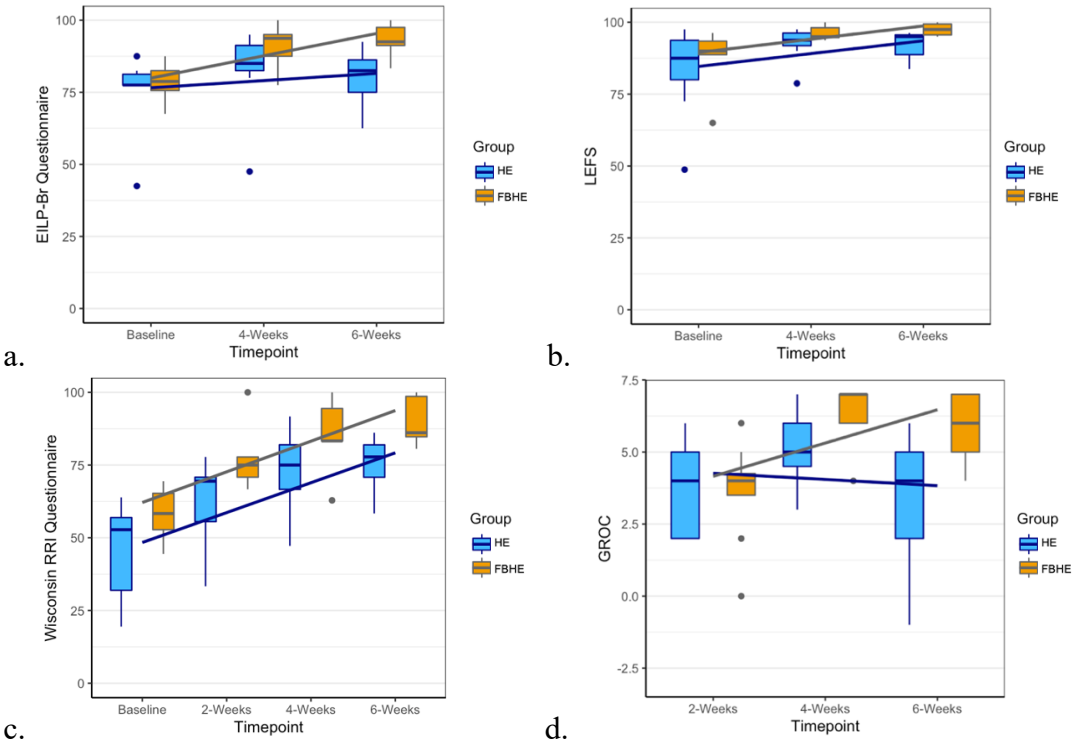
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; EILP-Br, Exercise-Induced Leg Pain – British Version; LEFS, Lower Extremity Functional Scale; Wisconsin RRI, Wisconsin Running Injury and Recovery Index; GROC, Global Rating of Change.

Figure 2.3. 100mm VAS (a) maximum pain, (b) pain at rest, (c) pain during runs, and (d) pain post-runs from baseline, 2-, 4-, and 6-weeks.



Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; 100mm VAS, 100-millimeter Visual Analog Scale

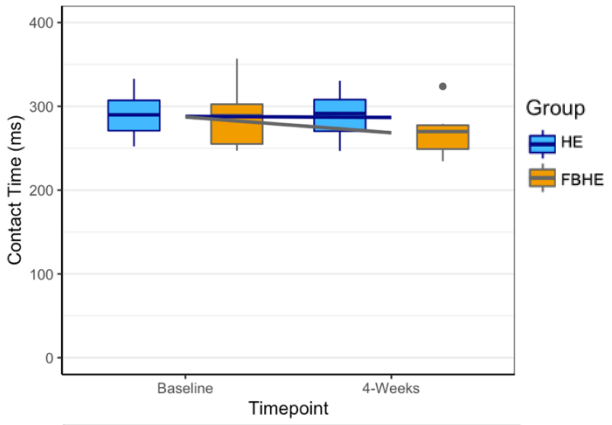
Figure 2.4. PROM scale responses from (a-b) baseline, 4-, and 6-weeks, (c) baseline, 2-, 4-, and 6-weeks, and (d) 2-, 4-, and 6-weeks.



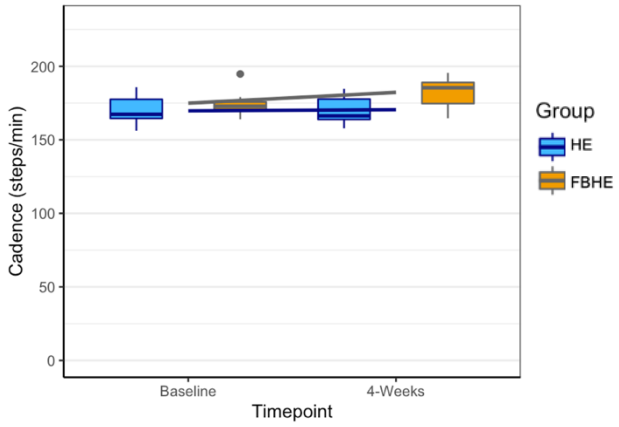
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; EILP-Br, Exercise-Induced Leg Pain – British Version; LEFS, Lower Extremity Functional Scale; Wisconsin RRI, Wisconsin Running Injury and Recovery Index; GROC, Global Rating of Change.

Figure 2.5. Sensor-derived (a, c) contact time and (b, d) cadence measures from baseline to 4-weeks.

a.

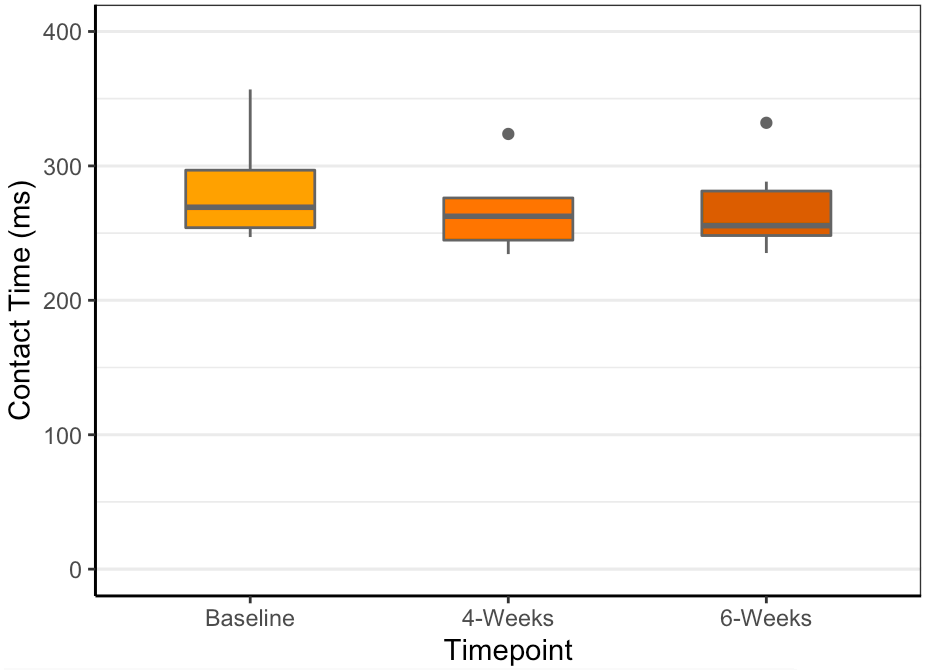


b.



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

Figure 2.6. FBHE retention at 6-weeks compared to baseline and 4-weeks.



Abbreviations: FBHE, contact time gait-training feedback with home exercise

SECTION II: MANUSCRIPT III

PROSPECTIVE RUNNING ASSESSMENTS AMONG DIVISION-1 CROSS-COUNTRY ATHLETES

ABSTRACT

Background: Prospective assessments of athletes have become increasingly integrated into sports medicine practice due to the advancement of wearable technology and development of concise wellness surveys. Although these assessments have been conducted in team sport settings, less information is available among individual sport athletes, such as cross-country runners, in the context of injury and well-being. **Purpose:** The purpose of this study was to prospectively monitor gait biomechanics and wellness measures in a cohort of Division-1 cross-country athletes over the course of a single competitive season to 1) determine the relationships between gait biomechanics and wellness measures, and 2) assess biomechanical profiles and wellness measures among runners who developed lower extremity injuries, with an emphasis on similar injury cases incurred across the season. **Methods:** Twenty-one healthy Division-1 collegiate cross-country athletes (9 males, 13 females) were prospectively followed over the course of a single competitive cross-country season. RunScribe wearable sensors were lace-mounted on the athletes' shoes to collect gait biomechanics twice per week to record long runs and recovery runs, and a session-rating of perceived exertion (sRPE) and wellness survey was completed to estimate internal load. Means and standard deviations were calculated for individual runners' biomechanical and wellness measures across the season, and were used to calculate z-scores of each measure. Separate mixed model linear regressions were used to assess the relationship among biomechanical measures to sRPE, and to wellness z-scores. Descriptive analyses of individual biomechanical z-scores were assessed for runners who developed injuries and compared against healthy male and female runners. **Results:** Stride length, contact time, impact g, pace, weekly mileage, and running a meet

in the day prior to the recorded run explained 25.4% of the variance in sRPE scores across the season (R^2=0.254, F=16.60, p<.001), while contact time and braking g helped explain 3.7% of the variance in wellness scores (R^2=0.037, F=5.70, p=.01). Eight runners developed overuse lower extremity injuries over the season (M=4, F=4), with five categorized as bone stress injuries, and three as soft tissue injuries. Bone injury cases presented with increased contact time, loading, and pronation measures, along with decreased cadence and stride length within two recorded days preceding injury. Soft tissue foot injury cases presented with increased pronation velocity, and decreased shock and braking forces within two recorded days preceding injury, while hamstring injuries presented with increased stride length compared to healthy teammates. **Conclusions:** This study serves as a framework for athlete monitoring among distance runners. There were notable associations between gait biomechanics and wellness measures throughout a competitive cross-country season, and several patterns of biomechanical changes for injury cases that lend insight into potential contributors to injury.

Word Count: 433

Keywords: collegiate athletes, wearable sensors, accelerometer, gait analysis, running, training

Introduction

Athlete monitoring has become increasingly integrated into collegiate sports settings to prospectively assess health and wellness among student-athletes. This notion of prospective monitoring is particularly important from a sports medicine lens, as data accrued over competitive seasons can provide objective insights into loading factors in light of sport-related injuries.[1,2] Clinicians and researchers have predominately integrated athlete monitoring models into popular field- and court-based sports by incorporating lightweight wearable technology during routine conditioning and gameplay to measure athlete training loads in relation to performance and player availability for competition.[3–5] However, to date there are limited prospective studies exploring athlete demands in relation to injury among more individualized sports, namely cross-country. While coaches and clinicians have used broad training load measures such as weekly mileage and pace as surrogates for external training demands, these measures alone overlook important training stressors and subsequent runner adaptations that can be determined from biomechanical spatiotemporal, loading, and kinematic measures.[6] Given the substantial risk of running-related injury among cross-country athletes,[7] incorporating wearable sensors to gain a thorough understanding of athlete responses to training and assess potential risk factors in relation to injury surveillance is an essential step to understanding outdoor running adaptations.[8,9]

Previous biomechanical assessments of running-related injury risk factors have elucidated that decreased cadence, increased stride length and loading, and increased lower extremity frontal plane motion are associated with some of the most prevalent running-related overuse injuries (i.e. exercise-related lower leg pain and patellofemoral

pain).[10–13] It is important to note that these assessments have previously been conducted at single assessment timepoints in laboratory settings, and therefore may not be representative of training demands and responses during sustained outdoor training over time.[14–16] While one previous study has assessed male collegiate track athletes over the course of the spring season analyzing loading metrics and training volume in the context of running-related injury, other key biomechanical measures were not assessed, and the limited sample size of male athletes alone precludes this information from being extrapolated to other cross-country runners.[17] Furthermore, past indoor and outdoor assessments alike have largely focused on average group measures using inferential statistics, which may wash out important fluctuations in biomechanical patterns in time series datasets.[1] Team-based athlete monitoring studies have instead begun to incorporate adjusted models that account for changes in athlete training measures over time. One main approach has been to incorporate the acute to chronic workload ratio which compares recent bouts of training to several weeks to months of training; however, this approach has recently been scrutinized as mathematically coupled data are entered into the numerator and denominator of the ratio, leading to potentially biased findings.[18] Instead, researchers have begun to turn to z-scores which assesses how session-based measures compare to season averages while accounting for fluctuations in the dataset.[19,20] The advent of lightweight wearable sensors allows for more robust, time-series data collections in athletes' natural training environment than has been previously feasible with laboratory-based running assessments.[8,17] Furthermore, utilizing technology to assess athletes provides the infrastructure to collect more specific movement analyses beyond typical volume-based assessments.[6] Sensor-derived biomechanical measures

including cadence, stride length, contact time, shock, and pronation excursion and velocity have demonstrated fair to excellent validity against gold standard gait analysis equipment,[21,22] and have been used to assess cross-sectional running outcomes during outdoor assessments and interventions.[23–26] Therefore, these sensors can reasonably be used to prospectively assess gait biomechanics over the course of a season among cross-country athletes.

Although biomechanical measures obtained from wearable sensors provide substantial insight into running-related injury risk, it is important to note that other personal factors feed into the overall running-related injury risk model that should be accounted for during athlete assessmetns.[27] Factors such as sleep quality and quantity, stress, mood, soreness, and session ratings of perceived exertion (sRPE) response to exercise have been shown to affect athlete performance and wellnesss.[19,20,28] Previous studies of wellness measures in team settings have validated a clinically-feasible 5-point rating scale of wellness measures along with sRPE to investigate injury risk;[2,19,20] these measures should be adapted into running assessments to provide a broader insight of factors related to running-related injury.[27] Prospective evaluations of gait biomechanics and wellness measures may provide clinicians insights into potentially modifiable risk factors in the face of prevalent running-related injuries and training response.

The purpose of this study was to prospectively monitor gait biomechanics and wellness measures in a cohort of Division-1 cross-country athletes over the course of a single competitive season. Through this approach, we sought to 1) determine the relationships between gait biomechanics and wellness measures, and 2) assess biomechanical profiles and wellness measures among runners who developed lower extremity injuries compared

to healthy team measures, with a particular emphasis on similar injury cases incurred throughout the season.

Methods

Participants

Twenty-one Division-1 collegiate cross-country athletes (9 males, 13 females) were prospectively followed over the course of a single competitive cross-country season. All participants were required to be currently participating in varsity cross-country practices, and free from any lower extremity musculoskeletal injuries within three months of initiation of the study. All participants provided informed consent prior to study procedures, and the study was approved by the university's Institutional Review Board (IRB #21756).

At the beginning of the study, participants completed baseline questionnaires, including the lower extremity functional scale (LEFS), Exercise-Induced Leg Pain Questionnaire – British Version (EILP), and a running and health history questionnaire.

Instrumentation

RunScribe™ Plus wearable sensors (Scribe Labs, Inc., Half Moon Bay, CA, USA, 2018) were used for all outdoor running assessments. Each sensor consisted of a triaxial accelerometer and gyroscope to collect spatiotemporal, kinematic, and kinetic data at a 200 Hz sampling rate, with on-board processing and memory capabilities. iPads (iPad Air2, Model A1566, Apple, Inc., 2014) were used in the field to deliver Qualtrics™ wellness surveys 10 minutes following each recorded run over the season. Independent variables of interest for this study included weekly mileage, sensor-derived

spatiotemporal, kinetic, and kinematic biomechanical measures. The wellness outcome measures of interest were sRPE and a composite wellness score.

Procedures

All participants were assigned a set of RunScribe Plus sensors. The sensors were lace-mounted on the dorsum of each shoe, and the athletes completed a 400-meter lap around a standard track as a means to calibrate the sensors at the beginning of the study period (August 2019).

Data collections were conducted twice per week over the course of the competitive cross-country season (August – November 2019), facilitated by the primary study investigator. Participants clipped the sensors onto the laces of their shoes immediately prior to setting off on one long run, and one easy recovery run per week. Long runs ranged in distance from 15-18 miles for males and 6-12 miles for females, and were expected to be at the athletes' tempo pace (approximately 80% of race pace). Recovery runs ranged in distance from 4-8 miles for both males and females, and were expected to be at athletes' conversational pace. Approximately ten minutes following each run and their stretching cool-down, participants returned the sensors to the primary investigator and completed a custom Qualtrics survey delivered on an iPad. Survey questions were based on 5-point wellness surveys previously used and validated in team sport settings.[19,29] Questions included weekly mileage, sleep quantity and quality, stress level, mood, soreness, and Borg's 10-point rating of perceived exertion.[19,28–30] Participants did not have access to previous responses to ensure accurate responses based on current wellness status as opposed to copying past reports.

Athletes that indicated they were either "experiencing an increase in tightness and soreness" or that they were "very sore" for the soreness question were presented with another set of questions asking which body parts were sore (20 options, Additional Methods Table 3Ci), and if their soreness was developing to pain. If the athletes indicated that their soreness was developing to pain, the primary investigator retrieved further injury information from the on-site team athletic trainers. For the purpose of this study, an injury was defined as any case that was currently being evaluated or treated by the team athletic trainers, including time loss and non-time loss cases. Athletes that sustained injuries during the competitive season and that continued to compete (i.e. injuries that were not season-ending injuries) were asked to fill out the Wisconsin Running Injury and Recovery Index (RRI)[31] immediately following the wellness survey to monitor recovery and return to running.

Data Processing

Gait Biomechanics

Sensor data from each run were downloaded onto iPads via the sensors' mobile application, and extracted from the online dashboard to obtain step-by-step data spreadsheets for analysis. Walking and standing events were visually identified in the datasets from when the flight ratio variable fell to zero, and were removed from analysis.[25,26] The primary sensor-derived outcomes of interest were pace, cadence, contact time, stride length, maximum pronation velocity, and shock.[21] Additional outcomes included foot strike type, impact g, braking g, and pronation excursion.

The season was sectioned into quarters to account for variations in training based on pre-season (weeks 1-3), early season (weeks 4-6), late season (weeks 7-9), and championship

competition time periods (weeks 10-11). Means and standard deviations were calculated for individual runners' biomechanical measures for all runs within each quarter of the season, and were used to calculate z-scores of each sensor-derived measure using the following equation to account for both season and individual run variability:

$$Equation\ 1: Gait\ biomechanics\ z\ scores = \frac{(mean\ session\ score - mean\ score\ across\ season)}{SD\ of\ session\ score}$$

Internal Load

Qualtrics survey responses were extracted from the company website and string responses were numerically coded for analyses. sRPE for each run was calculated by multiplying the rating of perceived exertion by the session duration as determined from the timestamps from the sensors.[30] Composite wellness z-scores were additionally calculated by combining the sleep quality, mood, stress, and soreness outcome measures and implementing the following equation:

$$Equation\ 2: Wellness\ z\ scores = \frac{(session\ score - mean\ score)}{SD\ of\ season\ wellness\ score}$$

Statistical Analyses

Descriptive analyses were conducted to assess participant demographics, wellness, sRPE, and sensor-derived metrics over the season. Unadjusted means and z-scores by season quarters were calculated for all biomechanical and wellness measures separately for male and female runners. Descriptive analyses and paired t-tests were additionally used to compare mean biomechanical outcomes for male and female runners between long runs and recovery runs, with alpha set *a priori* to .05.

Primary analyses to assess the relationships between gait biomechanics, running volume, and running a meet in the day prior to the recorded run with sRPE, and with wellness z-scores were conducted using mixed model linear regressions to account for the multiple observations per participant over the course of the season. All predictor variables were first tested separately, and significant predictors were included step-wise into the final regression models. Pearson's r correlation coefficients were calculated to assess the strength of the association between sensor-derived measures and perceived effort and wellness. Correlation coefficients were interpreted as |0-0.39| as weak, |0.40-0.59| as moderate, and |0.60-1.0| as strong. Alpha was set *a priori* to .05, and analyses were performed using SPSS (IBM SPSS Statistics, v27.0.0.0) and RStudio (R Development Core Team, 2011).

Individual z-scores for biomechanical and wellness measures were assessed for runners who developed injuries and were subsequently compared against healthy male and female runner z-scores. Males and females were assessed separately given that team training plans were sex-specific. Participants with running-related injuries were evaluated separately and descriptively compared to runners that remained healthy throughout the season to determine fluctuations in their wellness, sRPE, and sensor-derived measures compared to healthy team averages.

Results

Descriptive Season Outcomes

Participant demographics, including average pace and mileage, can be found in Table 3.1. Unadjusted means for mileage and sensor-derived measures for male and female athletes across the season can be found in Figure 3.1, and measures across the

season for individual athletes by sex can be found in Additional Results Figures 3.1a and 3.1b. z-scores for sensor-derived measures calculated by season quarters can be found in Figure 3.2 and these adjusted measures across the season for individual athletes by sex can be found in Additional Results Figures 3.2a and 3.2b. The saw-tooth appearance in the data reflects the differences between more intense long runs and shorter recovery runs that were recorded throughout the season. Long run and recovery run comparisons can be found in Additional Results Table 3.1, with significant difference in pace for males and females, and spatiotemporal measures for males alone being the most notable differences between run types.

Sensor-Derived Measures and sRPE

Preliminary analyses reflected that stride length, contact time, pronation excursion, impact g, pace, mileage run that day, and the presence of a meet prior to the recoded run day were all significant predictors for sRPE. When these predictors were included step-wise into the mixed model linear regression, pronation excursion resulted in a negligible R^2 change (<0.10) and was no longer a significant predictor, and therefore was removed from the model. The final model reflected that stride length, contact time, impact g, pace, mileage, and recent competition helped explain 25.4% of the variance in sRPE scores across the season (R^2=0.254, F=16.60, p<.001). As perceived effort during runs increased, stride length (ß= -74.57, t= -1.56, p=.04) and impact g (ß= -11.4, t= -2.55, p=.01) decreased, while contact time (ß= 18.8, t= 1.96, p=.05), pace (ß= 1512.8, t= 2.32, p=.02), and mileage (ß= 14.18, t= 6.33, p<.001) increased. Additionally, perceived effort was increased if there was a meet in the day prior to the recorded run (ß= 34.21, t= 1.77,

p=.05). Pearson's r correlation coefficients indicated that there was a weak association with all sensor-derived metrics and sRPE (Figure 3.3).

Sensor-Derived Measures and Wellness Z-Scores

The only significant predictors for wellness measures were contact time and braking g. When both predictors were included in the final mixed model linear regression model, contact time and braking g helped explain 3.7% of the variance in wellness scores across the season (R^2=0.037, F=5.70, p=.01). As wellness z-scores increased, reflecting that athletes were feeling better following a session, contact time (ß= -.01, t= -2.34, p=.02) and braking forces (ß= -.08, t= -2.53, p=.01) decreased. There was a weak association among the sensor-derived measures and wellness z-scores (Figure 3.4).

Injured Runner Cases

There were eight total injury cases reported throughout the season (M=4, F=4), with five categorized as bone stress injuries (2 sacral stress fractures [1M, 1F], 1 femoral neck stress fracture [F], 1 medial tibial stress syndrome [M], 1 5th metatarsal stress fracture [F]), and three as soft tissue injuries (2 hamstring strains [1M, 1F], 1 plantar fasciitis [M]). Injury information, including recovery measures from the Wisconsin RRI for runners that continued to compete during the season, can be found in Table 3.2. Internal wellness, sRPE, and mileage measures comparing healthy and injured runner groups across the season are depicted in Figure 3.5. Individual injured runner cases comparing sensor-derived measures to healthy teammate averages with 95% CI can be found in Additional Results Figures 3.3a-h.

Both female hip stress fracture cases presented with increased contact time, pronation excursion and velocity, impact and shock, yet decreased cadence and stride

length beyond the healthy female team ranges within two recorded days leading up to injury (Additional Outcomes Figures 3a-b). Similarly, the male hip stress fracture case presented with increased impact, shock, and pronation excursion and velocity, with decreased cadence within 2 recorded runs preceding injury (Additional Outcomes Figure 3c). The final bony injury was an isolated metatarsal stress fracture, and presented with increased cadence, contact time, pronation and impact force yet lower braking force leading up to injury (Additional Outcomes Figure 3d). Both of the male lower limb injury cases (medial tibial stress syndrome and plantar fasciitis) presented with increased pronation velocity, and decreased shock and braking forces within 2 recorded days of injury beyond the healthy male team range (Additional Outcomes Figures 3e-f). Finally, both hamstring cases presented with increased stride length in the recorded day preceding injury beyond healthy male and female team ranges respectively (Additional Outcomes Figures 3g-h). However, since both injuries occurred early in the season, there was insufficient time leading up to injury to fully illuminate injury risk patterns.

Discussion

To our knowledge, this is the first study to prospectively evaluate key biomechanical and wellness measures among competitive collegiate male and female cross-country runners during routine outdoor training across a competitive season. While past analyses aimed to quantify loading in a smaller sample of male collegiate track runners, our current study allowed for a more comprehensive understanding of biomechanical adaptations across cross-country runners and injury characteristics incurred throughout the season. Our findings demonstrated that there were gait biomechanical responses to changes in sRPE and wellness measures, albeit with weak

associations across the measures. However, the more compelling findings were that injury cases presented with deviations in the same predictor variables in the several recorded days preceding injury. Specifically, when contextualizing injured runners' biomechanical profiles to healthy teammates, there were commonalities among the injury cases with larger deviations in contact time, cadence, stride length, loading, and pronation velocity, depending on the injury type and location, that were outside of the healthy team ranges. While this study represents an initial approach to describing biomechanical and wellness measures among cross-country athletes, and assessing potential factors associated with injury, these findings importantly demonstrate the merit for incorporating athlete monitoring measures among individual sport athletes to ultimately improve clinical assessments and interventions.

Relationships between Gait Biomechanics and Wellness Measures

The regression models reflected that increased mileage and the presence of a meet in the day prior to a recorded run had a bearing on athletes' perceived difficulty of the exercise. When specifically assessing the relationships between biomechanical and wellness measures, contact time and pace increased with increased perceived exertion, while stride lengths and impact forces decreased. It is logical that pace would be higher with increased effort and lower with decreased effort, suggesting that more intense bouts of training imposed higher stress on the athletes compared to less intense runs. These findings also align with the higher mileage for more intense bouts of running, and that having raced the previous day resulted in increased perceived effort on the subsequent runs due to fatigue. Interestingly, contact time was also found to increase with more intense effort and decreased with easier perceived efforts. These findings highlight that

the athletes were spending longer time epochs in the stance phases of running gait as workloads were perceived to be harder, yet lesser time on the ground during lighter intensity runs, which we hypothesize was related to fatigue. Previous laboratory-based assessments have identified that over-striding, demarcated with a rearfoot strike pattern and an increased stride length, is associated with a higher peak vertical impact during running.[10,32–34] The additional findings from the regression model suggested that more intense runs were associated with a shorter stride length and subsequently decreased vertical and horizontal impact forces, which may have been a protective mechanism to keep the feet landing closer to the body's base of support thereby minimizing the demand on surrounding static and dynamic stabilizers.[35,36]

While the regression analyses did identify significant biomechanical predictors in the model that may have a bearing on athlete wellness across a competitive season, these results should be interpreted with caution as the predictors only explained between 3.7% and 16.5% of the perceived wellness and effort respectively. Given that regression analyses are based off of group-level average measures, these weak associations suggest that making decisions based on team measures for an individual sport such as cross-country may not be the most appropriate analytic approach. However, it is compelling that the same variables identified as significant predictors in the regression model were outside of the expected team ranges for injury cases. It is conceivable that slight variations in biomechanical measures would amplify over sustained distances, thereby affecting athlete's overall well-being and lending to chronic overuse injuries, however future assessments are needed to support this claim. Our approach to prospective monitoring utilizing sensor-derived biomechanical data provides the framework for

future hypothesis-driven practical prospective monitoring with cross-country athletes. Specifically, our findings suggest that measures of pace, contact time, stride length, and loading warrant consideration among individual athlete cases during outdoor training in conjunction with assessing athlete wellness.

Descriptive Team Measures

As with previous team-based athlete monitoring assessments, it was an important step to map out team outcomes over time to elucidate group responses to training demands.[1] This was particularly salient as we measured two different types of training activities throughout the season that had distinct purposes of accumulated distance and recovery respectively, which was strongly reflected in the variation between running types depicted in Figure 3.2. Although running is an individual sport, training prescriptions are often provided at the team level, and assessing collegiate cross-country athletes offers the unique opportunity to assess individual responses with the same dosage and training environment. We additionally recognize that training plans are highly individual based on the coaching style, highlighting the need to expand data collections among cross-country runners across teams to formulate a larger conglomerate of data for enhanced understanding of athlete responses to running. However, this descriptive prospective monitoring study was an essential step to our understanding of external training demands that may be adopted for multi-site studies in future research.

Overall, we determined that biomechanical outcomes were highly dependent on the training activity (Additional Results Table 3.1), and that simply taking a rolling average across all activities would have grossly over- or under-estimated the expected training response. This manifested in highly variable z-score measures that appeared as

saw-toothed curves when assessing changes across season segments, for example, with higher intensity runs appearing to have higher average pace and cadence. These findings corresponded with sRPE scores, however the wellness scores did not follow a similar trajectory and were less consistent across the season. The variability in biomechanical measures and intensity of exercise across training days highlights the importance of measuring different types of activities, and assessing the expected responses therein.[6,9] Similar approaches have previously been done with team-based monitoring by looking at different player positions, training drills, and activities.[37–39] While we opted to not assess interval-based training (such as track intervals), we instead limited the assessments to sustained runs to be able to more directly compare biomechanical measures across continuous running activities, and provide the infrastructure to compare injury cases against healthy teammates with reduced influence of training type on the athlete outcomes.

Injury Cases

There were eight injuries recorded over the course of the season, and although the injuries occurred at varying timepoints and were specific to the individuals, there were some similarities across cases that provide a lens into potential measures of interest for injury risk. The noted biomechanical alterations were largely aligned with previous laboratory-based findings of increased loading,[40–42] larger kinematic deviations at the foot and ankle complex,[13,43,44] and altered spatiotemporal patterns[32,45–47] in the several recorded days leading up to injury. Among the bone stress injury cases, the most frequently noted differences in the days leading up to injury were increased contact time, loading, and pronation measures, along with decreased cadence and stride length. These

findings coincided with the regression analyses described earlier such that the same biomechanical responses were seen with increased effort and decreased wellness. Finally, stride length was increased leading up to both hamstring injuries, which may be attributed to increased stress on the soft tissue structures with overstriding.[48] Surprisingly, wellness scores did not provide additional signaling in the days leading up to injury, and instead athletes who got injury mostly reported higher wellness measures in the preceding days beyond team measures. Our findings suggest that deviations in the wellness measures may not necessarily correspond to future injury, which aligns with recent work suggesting limited predictive capability of Likert-based wellness assessments for external and internal loading demands.[49]

While the biomechanical patterns noted during outdoor running align with previous laboratory assessments of injured runners, we caution that the results should be regarded as a series of inherently unique cases as there is insufficient data from a single season to draw conclusions on injury risk factors common across all distance runners.[9] This study instead lays the foundation for future assessments across a broader running sample to contribute to our understanding of injury mechanism with altered external loading. Our findings highlight several important parameters that should be incorporated into prospective biomechanical assessments, including contact time, cadence, shock and impact, and pronation velocity, which coincides with the regression analyses and strengthens the need to assess these measures over time. With larger databases of runners, we envision that the future of running medicine may consist of the ability to identify individual runners who exhibit changes in metrics of injury risk that are beyond the expected range of biomechanical and wellness measures.[9] Through this individualized

approach to monitoring, athletic trainers, physical therapists, and other key stakeholders can help to target intervention or injury prevention strategies to move towards individualized medicine.

Limitations

There were several limitations to this study. This study assessed a single team in a Division-1 university cross-country setting, and these findings may not be extrapolated to other teams nor to other runners of different ability levels. We were unable to assess other underlying physiological factors that contribute to the overall athlete injury model, including factors such as heart rate, nutrition, and other biomarkers. We decided to only record two runs per week to get a representative sample of sustained runs as compared to track workouts, which would inherently lead to differences in biomechanical measures.[17] This delimitation also precluded us from analyzing cumulative loading, however past work has suggested that cumulative loading metrics may not be an important measure for athletes who are prescribed similar training plans (within 80% of teammates).[17] However, by measuring two representative sustained running training days consistently over the season, we were able to determine trends across weeks to form the foundation for interpreting injury risk profiles. Future work should assess different training regimens to assess factors associated with injury during these activities, and continue to investigate the significance of cumulative loading among cross-country athletes. We were unable to measure races due to coaching preferences, thus it currently remains unclear as to how biomechanical measures would change during collegiate competitions. It is also important to note that male and female runners had different training schedules due to differences in competition distances and as these teams were overseen by different

coaches; separating the team by sex was an important element to understanding the biomechanical responses by training regimes and accounting for physiological differences.[50] Finally, we decided to utilize only validated sensor-derived metrics,[21,51] however we acknowledge that there are other biomechanical measures that can be considered in the context of running-related injury.

Clinical Utility

This study supports the importance of moving beyond group-level decision-making, and towards an individualized approach to cross-country athlete assessment and injury management. With the advancements in wearable technology, clinicians now have the ability to measure activities for each athlete to unearth training patterns that may contribute to pain and subsequent injury. Just as patients treated in the clinic should be regarded as unique cases, future approaches to athlete monitoring should utilize a tailored assessment, particularly for individualized sports. By accruing significantly more data for athletes over time, researchers can begin to leverage more advanced analytical approaches through machine learning and pattern recognition to create more objective, evidence-based decisions for patients to move towards injury mitigation and management. Larger samples of similar running-related injury cases will allow researchers to assess the likelihood of injury cases deviating beyond expected team measures in the context of z-score analyses to determine where biomechanical deviations signal subsequent injury in the days leading up to reported pain and disability.

Conclusions

Overall, this descriptive prospective assessment of collegiate cross-country runners reflected that stride length, impact, pace, and contact time were significantly associated

with sRPE, and that contact time and braking forces were related to athlete wellness. Several gait biomechanics measures, including stride length, loading, cadence, contact time, and pronation velocity were found to differ among injured athletes in the days leading up to injury as compared to healthy team measures. This study offers a foundation for prospective assessments among competitive runners to assess response to training demands and injury risk.

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Table 3.1. Male and Female Cross-Country Participant Demographics.

	Males (N=9) Mean ± SD	Females (N=13) Mean ± SD
Age (years)	20 ± 1	20 ± 1
Height (cm)	176.60 ± 5.13	166.65 ± 5.02
Mass (kg)	66.62 ± 6.72	58.43 ± 7.98
Running Experience (years)	8 ± 3	7 ± 2
Weekly Running Distance (miles)	78.78 ± 5.72	48.58 ± 12.34
Average Pace (min/mile)	6.57 ± 0.28	7.38 ± 0.27
LEFS	99.53 ± 1.06	98.44 ± 3.15
EILP	100 ± 0	97.81 ± 1.81
Year in Program		
1st Year	N = 0	N = 3
2nd Year	N = 3	N = 3
3rd Year	N = 3	N = 6
4th Year	N = 3	N = 1

Abbreviations: LEFS, lower extremity functional scale; EILP, exercise-induced leg pain questionnaire – British version.

Table 3.2. Injury Cases Recorded Throughout the Competitive Season Across

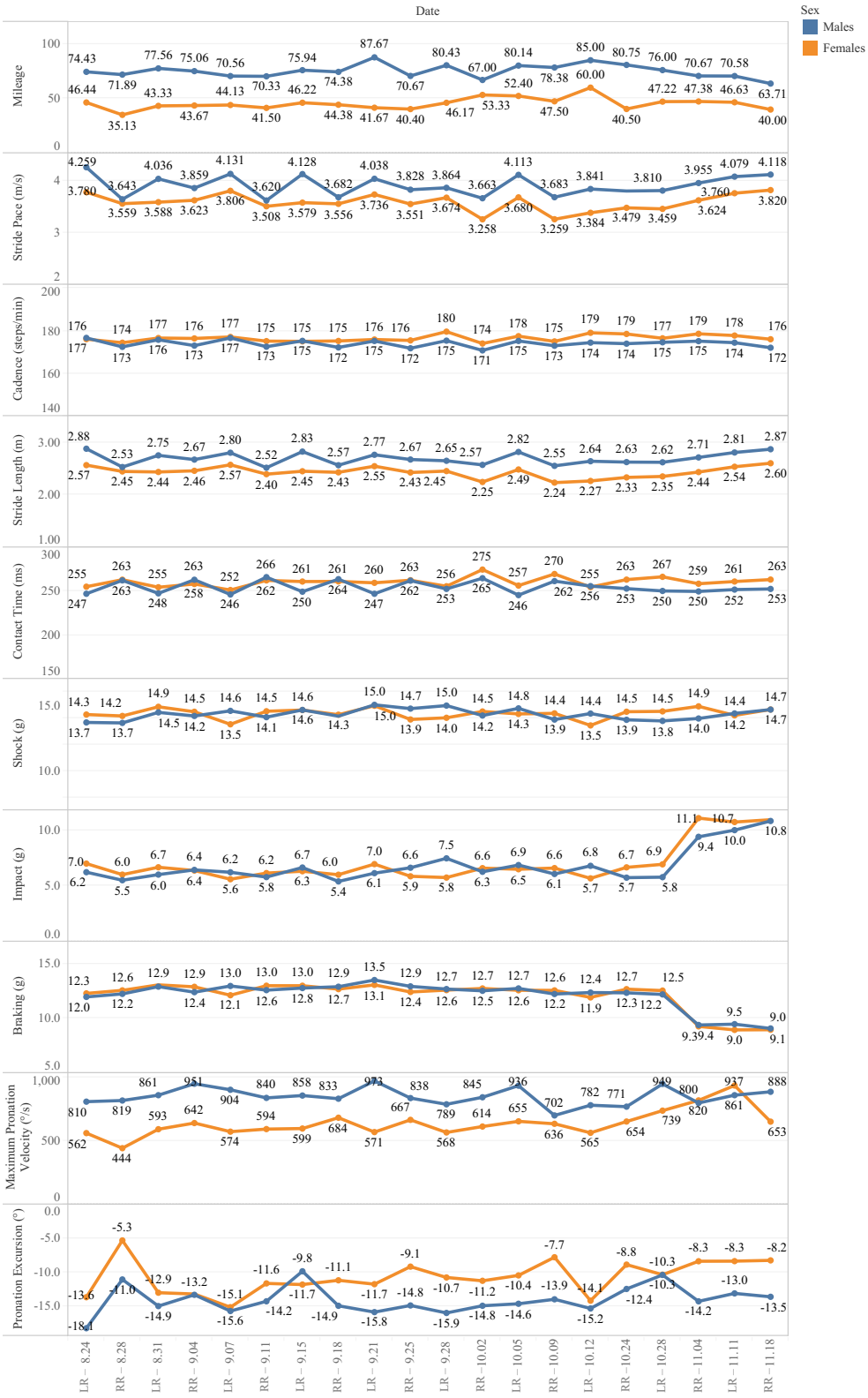
				Wisconsin RRI Post-Injury (Recorded Days Post-Injury)									
Injury Type	Sex	Injury Date	Return to Sport?	1	2	3	4	5	6	7	8	9	10
Sacral Stress Fracture	F	9.25	N										
Femoral Neck Stress Fracture	F	9.18	N										
Sacral Stress Fracture	M	10.02	N										
Metatarsal Stress Fracture	F	11.04	N										
Medial Tibial Stress Syndrome	M	10.09	Y	52.8%	55.6%	55.6%	58.3%	69.4%					
Plantar Fasciitis	M	9.15	Y	69.4%	83.3%	91.7%	100%	100%	100%	100%	100%	100%	100%
Hamstring Strain	M	9.18	N										
Hamstring Strain	F	8.31	Y	41.7%	55.6%	72.2%	63.9%	69.4%	72.2%	83.3%	72.2%	86.1%	91.7%

Cross-Country Athletes.

Caption: Injury survey data is presented solely for the athletes who returned to running training and competition during the season. The percentage indicates to what extent the athletes reported being recovered throughout their post-injury timeline in days post-injury.

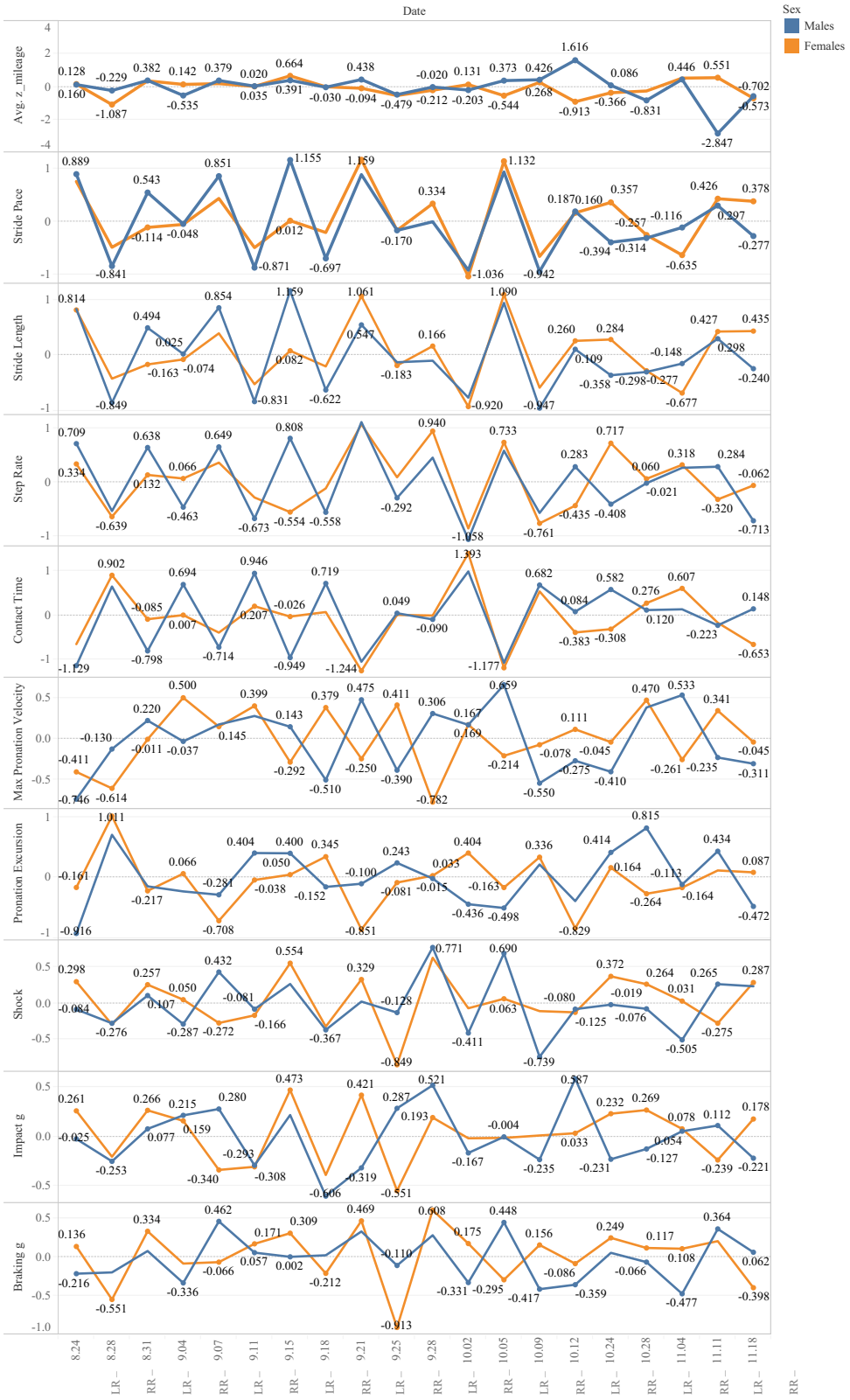
Abbreviations: RRI, running-related injury; F, female; M, male; N, no; Y, yes.

Figure 3.1 Mean mileage and sensor-derived measures for male and female cross-country runners across the competitive season.



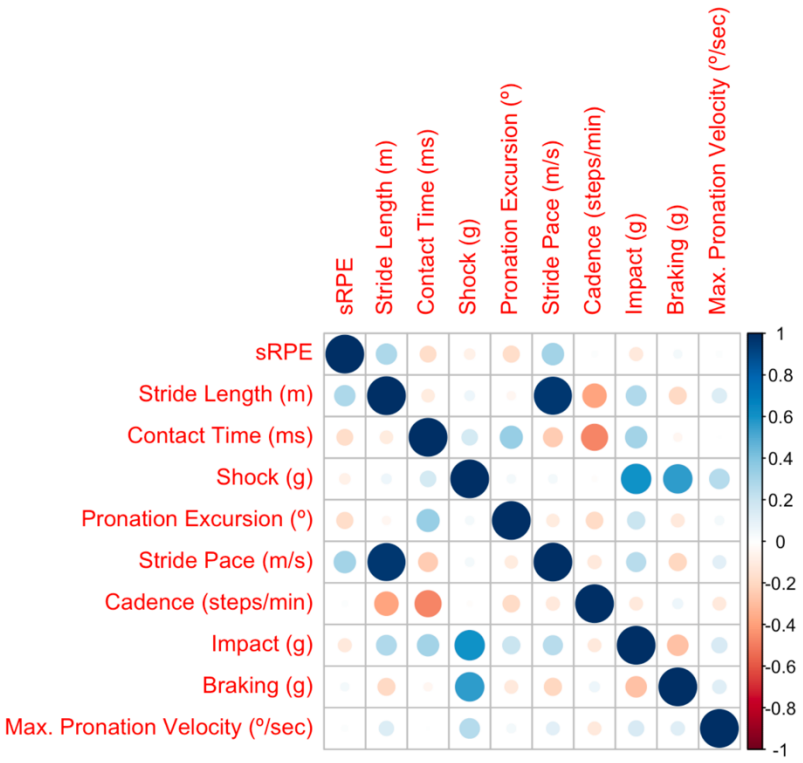
Caption: Male and female team average sensor-derived measures and weekly mileage are plotted across recorded runs throughout the season, with labeled long runs (LR) and recovery runs (RR) denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

Figure 3.2 Z-scores of mileage and sensor-derived measures for male and female cross-country runners across the competitive season.



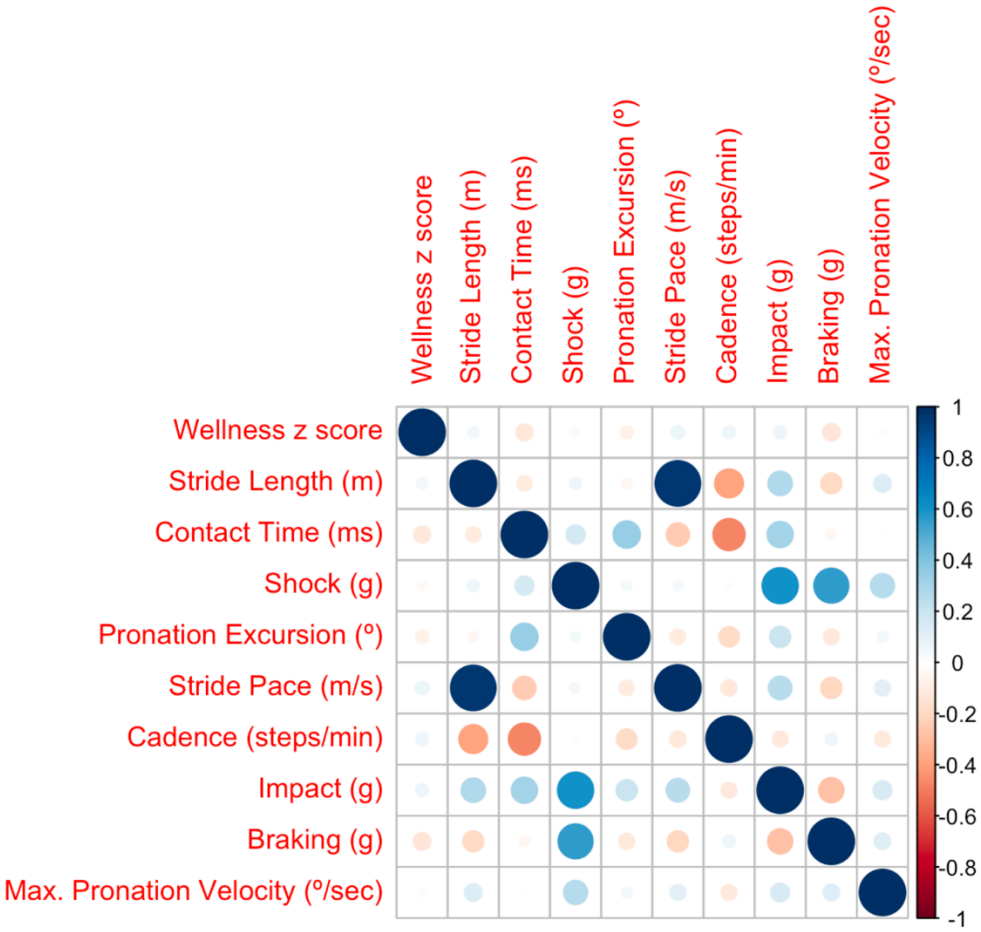
Caption: Male and female team z-scores of sensor-derived outcomes and weekly mileage are plotted across recorded runs throughout the season, with labeled long runs (LR) and recovery runs (RR) denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

Figure 3.3. Pearson's r correlations between sRPE and sensor-derived measures.



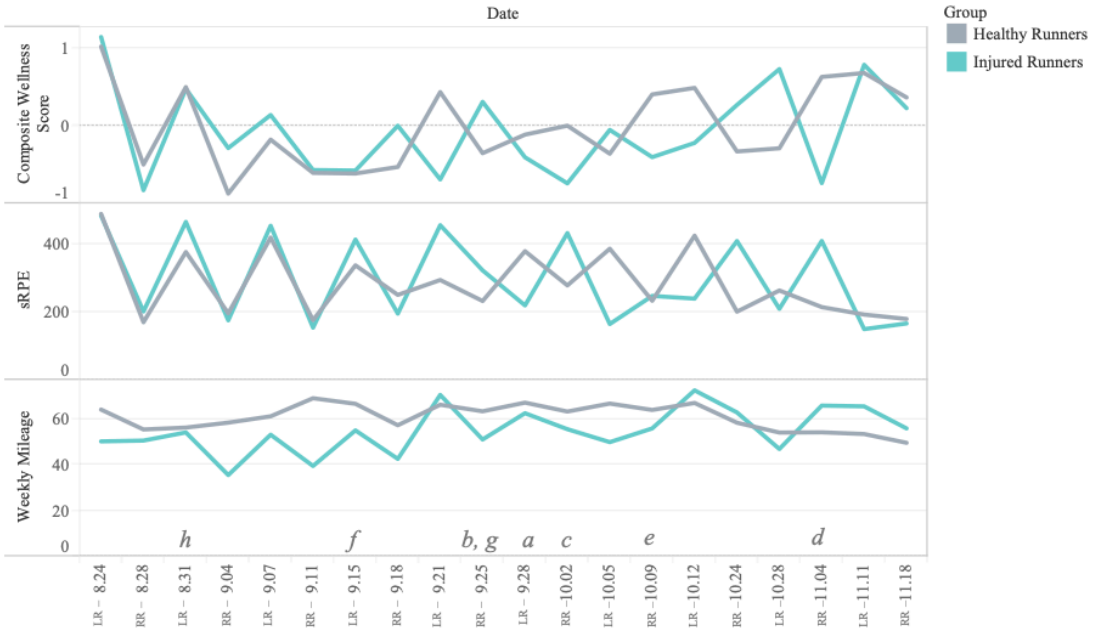
Caption: Figure representing results of the Pearson's r correlations between sensor-derived measures and sRPE, with larger and darker shaded circles representative of stronger correlations, and weaker and lighter shaded circles representative of weaker correlations. Shades of blue represent positive correlations, while shades of red represent negative correlations.
Abbreviations: sRPE, session rating of perceived exertion.

Figure 3.4. Pearson's r correlations between wellness z-scores and sensor-derived measures.



Caption: Figure representing results of the Pearson's r correlations between sensor-derived measures and wellness z-scores, with larger and darker shaded circles representative of stronger correlations, and weaker and lighter shaded circles representative of weaker correlations. Shades of blue represent positive correlations, while shades of red represent negative correlations.

Figure 3.5. Average wellness, sRPE, and mileage comparisons between healthy and injured cross-country across the competitive season.



Caption: Average injured runner cases plotted against average team outcomes for wellness, sRPE, and weekly mileage (7-day mileage leading up to recorded date). Long runs (LR) and recovery runs (RR) are denotated on the x-axis, and injury cases are denotated with the *a-h* symbols as follows: a – female sacral stress fracture; b – female femoral neck stress fracture; c – male sacral stress fracture; d – female 5th metatarsal stress fracture; e – male medial tibial stress syndrome; f – male plantar fasciitis; g – male hamstring strain; h – female hamstring strain.
Abbreviation: sRPE, session rating of perceived exertion; LR – long run; RR – recovery run.

APPENDIX A

The Problem

Running is one of the most popular recreational and competitive activities worldwide, and attracts 8.3 million United States road race participants annually according to a 2017 national survey.[1] Despite the substantial physical and psychological health benefits associated with running, epidemiological research reflects that approximately 40% of runners will go on to develop lower extremity musculoskeletal injuries.[2] Chronic lower extremity injuries comprise the majority of running-related injuries[2] which is problematic from a clinical standpoint as these pathologies require extensive time and resources, and have negative implications for patients' long-term health.

Lower limb injuries affect approximately 40% of the running community, with up to 66% diagnosed as chronic exercise-related lower leg pain (ERLLP; known in lay terms as "shin splints").[2,3] Exercise-related lower leg pain (ERLLP) is a broad injury category encompassing chronic pathologies to the lower limb, primarily in the anterior region of the lower limb spanning the region between the tibial plateau and the malleoli. According to the most up-to-date review of management of ERLLP, the only current rehabilitative recommendations supported in the literature are calf stretching and strengthening with low evidence.[4] These techniques have proven largely ineffective due to the persistently high rates of injury over the years. Instead, gait analyses have been used to identify movement patterns associated with injury occurrence and exacerbation to elucidate the etiology. Traditional gait analyses have utilized instrumented treadmills with motion capture equipment to quantify biomechanical deficits, and have identified increased peak and

average vertical ground reaction forces, decreased step rates, increased hip adduction, and decreased hip and shank muscle activity in ERLLP patients compared to healthy counterparts that are considered to contribute to patients' symptoms.[5] Although these findings are important to consider, there are inherent limitations with indoor gait analyses.

Indoor gait assessments are based on approximately 50 to 100 total steps in a constrained environment, and require extensive equipment, supervision time and technical expertise to conduct these analyses. As such, there is a substantial implementation barrier to clinical practice. There are also inherent differences between treadmill and over-ground outdoor running, such as changes in speed, terrain, incline, and environment that may influence biomechanics.[6–8] These limitations highlight the importance of moving beyond the confines of the laboratory setting to assess runners in natural training environments. RunScribe wearable sensors (RunScribe™, Half Moon Bay, CA, USA) are inexpensive, lightweight equipment designed to measure running biomechanics, and have the capacity to collect upwards of 15,000 steps per run in any training environments.[9] These devices have proven reliable against laboratory gold standard equipment and thus offer a valid means to collect injured runners' movement profiles during typical training.[10,11]

Although laboratory analyses suggest that runners with ERLLP primarily present with increased loading during landing gait phases and decreased step rates,[12,13] it is unknown if these alterations persist during outdoor running. Given that running training mainly occurs outdoors, there is a substantial need to quantify adaptations in runners with ERLLP compared to healthy runners in these environments. We have conducted a pilot descriptive study using the RunScribe sensors to evaluate running mechanics across multiple categories of runners during a typical week of training, and have a preliminary

dataset on 16 runners with ERLLP and 16 healthy matched counterparts. Primary analyses of variance analyses comparing all biomechanical outcomes collected across the week reflected that runners with ERLLP had comparable loading outcomes to healthy runners, which is contrary to current treadmill-based findings. Instead, runners with ERLLP had decrease step rates, increased foot contact time, and tended to land primarily on their heels as compared to the healthy cohort. Though this is a relatively small sample size and utilized traditional statistical approaches that may not fully elucidate the biomechanical relationships over time, this information provides a basis for larger pattern recognition and machine learning analyses to identify important features that may differentiate injured versus healthy runners. This additionally supports the notion that previously unrecognized biomechanical profiles emerge when looking at sustained, unsupervised running in natural settings as opposed to the limited information from indoor analyses.[6–8] Utilizing information from the RunScribe sensors will help to create a profile on running maladaptations in runners with ERLLP to guide impairment-based interventions.

We recently conducted a systematic review of gait-training for prevalent lower extremity injuries, and while there are multiple studies on gait-training in healthy populations with injury risk profiles based on previous laboratory findings, there is no information to date on gait-training in runners with ERLLP.[14] The interventions conducted on runners with injury risk have primarily focused on increasing step rates and decreasing loading with promising results.[15–17] However, it is unknown how these effects would transfer to an injured group for objective and subjective patient-reported outcomes. Further, the majority of interventions have used arbitrary cut-off values to dictate the gait-training programs (i.e. increase step rate by 10-15% or decrease loading by 20-50%) as there are

no prospective studies to date that have established risk profiles in the field among running cohorts. It would be beneficial to explicitly measure injured runners' biomechanics during typical running training to guide impairment-based interventions as opposed to a one-size-fits-all approach. Our pilot data suggest that the previously targeted biomechanics may also not be meaningful to outdoor running. A recent study supported this notion as researchers found that indoor gait-training did not transfer to outdoor movement patterns.[18]

Using objective measurements from the wearable sensors would help focus gait-training interventions to maximize runners' responses to interventions, and help guide clinicians on selecting interventions to include into clinical practice. We have the capacity to provide timely, sensor-driven feedback as the RunScribe™ sensors are able to pair with Garmin wristwatches to alert runners' when they may be falling into maladaptive running patterns. Through these capacities, we can now effect ecological changes in running patterns that would positively transfer to clinical practice as a realistic approach to injury management.

It is important to note that all work to date exploring biomechanical profiles for running-related injuries are either conducted cross-sectionally on a group of runners that are already injured or have a history of the injury,[12,19,20] or on many runners with prospective injury incidence data to identify risk factors from the singular baseline assessment.[5,21] Although these assessments add to our current knowledge of running-related injuries, it is not wholly possible to establish causality of running-related injuries as there are no true prospective studies assessing biomechanics over time leading up to injury. Monitoring studies have become increasingly popular in team-based sports, particularly in rugby and soccer, to establish injury risk using external loading metrics from

wearable sensors.[22–25] Further, previous studies have established the importance of combining internal wellness metrics in conjunction with biomechanical outcomes to better understand the cumulative load individuals experience that may contribute to injury risk.[25–28] Internal metrics are most commonly comprised of session ratings of perceived exertion, sleep quantity and quality, energy level, mood, stress, and soreness scales.[25–28] Although these outcomes have traditionally been measured in team settings, there is no work to date that has assessed internal and external loading metrics in relation to injury over time in runners over time. Therefore, utilizing wearable sensors prospectively among a running cohort would provide information on what biomechanical factors may exist in conjunction with wellness measures to establish injury risk profiles versus biomechanical adaptations following injury. The overarching research question for this dissertation was, how can we utilize wearable sensors for assessment, intervention, and prospective monitoring among runners in the presence of lower extremity injuries?

Experimental Hypotheses

Specific Aim I: To identify thresholds of biomechanical alterations in runners with ERLLP compared to healthy comparison groups during bouts of typical outdoor running to generate an impairment-based gait-training intervention.

Primary Hypothesis I: Based on our preliminary data, we anticipate contact time to be the defining feature of ERLLP patients compared to healthy cohorts during outdoor running.

Specific Aim II: To evaluate the effects of 4 weeks of field-based gait-training using real-time biomechanical feedback in conjunction with a home exercise plan in runners with ERLLP on spatiotemporal and kinetic outcomes compared to home exercise alone (control group).

Primary Hypothesis II: Runners with ERLLP who receive gait-training based on the identified impairments from Aim 1 along with standard of care home exercises will demonstrate decreased contact time, increased cadence, and improved patient-reported outcomes as compared to baseline measures and to the control group.

Specific Aim III: To prospectively monitor spatiotemporal, kinetic, and kinematic outcomes along with wellness outcomes in a cohort of Division-1 cross country athletes over competitive seasons.

Hypothesis III: Runs associated with lower wellness metrics will demonstrate increased contact time, stride length, loading, and pronation velocity outcomes compared to runs with higher wellness scores.

Assumptions

- Participants will be honest when answering all questions related to inclusion and exclusion criteria
- Participants will perform to the best of their ability during baseline and follow-up assessments
- Participants will run as normally as possible during all running assessments
- Participants will give their best effort during the home exercise rehabilitation programs, and during the in-field gait-training interventions (if allocated to the intervention group)
- If participants are in the intervention group, they will adhere to the faded feedback design
- Participants will remember to wear the sensors during all running sessions over the 4 weeks
- Participants will honestly maintain a running and exercise log over the 4-week period
- Participants will respond honestly to all questionnaires throughout the study period
- Measurement tools will accurately collect the data

Delimitations

- Participants were limited by our inclusion and exclusion criteria
- All participants were 18-45 years of age
- All participants were active runners, running at least 3 times per week for a total of at least 6 miles

- Participants were recruited from the university, local running clubs, and the university Division-1 cross-country program
- Participants were not currently seeking physical therapy or medical treatment
- Indoor gait assessments were completed as a standardized running speed, as well as a preferred running speed
- For Manuscript 3, we decided to only record two runs per week to get a representative sample of sustained runs as compared to track workouts, which would inherently lead to differences in biomechanical measures and athlete loading.
- Participants were encouraged to maintain running habits outside of the study intervention for Manuscript 2
- Habitual runs, without any restrictions on terrain and running types, were considered for Manuscript 1

Limitations

- We were unable to assess other underlying physiological factors that contribute to the overall athlete injury model across studies, including factors such as heart rate, nutrition, and other biomarkers.
- For Manuscript 1, this was a cross-sectional assessment of runners with ERLLP, and therefore we cannot determine from this study if increased and more variable contact time is associated with injury risk or injury exacerbation
- For Manuscript 1, recorded runs were all performed outdoors during runners' habitual training, thus limiting the amount of control we had over their running duration, pace, terrain, and other environmental factors.

- For Manuscripts 1 and 2, the majority of runners had bilateral symptoms, and therefore the findings may not necessarily be extrapolated to runners with unilateral symptomology. However, this is reflective of the most common patient presentation.
- For Manuscript 2, we were unable to assess longer term retention of study interventions beyond the 6-week timepoint.
- For Manuscript 2, all exercises were performed at home without direct supervision, hindering our understanding of patient form during activity, and required us to rely on patient-reported adherence to exercise.
- Due to COVID-related restrictions, the sample was limited to a subset of the intended patient sample size for Manuscript 2, and only one season of cross-country data could be included for Manuscript 3
- For Manuscript 3, we acknowledge that there are other biomechanical measures that can be considered in the context of running-related injury beyond the context of sensor-derived metrics

Significance of the Study

This project will help clinicians to identify what biomechanical alterations exist in an injured running cohort in the field, test the effectiveness of an impairment-based gait-training intervention in the field on biomechanical and patient-reported outcomes, and highlight what biomechanical outcomes change in response to patient wellness score fluctuations over time. There are currently significant clinical barriers to evaluating gait and implementing a structured gait assessment for runners in the field, or in-field gait-training protocols for injured runners. As there is no consensus on best gait-training techniques, clinicians often implement a non-specific approach, which may not sufficiently address runners' impairments. This is frustrating for all parties as patient progress often stagnates and interventional efforts may not maximize patients' subjective and objective responses to treatment. Recent articles have highlighted the need to measure biomechanical parameters outside of the laboratory to have a better understanding of patient biomechanics is realistic training scenarios to drive assessment, intervention, and ultimately positively affect patient outcomes.[9] Evaluating runners using the commercially-available RunScribe wearable sensors to guide assessment, interventions, and prospective monitoring would allow for an ecological approach to addressing these questions, and would provide concrete evidence to clinicians on best practices for maximal patient benefit.

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APPENDIX B

Literature Review

The purpose of this literature review is to: I. Review the injury epidemiology, etiology, and characteristics of exercise-related lower leg pain, II. Review current assessment and management techniques for exercise-related lower leg pain, III. Review current approaches to athlete monitoring accounting for wellness and biomechanical factors.

Section I: Exercise-Related Lower Leg Pain

Epidemiology

Lower extremity pathologies are extremely prevalent among the running community, regardless of participation level. Epidemiological research reflects that approximately 53% of running-related injuries among collegiate NCAA cross country runners' injuries are localized to the lower limb,[1] while the rate is slightly lower at 42% for recreational runners.[2] Between 49% and 75% of lower limb injuries have been reported as recurrent,[3,4] given that a primary risk factor for incurring lower extremity running-related injuries is injury history.[5] As such, these pathologies present a substantial barrier to running participation for patients due to pain experienced during or immediately following activity. Lower limb injuries are problematic from a clinical health care perspective as they require extensive time and resources, and have negative implications for patients' long-term health.[6]

Injury Description

Despite the high rates of lower limb running-related injuries, there is currently no consensus on injury terminology. However, recent research has advocated using "exercise-related lower leg pain" (ERLLP) as the preferred nomenclature.[7,8] ERLLP is

described as pain in the region spanning between the tibial plateau and the malleoli, experienced during or immediately following running that occurs in the anterior or medial aspect of the leg.[7] As such, ERLLP broadly encompasses a variety of injuries, including medial tibial stress syndrome, exertional shin pain, tibial stress reactions, and, in lay terms, shin splints.[9] There are multiple static and dynamic structures that have been cited as potential contributors to ERLLP, including the tibia and periosteum, tibialis anterior, tibialis posterior, soleus, and flexor digitorum longus muscles.[10–14] Symptomology typically includes cramping, muscle weakness, tenderness, tightness, or generalized pain of any of the aforementioned anatomical structures of the lower limb.[7,8,15] In order to adequately capture ERLLP diagnoses, patients are required to have experienced pain for at least one week, with intensity levels between 20 and 80 mm on the 100-mm Visual Analog Scale (VAS).[16,17] Researchers have also developed a scale specific to ERLLP to determine symptom severity, named the Exercise Induced Leg Pain Questionnaire – British Version (EILP; Figure 1).[7] This scale asks patients to rate how much difficulty they have completing a variety of functional activities due to the pain they experience in their lower limbs, with a cut-off score of <90% used to rule-in the condition.[7]

Figure 1. Exercise-Induced Leg Pain Questionnaire – British Version[7]

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to Perform	NA
When beginning to run						
Running after about 10 minutes						
Running after about 15 minutes						
Running after 30 minutes or longer						
Jumping						
Landing						
Starting and stopping quickly						
Sideward cutting movements						
Low-impact activities						
Ability to participate in your desired sport as long as you like						

Along with patient-reported outcome measures, objective clinical examinations are used to confirm ERLLP diagnoses.[18] Common tests include palpation of the tibia and tibialis anterior, and manual muscle testing of the tibialis anterior and posterior to rule in the pathology.[8,18,19] Positive tests would elicit pain along the medial border of tibia, or along the soft tissue structures during palpation or strength testing. Clinical examinations are also used to rule out other pathologies, including palpation over the Achilles tendon, popliteal fossa, or the lateral or superficial posterior compartment of the lower leg.[7,20] These tests should not elicit pain in an ERLLP population as these areas fall outside the pathoanatomical region of interest, and instead are indicative of Achilles tendinitis, neurovascular conditions, and lateral compartment syndrome respectively. Additionally, pain intensity exceeding 80 mm on the VAS scale and localized to one specific region on the tibia is more indicative of a tibial fracture, and is typically referred for x-ray or magnetic resonance imaging (MRI).[19] X-ray imaging should only be used to rule out fractures as ERLLP patients have previously been found to have unremarkable radiographs; however, bone scans, ultrasound imaging, and MRI may reveal mild abnormalities in ERLLP patients as some cases present with inflammation around the tibial periosteum.[11,21,22]

Etiology & Injury Characteristics

Given the ambiguity of the pathology, there is no consensus on the direct injury etiology for developing ERLLP. Instead, ERLLP has largely been explored in the running-related injury framework developed by Bertelsen and colleagues in 2017.[23] This framework acknowledges personal, training, and running attributes as key components

affecting tissue load capacity, and ultimately the development of a running-related injury.[23]

Body mass, sex, anthropometrics, sleep, stress, injury history, mood and affect are all included under the umbrella of personal attributes that contribute to running-related injury. A recent systematic review with meta-analysis conducted a pooled assessment on twenty-two articles assessing personal risk factors for developing ERLLP spanning modifiable and non-modifiable factors.[24] There was strong evidence to suggest that female sex, increased body mass, previous running injury, greater navicular drop, and increased hip external rotation range of motion were all significant risk factors for ERLLP development.[24] However, all other static alignment and passive motion measures had mixed results and therefore were not found to be significantly associated with ERLLP.[25–30] It is important to note that most studies that did not yield consistent results and were heterogenous in terms of assessment techniques. Therefore, it is not possible to concretely conclude that other anthropometric measures do not contribute to the pathology. Further, it has been postulated that sub-categorizations of ERLLP patients may exist.[19,31] Pooling patient outcomes to make general claims about risk factors may not be the most appropriate approach to classifying ERLLP patients, and instead should be conducted on a patient-by-patient basis.

There are generally two schools of thought around subgroupings of contributing anthropometric factors associated with ERLLP. The first hypothesis is that the musculotendinous structures attaching to the anteromedial and posteromedial tibia, including the tibialis anterior and posterior, soleus, and flexor digitorum longus muscles, are excessively tight and create traction on the periosteum, eliciting pain.[19,25,32]

Researchers have also postulated that hypomobility may lead to excessive loading on the static lower extremity structures leading to injury progression.[33,34] Several studies have found ERLLP patients have decreased ankle dorsiflexion range of motion supporting this theory,[28] and posterior chain stretching is often recommended in the literature.[15,34] Foot posture assessments have also found that highly supinated foot posture indices are related to ERLLP, and that patients may present with higher standing tibial varus compared to healthy runners.[35]

The contrary hypothesis to ERLLP development as a subgroup is that patients have increased laxity and hypermobility, hindering shock absorption from dynamic stabilizing structures and lending to excessive loading on the lower limb.[36] Previous research has identified increased passive frontal plane ankle range of motion among ERLLP patients to support this idea.[31] Similarly, excessive foot pronation has been noted among ERLLP populations,[26,28,37] especially in military populations.[38,39]

Varied findings from anthropometric assessments support the continued study of risk factors contributing to ERLLP development and progression, and highlight the need to assess individuals on a case-by-case basis. Further, it is important to note that to date there are no studies that have investigated personal intrinsic health and wellness metrics, such as mood and sleep quality, as they contribute to ERLLP that hinders our understanding of the pathology. Continued investigations of personal factors for this injury group are warranted moving forward.

Section II: Current Assessment and Management Techniques for Exercise-Related Lower Leg Pain

Clinical Assessment & Management Approaches

There is currently limited information on contributing factors to ERLLP, which has unfortunately led to vague clinical management guidelines. According to the most up-to-date review of best management approaches for lower limb pathologies, there is weak evidence to support incorporating calf stretching and strengthening to reduce symptomology as some patients may demonstrate tight and weak posterior chain musculature.[15,40] Current clinical trials performing these aforementioned interventions have been focused in small sample size and had a relatively high risk of bias.[15,34,41,42] Researchers have also elucidated increased hip internal rotation,[43] and hip abduction strength weakness in runners who currently have ERLLP or runners who went on to develop ERLLP;[44,45] however, there are no studies to date that have assessed the effectiveness of proximal muscle strengthening in this population. Further, previous management approaches have proven largely ineffective given the persistently high injury rates.[1–4] Researchers have instead turned to biomechanical assessments of contributing factors to injury development, particularly as pain occurs during or immediately following bouts of running.[7]

Biomechanical Assessment & Management Approaches

Gait analyses have been increasingly incorporated into patient assessments to identify movement patterns associated with injury occurrence and exacerbation to elucidate the etiology. The current gold standard in gait analysis is through the use of instrumented treadmills with force plates to obtain loading outcomes, motion capture equipment to quantify biomechanical movement patterns, and with surface electromyography to measure muscle activation properties that are associated with injury. There is substantial research to support that runners with ERLLP demonstrate aberrant

movement patterns using these various assessment techniques. Specifically, researchers have found kinematic alterations at the foot and ankle complex with increased rearfoot eversion throughout the stance phases of gait,[35,46] greater peak eversion,[47,48] and greater overall time in the gait cycle spent in rearfoot eversion compared to healthy runners.[35] Alterations have also been noted further up the kinetic chain with increased peak hip adduction angles compared to healthy counterparts.[47–49] Researchers have also identified kinematic alterations in other dynamic loading tasks, representative of demands imposed on the lower limb during weight acceptance in running. For example, runners who went on to develop ERLLP demonstrated increased transverse plane hip and trunk motion during a single-limb drop jumping task compared to runners who remained injury-free.[50]

In terms of kinetic adaptations associated with ERLLP, there is a considerable body of research supporting that instantaneous, peak, and average vertical ground reaction forces are increased in patients that currently have ERLLP or those who go on to develop ERLLP compared to uninjured runners.[48,51–56] These findings are often accompanied with increased rates of rearfoot striking as opposed to midfoot and forefoot strike patterns, as there is a distinct loading impulse associated with landing on the rearfoot compared to other landing patterns.[51,52]

Spatiotemporal gait alterations, particularly decreased step rate and increased stride length, have been identified in ERLLP runners compared to uninjured comparison groups in past indoor gait assessments.[49,57–60] Previous research has suggested that when step rates, or cadence, is decreased, runners automatically compensate by over-striding to achieve the same distance per unit of time as a runner with increased step rate.[58] Decreased step rate and increased stride length have similarly been linked to increased

overall load imposed on the lower extremity,[58] exacerbating the symptomology in this injured running population.

There has been one previous study investigating muscle activation during running in ERLLP patients that has demonstrated increased shank muscle activation variability compared to healthy counterparts, particularly in the soleus and tibialis anterior muscles.[61] However, less is known about muscle activation amplitudes throughout the kinetic chain. It is plausible that gluteus medius muscle activity would be dampened during running due to noted muscle weakness and increased frontal and transverse plane motion at the hip during running in this population. However, a study exploring the effects of a 6-week gluteal muscle strengthening program found that although runners' hip strength increased, there were no significant changes in hip kinematics during running.[62] Hip muscle activity during running remains largely unexplored in this injured runner population.

Given the substantive evidence of altered running biomechanics in ERLLP patients, gait-training options have been frequently explored in the literature, albeit almost exclusively in uninjured or risk factor populations.[51,60,63–76] A recent systematic review and meta-analysis evaluated gait-training interventions in ERLLP, and found that among these studies, the majority incorporated multimodal gait-training, with various combinations of loading, foot strike, cadence, surface, incline, footwear, and speed manipulations.[63,64,66,68,71,73,77] The remaining studies largely focused on decreasing loading,[51,67,76,78] altering speeds,[70,79,80] increasing cadence,[60,69,72] adapting forefoot or midfoot foot strike patterns,[65] or altering incline.[74] Wearable devices, such as accelerometers, were the most common devices used to facilitate these feedback

mechanisms, and the majority remain confined within the laboratory context.[51,60,64,66,67,70,78] However one of the interventions was administered in a field-based setting for risk factor populations.[60] Metronomes[65,68,69,72] and music applications[69,76] were used for maintaining an increased cadence typically 10% above preferred step rates. Plantar pressure mats[73,80] and instrumented treadmills with video screens for feedback[63,65] were used to encourage decreased loading. Outcomes ranged from immediate effects to up to 6 weeks in duration. The vast majority of interventions used arbitrary cut-off values to dictate the gait-training programs (i.e. increase step rate to 180 steps per minute).

Overall, the meta-analysis reflected that gait-training interventions for patients with ERLLP have been successful for reducing instantaneous loading rate, average loading rate, and peak tibial accelerations.[81] Based on individual techniques, foot strike manipulations and immediate to short-term effects of loading and tibial acceleration feedback were most successful in reducing instantaneous and average loading rates as these effects favored positive outcomes without crossing the line of no effect. Only feedback for tibial acceleration fully supported decreased peak tibial acceleration, while the remaining interventions had mixed outcomes.

In terms of individual approaches to gait-training, feedback for decreasing speed and loading, and increasing cadence had favorable patient outcomes. Increasing cadence had positive effects on hip adduction kinematics (decreases ranging from 1.8 to 2.9 degrees) and vertical loading rates (decreases ranging from 1.8 to 18.1 BW/s), suggesting a carry-over effect of this particular gait-training strategy.[60,69] It is important to reiterate that the majority of studies were multimodal in nature, thus it is difficult to conclude that a single technique would be most beneficial. However, foot strike and loading were the

most commonly-reported interventions with consistently positive outcomes in this population.

Current Limitations to Biomechanical Assessments and Interventions

Throughout all interventions within the ERLLP literature, only uninjured participants have been included thus far. It is not possible to conclude if the same outcomes would uphold in an ERLLP population, nor do we have evidence to suggest that these approaches would improve pain and functional outcomes. Further, all of our current understanding of biomechanical outcomes in this population are limited to treadmill-based assessments. While recent meta-analyses found that there are many parallels between treadmill running and over-ground running,[82,83] there still remain some lower extremity kinematic differences in running styles. For instance, it has been determined that individuals have increased ankle dorsiflexion during treadmill running.[83] Instrumented treadmill analyses also require extensive, costly equipment that require resources in the clinic, or outsourcing to specialized facilities that are not plausible in most clinical settings. Further, current assessments can only reasonably measure 50 to 100 total steps in an artificial setting. Environmental considerations such as instantaneous changes in speed, inclination, and running surface cannot be effectively mimicked in the laboratory setting.[84–86] With the current state of gait assessments, we are missing a key clinical piece by not meeting runners' in their natural running environment.

It is also problematic that the majority of gait-training intervention studies are housed within laboratory settings, and based off of previous laboratory findings. Instead, it would be beneficial to use injured runners' biomechanical outcomes during typical running training to guide impairment-based interventions as opposed to a one-size-fits-all

approach. A recent study supported this notion as researchers found that indoor gait-training did not transfer to outdoor movement patterns.[87] Thus, using objective measurements would help focus gait-training interventions to maximize runners' responses to interventions, and help guide clinicians on selecting interventions to include into clinical practice.

Advances in Biomechanical Analyses and Interventions

The advent of wearable technology has begun to revolutionize gait analysis and gait-training intervention capabilities, as there is now the opportunity to monitor multiple gait parameters during in-field running scenarios.[88,89] Wearable sensors are able to detect multiple gait-specific parameters simultaneously with light-weight technology including accelerometers, gyroscopes, and magnetometers that overcome the cumbersome and expensive aspects of traditional gait laboratory technology.[90] Wearable devices allow for the patient to be monitored in more natural training environments, and can collect data and provide feedback on hundreds of thousands of steps whereas most laboratory procedures target far fewer steps (i.e. collecting several hundred steps on a treadmill versus the entirety of a 42 kilometer run).[91] Although previous ERLLP intervention studies implemented accelerometers and other sensors into the protocols to monitor and provide feedback on cadence and vertical loading, there are many more parameters that can be measured but have not yet been investigated in the context of ERLLP.[92] There are no studies that have evaluated gait-training effects in the field in an injured population. Moving forward, using objective measurements from wearable sensors in this injured population would help focus gait-training interventions to maximize runners' responses

to interventions, and help guide clinicians on selecting interventions to include into clinical practice.[93]

Section III: Current Approaches to Athlete Monitoring – Wellness and Biomechanical Factors

Revisiting the running-related injury model from Bertelsen and colleagues in 2017,[23] there are both external and internal factors that feed into the overall load imposed on the running athlete. External measures in this context are referring to both training attributes as well as the runners' biomechanics. Training attributes include the runner's past experience, current weekly mileage, running intensity, and running duration. Training factors in the running athlete monitoring realm are primarily controlled by coaching and training staff, and therefore should be measured by sports scientists and athletic trainers, but cannot always be directly manipulated. Running attributes encompass kinematic, kinetic, and spatiotemporal components of running patterns, which are modifiable as previously discussed. Internal training loads encompass personal attributes of the running athlete, including body mass, anthropometrics, sleep, stress, injury history, mood and attitude, and many other physiological functions.

Athlete Monitoring – External Factors

Wearable sensors allow clinicians and researchers to collect exponentially more biomechanical, running-related data in the field over time.[89] Wearable technology specific to measuring running biomechanics has previously been validated against gold standard laboratory equipment,[92,94] and have begun to be used in running assessments and interventions.[60,88,90,91,95–102] In particular, running mechanics during higher intensity speed workouts and during racing scenarios have been assessed in the field to determine

how runners adapt to these increased demands that cannot reasonably be simulated in a laboratory setting.[91,96,99] Wearable sensors have also been used in the field to assess different influences on running biomechanics, such as running surface,[96] fatigue,[98,102] ankle bracing,[100] and weather.[101] As stated previously, running wearable sensors have also been used to administer running gait-training interventions with promising results.[60,89,90]

Currently, there are very limited studies that have looked at prospective monitoring of running-related outcomes using wearable sensors.[60,99,103] Given the perpetually high risk of running-related injuries in runners, particularly at the collegiate level,[1] evaluating running biomechanics over time to elucidate in-field risk factors is warranted. Athlete monitoring in relation to injury risk is not a novel concept, particularly in team sport settings, such as rugby, Australian rules football, and other field-based activities.[104–110] There is only one study to date that has prospectively monitored running athletes using accelerometers and injury risk, and this was performed in track athletes which have different demands than cross-country runners.[103] There remains a need to prospectively monitor cross-country athletes over competitive seasons in order to determine risk factors for recalcitrant lower extremity injuries in this population.

Athlete Monitoring – Internal Wellness Factors

There is a myriad of studies that have implemented internal wellness assessments to track physiological responses to athletic demands, primarily in regards to training and physical performance in team sport settings. These assessments have included measures including but not limited to heart rate variability,[111] biomarkers,[112] ratings of perceived exertion (RPE) to bouts of exercise,[113–115] sleep quality and quantity,[116,117] mood,[113,115]

stress and soreness,[113,115] and recovery.[118,119] Measuring outcomes such as RPE, sleep, mood, stress, and soreness are more clinically feasible to implement in the field using simple surveys delivered in the field in either paper or electronic formats,[113,114] and can be used to calculate a composite score of wellness to relate to external demands.[113,115,120] Additionally, session-RPE ([duration of activity]*RPE) has been validated against gold standard heart rate and blood lactate level testing, eliminating the need for more extensive internal measurement testing.[121]

While internal loading metrics are helpful to sports scientists and coaches to gauge sport performance, these outcomes may also be beneficial to track from a clinical perspective to contextualize wellness measures to injury risk and recovery. Gastin in 2013 advocated for the use of 5-point rating scales to efficiently and effectively capture internal loading measurements in team sport settings in relation to injury outcomes.[115] Despite the ease of application and validation of these outcome tools in team sport settings, there have been no studies to date that have explored these outcomes among collegiate cross-country athletes. Researchers have recently developed and validated an outcome measurement tool specific to tracking recovery outcomes for collegiate cross-country settings.[118,119] Implementation of prospective internal loading assessments in relationship to injury and recovery are warranted in this individualized athletic setting to best inform clinical decision-making and injury reduction.[106]

Approaches to Analyzing Internal and External Load

Traditional, inferential statistical analyses may not be the most appropriate way to assess internal and external loading datasets as group-level comparisons cannot adequately capture the intricacies of internal and external load metrics over time, since

these are time-series data. Further, fluctuations within larger scale time-series datasets become washed out with broader descriptive statistics. Instead, a recent consensus statement on implementing and evaluating athlete training loads provided multiple alternative appropriate approaches to assessing these types of data.[106]

One of the major approaches to capturing load changes over time is evaluating acute:chronic-workload ratios, which takes rolling averages to compare training loads completed in a smaller period of time (i.e. week-to-week fluctuations).[105,106,122,123] This approach has been helpful for elucidating injury risk in a variety of sport settings, as researchers can assess peaks and valleys in external training demands in conjunction with internal loading outcomes.[104,105,108,122–125] This model has also been adjusted to control for time effects by taking exponentially weighted moving averages, where more recent bouts of training are weighted more heavily in regards to load.[126] Finally, z-scores have been used to determine how session-based scores compared to season or quarter outcomes while accounting for fluctuations in the dataset.[113,115] This analytic approach helps account for more of the variability over time, and may be useful in endurance sport settings where training programs are fairly consistent, and therefore determine how athletes training response varies over the course of a season in regard to injury risk or development.

Non-linear, complex regression analyses, machine learning assessments, and hierarchical models have been recommended to detect group and individual changes over time that can account for both internal and external load changes to predict injury outcomes.[106,124,127] While there is no single recommended approach to assess these time-

series data, these examples among many others of non-linear, adaptive approaches should be used to account for the complexities of athlete monitoring datasets.

Finally, it is important to consider smaller scale fluctuations within single timepoints in long, time-series datasets, particularly when considering running gait data.[128,129] As steps taken during a run cannot be treated as fully independent observations, it is important to consider how variable each step is over running bouts to determine if there is very high or very low step-by-step variability. From a dynamical systems standpoint, these two extremes have been postulated to relate to injury, however there are no studies to date that have explored these outcomes in regard to running outcomes. One such approach that has been used is approximate entropy, which examines how predictable subsequent steps are from one another over time (i.e. score approaching zero indicates highest predictability).[128–131] This assessment approach has been for other physiological assessments, such as heart rate variability,[128] and fatigue in quadriceps muscles;[130,131] this assessment type can similarly be leveraged to detect changes over the course of runs in a season in relation to injury risk.

Combining External and Internal Loading Factors in Running Assessments

Previous studies have combined external and internal factor load outcomes to assess running training and physical performance in a clinical context.[132,133] There is also a body of literature exploring how external loading factors affect running economy, which also relates to internal loading outcomes in more of the performance context.[134] However, it remains unknown how sensor-derived external metrics relate to wellness measures in runners, and importantly, it is unknown how the combination of these factors relate to injury over time in running athletes.[132] The ability to interpret these factors in

tandem would help guide clinical practice to identify injury risk, and potentially inform clinical decision-making to reduce running-related injury rates. This approach to injury monitoring is currently being conducted in team-based sports, including rugby,[105] cricket,[123] Australian rules football,[108,122] and soccer,[125] among others. Given the unique demands of competitive running training and the perpetually high lower extremity injury risks, this line of research should be carried forward in running contexts.

APPENDIX C

Additional Methods

Table C1 – Summary of Protocol Procedures

1. Institutional Review Board Documents
    a. Manuscript 1
    b. Manuscript 2
    c. Manuscript 3
2. Questionnaires
    a. Running and Health History Questionnaire
    b. Exercise-Induced Leg Pain Questionnaire – British Version
    c. Lower Extremity Functional Scale
    d. 100-mm Visual Analog Pain Scale
    e. Godin Leisure-Time Exercise Questionnaire
    f. Global Rating of Change Score
    g. University of Wisconsin Running Injury and Recovery Index
    h. Rating of Perceived Exertion 10-point scale
    i. Custom Running and Wellness Questionnaire (adapted from Gastin et al. 2013)
        i. Current distance in miles logged this week
        ii. Hours of sleep last night
        iii. Sleep quality (1-5)
        iv. Energy level (1-5)
        v. Stress level (1-5)
        vi. Mood (1-5)
        vii. Soreness level (1-5) and location (20 options)
        viii. Soreness progressing to pain (Y/N)
3. Laboratory Measures
    a. Instrumentation & Procedures
    b. Data Collection Sheet
4. Functional Movement Assessments
    a. Instrumentation & Procedures
        i. Star Excursion Balance Test
        ii. Single Leg Squat
        iii. Lateral Step-Down
        iv. Gait Assessment
    b. Assessment Criteria Sheet
5. Laboratory Gait Assessments
    a. Instrumentation & Procedures
    b. Data Collection Sheet
6. RunScribe™ Assessments
    a. Set-up, Sensor Designations, and Calibration
    b. Run Downloads
    c. Accessing Data from Dashboard

    d. Instruction Sheet for Patients
7. Garmin™ Feedback
    a. Garmin Set-up (Instruction Manual)
    b. Feedback Set-up
8. Home-Exercise Programs
    a. Links to Video Demonstrations
    b. Criteria-based exercise prescriptions
    c. Progression Table
9. Gait-Training Schedule
    a. Volume-based feedback design
    b. Weekly check-ins for compliance

Table C2a – Institutional Review Board Documents – Manuscript 1

RESEARCH APPLICATION

Investigators' Experience

Dr. Jay Hertel, PhD, ATC
Dr. Hertel is a certified athletic trainer and is the director of graduate programs in Athletic Training & Sports Medicine and co-director of the Exercise & Sports Injury Lab at the University of Virginia. He has been the primary investigator for numerous studies through the University of Virginia's IRB-HSR, with primary research interests in lateral ankle instability, and additional interests in lower extremity biomechanics during functional tasks.

Study Coordinator I – Alexandra DeJong, MEd, ATC
Ms. DeJong is a certified athletic trainer and graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Ms. DeJong's research focus is in hip muscle function as it relates to lower extremity biomechanics during gait. Ms. DeJong has participated in a previous descriptive laboratory study while completing thesis requirements at the University of Virginia.

Study Coordinator II – Rachel Koldenhoven, Med, ATC
Mrs. Rolfe is a certified athletic trainer and graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Mrs. Rolfe's research focus is in gait mechanics related to lateral ankle instability. She has conducted and participated in multiple studies while completing thesis and doctoral requirements at the University of Virginia.

Sub-Investigator – Amy Virostek, ATC
Ms. Virostek is a certified athletic trainer and graduate assistant in the Masters program in Kinesiology – Athletic Training at the University of Virginia. Ms. Virostek's research interest is in gait mechanics using wearable senesors in runners, and is under the direct advisement of Dr. Hertel.

Sub-Investigator – Revay Corbett, MS, ATC, PES
Ms. Corbett is a certified athletic trainer and graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Ms. Corbett's primary research interests are in lateral ankle instability and subjective patient outcomes. She has participated in multiple studies while completing her doctoral requirements at the University of Virginia.

INSTRUCTIONS: DO NOT delete the Investigator agreement and signature section below even if signatures will be obtained through Clinical Research Connect.
These sections will be needed in the future if there is a change in Principal Investigator.

Investigator Agreement

Will the Investigator Agreement and Signatures be obtained in Clinical Research Connect? No

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The protocol will abide by the ethical standards of The Belmont Report
5. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
6. That no personnel will have access to subjects in this protocol or their information until they have completed the human subject research protection on-line training through CITI and the IRB-HSR has been notified.
7. That all personnel working on this protocol will follow all Policies and Procedures of:
   - the UVA Human Research Protection Program (HRPP SOPS)
   - the IRB-HSR http://www.virginia.edu/vprgs/irb/
   - the School of Medicine Clinical Trials Office: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm.
   - and any additional UVA requirements for conducting research.
8. I will ensure that all those personnel delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training, experience or credentialing to undertake those tasks.
9. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
10. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
11. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
12. That all subjects will give informed consent unless the requirement has been specifically waived by the IRB.

13. That unless written consent has been waived by the IRB all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
14. They will establish and maintain an open line of communication with research subjects within their responsibility.
15. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
16. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
17. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
18. That any serious deviation from the protocol will be reported promptly to the Board in writing.
19. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
20. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
21. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
22. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI leaves UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
23. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
24. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept according to UVA Records Management policies.
25. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.
26. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

<u>IF THE IRB-HSR WILL BE THE IRB OF RECORD FOR MULTIPLE SITES IN A MULTISITE TRIAL, THE UVA PI AGREES TO CARRY OUT THE FOLLOWING RESPONSIBILITIES:</u>

2. Ensure all UVa personnel designated as Conflict of Interest Investigators complete Reviewing IRB's financial interest disclosure requirements unless the UVa personnel will adhere to the UVa conflict of interest policies that are compliant with DHHS requirements.
3. Promptly provide the Principal Investigator at each site with:
    a. Current approved protocol and consent documents;
    b. Approved modifications, amendments or changes to research protocols; and
    c. Approval of continuing reviews and reviews of unanticipated problems;
4. Notify the Principal Investigator at each site of standards and guidelines for reporting any post approval events such as adverse events, subject injuries, unanticipated problems, and protocol violations. Collect reports from Principal Investigator at each site of any unanticipated problems, deviations, suspensions and terminations, non-compliance, subject complaints, and submit such reports to Reviewing IRB per reporting requirements.
5. Notify the Principal Investigator at each site promptly of any unanticipated problems involving risks to subjects or others as determined by the Reviewing IRB.
6. Collect required information from the Principal Investigator at each site necessary for completing continuing review submissions.
7. Notify the Principal Investigator at each site promptly about any lapses of approval. Forward to the IRB of Record any request from the Principal Investigator of a site for continuation of a specific research subject on a protocol during a lapsed period of approval.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

INSTRUCTIONS:
The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

Department Chair

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

- To work with the investigator and with the board as needed, to maintain compliance with this agreement.
- That the Principal Investigator is qualified to perform this study.
- That the protocol is scientifically relevant and sound.
- He/she is not the Principal Investigator or a sub investigator on this protocol.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

INSTRUCTIONS:
The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

Brief Summary/Abstract

There are two primary purposes of this study. The first aim is to identify differences in running gait biomechanics (impact g's, baking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors across one week of routine training in runners with exercise related lower leg pain (ERLLP) compared to healthy runners. Our hypothesis is that runners with ERLLP will have higher impact g's, faster pronation velocity, and longer contact time than healthy runners. The other primary aim is to identify differences in running gait biomechanics using wearable sensors during one week of participants' routine runs between groups of novice young adult runners, competitive young adult runners, ROTC cadet runners, novice middle-aged adult runners, and competitive middle-aged adult runners. Our hypothesis is that novice runners in both age groups will display biomechanical patterns that are associated with increased risk of running-related injury (higher impact g's, faster pronation velocity, longer contact time) than competitive runners.

The secondary purpose of this study is to identify novel data analysis schemes in an effort to maximize the use of the large volume of biomechanical data to be collected. Analysis approaches will include, but not be limited to, principal components analysis, machine learning, and pattern recognition. Our hypothesis is that advanced data analytics approaches will reveal group differences, the same as those hypothesized in the primary aims, that traditional parametric analyses do not.

Research Involving Students and Employees as Subjects

1. **Explain which study procedure the employees or students will participate in.** (i.e. all procedures, lab controls, MRI dry run)?

Employees or students may participate in this study based on the specific inclusion criteria, and as such would participate in all procedures.

2. **Provide justification for recruitment of the employee/student in this research proposal**:

Student participants will be recruited from the UVA Lifetime Physical Activity classes that focus on running to attain a sample of novice young adult runners, from UVA's varsity cross-country and track teams to attain a sample of competitive young adult runners, and from UVA's ROTC cadets to attain a sample of military-related runners. Collecting from these two groups will help us to achieve representative samples of our target populations. Employees may qualify as middle age novice or competitive runners that will be recruited though Men's and Women's 4-Miler Training Programs and flyers and advertisements around UVA grounds and the Charlottesville community. Employees will not specifically be recruited, but may qualify in these running categories for participation.

3. **Does the Principal Investigator of this study directly supervise/evaluate the Employee/Student within the work or educational setting?** E*mployees and students assigned to a particular investigator or laboratory should not be directly recruited for participation in any study conducted by that investigator or laboratory, although such employees and students may, on their own, volunteer to participate.*

The Principal Investigator will not be in the position of directly supervising or evaluating the participants in this study. All participation by UVA students or employees will be strictly voluntary.

4. **Explain what provisions are implemented to mitigate the risks involved in including employees/students as subjects in the study.**

Participation in this study is voluntary, and informed consent will be obtained from all participants by an individual who is not in a position of power over the subjects. Salary and course grades will not reflect participation in this study. All participants will be compensated equally for participation in this study.

5. **Describe how students and employees are recruited for this study. (e.g.- verbal scripts, flyers, listservs, and/or web-based systems for student subject pools)**

Novice young adult runners will be recruited from UVA Lifetime Physical Activity classes that focus on running. A member of the study team will attend a session of these classes, explain the study methods, and answer any questions that may arise.

Competitive young adult runners will be recruited from the UVA varsity cross-country and track teams. A member of the study team will attend a practice session for these teams, explain the study methods, and answer any questions that may arise.

ROTC runners will be recruited from the UVA's ROTC program. A member of the study team will attend a training session for the ROTC cadets, explain the study methods, and answer any questions that may arise.

Novice middle aged adult runners will be recruited from the Men's and Women's 4-Miler Training Programs. A member of the study team will attend a training session for each program, explain the study methods, and answer any questions that may arise.

Competitive middle age runners will be recruited from the area running community will be recruited through flyers and advertisements placed on the UVA grounds and throughout the Charlottesville community.

Likewise, injured runners with ERLLP will be recruited through flyers and advertisements placed on the UVA grounds and throughout the Charlottesville community. Following informed consent, all injured runners will be evaluated by an athletic trainer in the Exercise & Sport Injury Lab who will confirm the diagnosis of ERLLP per the use of established clinical practice guidelines.

6. **Are there financial or other types of compensation offered for participation in this study for students and employees who are participating?**

Yes, there is financial compensation for all who participate in this study.

If YES, describe the amount and/or nature of this compensation/alternative which should include equal methods for meeting course credit (or extra credit) requirements, such as attending a series of research presentations by faculty, writing a brief paper, conducting one's own research.

The compensation will be a $100 check for all participants who complete the study.

While students will be made aware of the protocol through recruitment in appropriate settings, participation in this protocol is not part of a course requirement, nor is course credit given for participation.

Recruitment

1. **How do you plan to <u>identify</u> potential subjects?**

a.____ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project .

b____ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research database or use of data from a separate current active research protocol.

IRB# _____

c. ____ Patient's UVa health care provider supplies the UVa study team with the patient's contact information without patient's knowledge.

d. ____ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be the a member of the study team)

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

DHHS & HIPAA: NA

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.

IRB# of registry/ database: _____

g. __X__ Other*:* Potential subjects will be identified by virtue of their presence on the UVA XC/Track team, UVA Lifetime Physical Activity classes, and Men's and Women's 4-Miler running groups. will be presented information about the study for recruitment.

If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true?

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

Does not apply.

2. How will potential subjects be <u>contacted?</u>

a.____Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

c.____Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients.

d. ___X_ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

DO NOT UNCHECK THIS BOX EVEN IF YOU DO NOT INTEND TO USE THIS RECRUITMENT METHOD AT THIS TIME.
The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need to review any type of script to use when the potential subject responds to the indirect method.

DHHS & HIPAA: NA

- __X__ Potential subjects are not patients. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.

When entering a classroom to recruit students and conduct research, e.g., administer a survey, investigators must do so at the end of the class period to allow non- participating students the option of leaving the classroom, thereby alleviating pressure to participate.

DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPPA: NA

3. **Will any additional information be obtained from a potential subject during "prescreening"?**
Yes, potential participants will be screened prior to consent to determine eligibility. All of the screening questions will encompass the inclusion and exclusion to ensure that we are reaching the target populations. Please see

the attached screening form. All information will be gathered in person. If they meet the criteria, they will be given the option to consent or not at this time.

IF YES, Will any of the questions involve health information?
Yes, a questionnaire of injury history will be obtained. Please see attached form.

IF YES, will you collect HIPAA identifiers with the health information?
Answer/Response:
Yes, we will be collecting HIPAA identifiers.

IF YES, which HIPAA identifiers will be recorded?
Name and contact information (telephone number, email address) will be collected at this time.

Do you confirm that health information with HIPAA identifiers will not be shared outside of UVa until a consent form is signed or only shared in a de-identified manner? Yes.

4. **Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?**
   No, potential participants will only answer questions prior to obtaining consent.

5. **How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?**
   Participants will report to the Exercise & Sports Injury Laboratory (EASIL) in Memorial Gymnasium to be screened for eligibility and provide informed consent. One of the study coordinators will discuss the study with the potential participant. Participants will be given the opportunity to ask questions or clarify information to ensure understanding, and written informed consent will be obtained. The study procedures will begin immediately after eligibility is determined or the subjects could choose to return at a later date to proceed with the study.

6. **Will subjects sign a consent form for any part of the study?**
   Yes, written consent will be obtained from all participants.

7. **Will the study procedures be started the same day the subject is recruited for the study?**

Yes, the study procedures may begin immediately after eligibility is determined and informed consent is obtained, or the subjects could choose to return at a later date to proceed with the study.

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.
The subject may feel comfortable consenting to the study at the initial screening in which case they can consent immediately, or if they do not feel comfortable, they will be given time to consider consenting.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.
The potential participant will be given as much time as they need to make an informed decision. They may come back at a later date if they do not wish to consent immediately.

8. Is there the potential to recruit a vulnerable population? (e.g. economically or educationally disadvantaged subjects, or other vulnerable subjects such as students , employees, investigator is health care provider of potential subject, pregnant women, children or prisoners?

Yes, there is the potential to recruit a vulnerable population as flyer and advertisements will be posted around the Charlottesville community, and certain student groups are included in the study design. Students and employees may participate in this study. See section above, entitled Research Involving Students and Employees as Subjects.

IF YES, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?

Check all applicable options:

___ Consent will be obtained by the CRC rather than the Investigator

_X__ Subjects will be assured that their relationship with their UVA health care providers will not be affected if they decide not to participate

_X___ Subjects will be given all the time needed to make their decision, and will not be pressured for a quick decision. They will be encouraged to seek advice from friends and family before signing consent.

_X___ Employees will be reassured that their decision will not affect their job or benefits.

_X__ Students will be reassured that their decision will not affect their status as a student or their grades.

___ If minors are enrolled, parental permission will be obtained prior to explaining the study to a minor and the minor's assent will be obtained prior to initiation of study procedures.

_X___ all subjects, especially those who are educationally disadvantaged will be asked open ended questions to confirm that they understand the study.

9. Do you need to perform a "dry run" of any procedure outlined in this protocol?

No, we will not need to perform a dry run. We have previously collected data for other approved projects using these same methods.

10. Is the study regulated by the Department of Defense (DoD)?

No, this study will not be regulated by the DoD.

11**. Non-Monetary Retention Incentives**

If subjects will be provided with non-monetary gifts or tokens of appreciation, such as totes, books, toys, or other such materials, the study team will submit a description and approximate retail value of the item to the IRB.

Study Procedures- Biomedical Research

1. Where will the study procedures be done?

Check One:

____ UVA medical center facilities (In patient or outpatient)

__X__ UVA but not medical center facilities: LIST specific location Answer/Response: Exercise and Sports Injury Lab (EASIL) in the Department of Kinesiology

__X_ Other: Participants will perform usual training runs throughout the greater Charlottesville or surrounding area using the study's wearable sensors over a one-week period.

2. If the study involves medical risk and study procedures will be done outside of the UVa Medical Center what is your plan to protect the subjects in case of a medical emergency?

__X__ NA

3. List the procedures, in bullet form, that will be done for <u>RESEARCH PURPOSES</u> as stipulated in this protocol.

ALL procedures that will be done are for research purposes. Training runs that occur during study participation are part of the subjects' normal activities- subjects will be asked to wear the sensors during their usual runs.

4. Do you confirm that, except for blood draws through a peripheral site, that all invasive procedures will be performed by a licensed health care provider under the supervision of an MD? Invasive procedures will not be performed in this study.

5. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?

Answer/Response:

No data or specimens will be used that were previously collected through another research study.

6. Will any of the procedures listed in item # 3 have the potential to identify an incidental finding? This includes ALL procedures, assessments and evaluations that are being done for RESEARCH PURPOSES that may or may not be considered investigational.

Yes, there is a potential for incidental findings.

__X___The examination(s) utilize(s) the same techniques, equipment, etc., that would be used if the subject were to have the examination(s) performed for clinical care. **There exists the potential for the discovery of clinically significant incidental findings.**

- The PI takes full responsibility for the identification of incidental findings:
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- If an incidental finding is serious and emergent (e.g. subject answers questionnaires implying they may be suicidal/mass on x-ray), the study team will inform the subject and contact the subject's health care provider.
- A follow-up letter describing the finding should be provided to the subject with instructions to either show the letter to their PC or if the subject has no PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic**.**

____This examination(s) utilizes non-standard/investigational, technique, equipment, etc. It is impossible to determine the significance of such results, therefore abnormalities will not be shared with the subject because the meaning of the exam is not yet proven and is of unknown clinical benefit.

7. Do any of the procedures listed above, under question # 3, utilize any imaging procedures for RESEARCH PURPOSES?

Yes, we will perform imaging procedures.

IF YES, list procedures:

Ultrasound Imaging of the deep posterior compartment of the lower leg will be used in this study.

___**X**__This imaging research examination utilizes the same imaging techniques, equipment, scanning sequences that would be used if the subject were to have the imaging performed for clinical care. There exists the potential for the discovery of clinically significant incidental findings.

Will the images be read by a licensed radiologist and the reading placed in the subject's medical record? No

►IF NO: The PI takes full responsibility for the identification of incidental findings:

- The PI will have all incidental findings reviewed by a radiologist who will advise the PI regarding clinical significance.
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided t**o t**he subject with instructions to either show the letter to their PC or if the subject has **no** PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic.

8. Will your study involve measures used to screen or assess for depression and/or suicidality <u>for research purposes?</u>

No measures will be used to screen or assess for depression or suicidality.

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?

There are no direct benefits for the participants in this study; however, subjects will be able to access the RunScribe data during the collection period. This study will provide information on running gait mechanics in more natural running environments (outside of the laboratory), and will allow for a larger sample of running data to be collected in a relatively short time frame to accrue a sizable amount of data. This information would greatly increase the ability to identify risk factors in runners and lead to more effective injury prevention initiatives.

2. Do the anticipated benefits justify asking subjects to undertake the risks?

The risks of this study for participants are low; laboratory measures will not pose any risk to the participants, and the only risks present during running are the same as the runners would incur during normal training. Even without direct benefits for participants, the findings that could results from this study can be helpful in better understanding running gait mechanics in natural environments and more successfully identify of running risk factors. The risk benefit ratio is acceptable.

Payment

1. Are subjects being reimbursed for travel expenses?

No, subjects will not be reimbursed for travel expenses.

2. Are subjects compensated for being in this study?

Yes, subjects will be compensated for being in this study.

2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?

Each participant will receive $100.00 dollars of total compensation for participation in this study. Subjects will be required to return the RunScribe sensors to the study team.

2b. Explain compensation to be given.

Participants will receive a check to be compensated for participation in this study.

2c. Is payment pro-rated?

No, payments will not be pro-rated.

If No, explain why payment cannot be pro-rated.

Only two visits are required for this study. Without complete data (including the running log and sensor data), the data from the first visit would not be meaningful. The consent form will include the wording that the subject must complete the study to receive the compensation.

2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?

Yes, the money will be paid from an account in the Curry School of Education. The PI received seed funding for this project from the Curry School Dean's Office.

2d(i). How will the researcher compensate the subjects?

__X__ Check issued to participant via UVA Oracle or State system

_____ Petty cash account*

_____ Gift card/Debit Card

_____ Other type of compensation:

2d(ii). Which category/ categories best describes the process of compensation?

__X___ All compensation will be made via check issued to participant via UVA Oracle or State system

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information will be collected, securely stored, and submitted electronically to Procurement Services as required.

►If this box is checked and an alternate method will be used, justify why you are unable to issue checks through the UVa Oracle or state system.

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information cannot be collected. Total possible compensation per participant for participating in the research study over one year is limited to <=$50.

►If an alternate method will be used justify why you are unable to issue checks through the UVa Oracle or state system:

►If you are unable to collect the tax information justify why it cannot be collected.

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

DELETE SECTION 1 BELOW IF THERE IS A PROTOCOL THAT ALREADY INCLUDES THESE DEFINITIONS.

1. Definitions

1.1 How will you define adverse events (AE)?

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 How will you define an unanticipated problem?

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g. serious loss of social status, loss of job, interpersonal conflict.)

1.3 What are the definitions of a protocol deviation and/or noncompliance?

A protocol deviation is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol deviations may be major or minor.

Noncompliance can be a protocol deviation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulations**.** Noncompliance may be minor or sporadic, or it may be serious or continuing.

2. What risks are expected due to the intervention in this protocol?

Expected Risks related to study participation	**Frequency**
There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	Occurs rarely
Incidental injury during calibration run	Occurs infrequently

3. When will recording and reporting of unanticipated problems/adverse events begin?

___X__After subject signs consent

4. When will the recording/reporting of unanticipated problems/adverse events end?

__X___Subject completes participation in the protocol

____End of intervention

_____30 days post intervention

_____Subject completes intervention and follow up period of protocol

5. What is your plan for safety monitoring?

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Deviations or Data Breach?

Type of Event	**To whom will it be reported:**	Time Frame for Reporting	How reported?

Unanticipated Problems that are not adverse events or protocol deviations This might include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. Unanticipated Problem Report Form
Protocol Deviations/Noncompliance (*The IRB-HSR only requires that MAJOR deviations be reported, unless otherwise required by your sponsor, if applicable.)* **OR** **Protocol Exceptions**	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Deviation, Noncompliance and Protocol Exception Reporting Form Protocol Deviation Protocol Exception Reporting Form
Data Breach* of Protected Health Information	The UVa Corporate Compliance and Privacy Office ITC: if breach involves electronic data Police if breach includes items that are stolen: Stolen on UVA Grounds OR Stolen off UVa Grounds- contact police department of jurisdiction of last known location of PHI	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVa Corporate Compliance and Privacy Office- Phone 924-9741 **ITC:** Information Security Incident Reporting procedure, http://www.itc.virginia.edu/security/reporting.html Police: phone- (434) 924-7166

*A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

Privacy Plan

The following procedures must be followed.

- The data will be secured per the Data Security Plan of this protocol.

- Only investigators for this study and clinicians caring for the patient will have access to data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*
- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

  If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.
- UVa University Data Protection Standards will be followed http://www.virginia.edu/informationsecurity/dataprotection.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the University's Requirements for Securing Electronic Devices.
- If identifiable data is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- Data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards .
- Data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

If you have a question or concerns about the required security standards contact InfoSec at it-security@virginia.edu

Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data is:
-personal information that can lead to identity theft if exposed or
-data that reveals an individual's health condition and/or history of health services use.
Protected Data (PHI) a type of Highly Sensitive Data, is data combined with a HIPAA identifier
Identifiable Data under HIPAA regulations is considered to be *Highly Sensitive Data at UVa.*
A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data* at UVa. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See Encryption Solutions Guidance *Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the “F” and “O” managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your	

computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with InfoSec or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center:	
Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*

Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with InfoSec or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center:	
Individual-Use Device	*Individual-Use Device*

Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with InfoSec or Health System Web Development Office: 434-243-6702 ▪ University Side: IT-Security@virginia.edu ▪ Health System: Web Development Center: Contract must include required security measures.	
May be stored in Qualtrics. May NOT be stored in places like UVaBox, UVaCollab or QuestionPro May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May be stored in places like UVaBox, UVaCollab, Qualtrics May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.
LOST OR STOLEN:	*LOST OR STOLEN:*
Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy. Any data breach will also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem.	Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy. Any data breach will also be reported to the IRB of Record if

	the report meets the criteria of an Unanticipated Problem.

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*
***The UVa HIPAA covered entity includes the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory, the Exercise Physiology Laboratory and the UVA Center for Survey Research.*

Legal/Regulatory/Ethical Considerations

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVa Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.

- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/924-2620) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the UVa Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records

- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/924-2620), the UVa Health System Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

Informed Consent

Unless waived by the IRB, subjects will be fully informed of the:

- purpose of the study,
- reasonably anticipated benefits,
- potential risks or discomfort participation in the study may entail,
- and any alternative treatments.

They will also be informed that their

- consent is voluntary and that they may withdraw their consent to participate at any time, and
- (if applicable) choosing not to participate will not affect the care the subject will receive for the treatment of his or her disease.

The consent documents used to obtain informed consent of the subject must be approved by the IRB prior to use. Any written materials (consent/ short form) will be provided to the potential subject in a language they can read understand. The subjects will be given sufficient time to read the consent form and have the opportunity to ask questions.. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled. After this explanation and before entry into the study, consent should be appropriately recorded. Subjects will be given a copy of the signed consent/ short form.

Institutional Review Board (IRB)

No subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment.

Any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

Investigator Responsibilities

The investigator is responsible for ensuring that the study is performed in accordance with the protocol, current ICH guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles that originated in the Declaration of Helsinki, and that the study data are credible.

PROTOCOL

Background

1. Provide the scientific background, rationale and relevance of this project.

Distance running is the most popular means of exercise undertaken by adults in the United States. While there are several profound health benefits associated with running, musculoskeletal injuries have been identified as a substantial barrier to participation.[1] Running-related injuries are common in competitive and recreational runners, as well as in military personnel where running-related injuries are a frequent occurrence during basic training.[2] Despite the recognition of the high prevalence of running-related injuries since the 1970's, injury rates among runners are essentially unchanged in the past 40 years.[1]

Assessment of running biomechanics has been a common mode of inquiry in the study of running-related injuries; however, traditionally it has been confined to laboratory settings. This has typically been done as a runner fitted with dozens of reflective markers which are tracked with high speed cameras ambulates on a 10 meter runway on which they must specifically land one of their steps on a small forceplate embedded in the middle of the runway.[3] This provides a single stride that may be subjected to biomechanical analysis. Multiple trials are needed to capture a representative sample of strides to be analyzed for each subject and consecutive strides cannot be analyzed. More recently, instrumented treadmills have been developed which have force plates embedded beneath the treadmill belts. This allows for continuous data collection while subjects run on a treadmill; however, there are documented biomechanical differences between treadmill and overground running.[4–6] Additionally, despite the ability to easily record a large number of strides with an instrumented treadmill, most research articles still only report biomechanical analysis of less than a few dozen strides per subject. Thus, the running injury biomechanics literature predominantly consists of studies that have analyzed a small number of strides per subject, with data collection occurring in highly controlled laboratory environments that do not reflect the conditions under which running related injuries occur (track, road, trail, etc.)

The advent of wearable sensors allows for biomechanical data to be collected in a runner's natural training environment while collecting thousands of steps in a single run. Our lab group has recently collected biomechanical data using commercially available sensors (RunScribe Labs, San Francisco, CA) that are mounted on a runner's shoes and transmit data after a run to a mobile phone app via Bluetooth technology. We presented a series of three research abstracts at the 2017 NATA conference this summer demonstrating many aspects of validity of these sensors in measuring common biomechanical measures during continuous running.[7–9] The ability to capture thousands of steps per day over weeks or even months for an individual runner should greatly increase the ability to identify injury risk factors in runners and lead to more effective injury prevention initiatives. The exponential increase in the number of strides that can be collected also open the analysis options to "big data" analytic techniques such as

principle components analysis, machine learning, and pattern recognition that were not feasible with previous data collection methods.

Objectives/Hypothesis

Primary Specific Aims:
1) To identify differences in running gait biomechanics (impact g's, braking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors across one week of training in runners with exercise-related lower leg pain (ERLLP) compared to healthy runners. Our hypothesis is that runners with ERLLP will have higher impact g's, faster pronation velocity, and longer contact time than healthy runners.

2) To identify differences in running gait biomechanics (impact g's, braking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors during one week of participants' routine runs, between novice young adult runners, competitive young adult runners, ROTC cadet runners, novice middle age adult runners, and competitive middle age adult runners. Our hypothesis is that novice runners in both age groups will display biomechanical patterns that are associated with increased risk of running-related injury (higher impact g's, faster pronation velocity, longer contact time) than competitive runners.

Secondary Specific Aim:
3) To identify novel data analysis schemes in an effort to maximize the use of the large volume of biomechanical data to be collected. Possible analysis approaches include, but will not be limited to, principal components analysis, machine learning, and pattern recognition. Our hypothesis is that advanced data analytics approaches will reveal group differences (same comparisons from Aims 1 & 2) that traditional parametric statistical analyses do not.

Study Design: Biomedical

1. Will controls be used? Matched controls will be selected from groups 1-5 to mirror the demographics of subjects in the ERLLP group in regards to age, sex, and weekly running mileage.

8. What is the study design? This will be a descriptive study design.

9. Does the study involve a placebo? No, no placebo will be used in this study.

Human Participants

Ages: _18-45 years___
Sex: **_Males and Females__**
Race: **_**All races**___**

Subjects- see below

1. **Provide target # of subjects (at all sites) needed to complete protocol.**

   96

   Eighty volunteers will be recruited with 16 runners (8 male, 8 female) in each of the six cohorts: 1) novice young adult runners, 2) competitive young adult runners, 3) ROTC cadet runners, 4) novice middle aged adult runners, 5) competitive middle aged adult runners, and 6) adult runners currently experiencing exercise-related lower leg pain (ERLLP).

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**

   We expect a cumulative 20% rate of screen failure, dropouts, and withdrawals.

3. **How many subjects will be enrolled at all sites?** 116

4. How many subjects will sign a consent form under this UVa protocol? **116**

Inclusion/Exclusion Criteria

1. **List the criteria for inclusion**

<u>All subjects must be willing to use their own smart phone device (iPhone or Android) to download the RunScribe application for study procedures.</u>

A. Inclusion criteria for novice young adult runners

a. Ages 18-25 years___
b. Male or female
c. Participating in distance running at least 3 times per week with a weekly mileage of at least 6 miles
c. Have never been involved in distance running on a regular basis prior to the past 3 months

B. Inclusion criteria for competitive young adult runners

a. Ages 18-25 years___
b. Male or female
c. Trained runners that compete at a regional to national level at race distances varying from 800 m to marathon (42.2 km)
d. Involved in specific running training at least three times per week over the past two years[10]
c. Currently participating in distance running at least 5 times per week with a weekly mileage of at least 15 miles

C. Inclusion criteria for ROTC cadet runners

a. Ages 18-25 years

b. Male or female

c. current participation in formal ROTC training at the University of Virginia.

D. Inclusion criteria for novice middle age adult runners

a. Ages __26-45 years__

b. Male or female

c. Participating in distance running at least 3 times per week with a weekly mileage of at least 6 miles

c. Have never been involved in distance running on a regular basis prior to the past 3 months

E. Inclusion criteria for competitive middle age adult runners

a. Ages __26-45 years__

b. Male or female

c. Trained runners that compete at a regional to national level at race distances varying from 800 m to marathon (42.2 km)

d. Involved in specific running training at least three times per week over the past two years[10]

e. Participating in distance running at least 5 times per week with a weekly mileage of at least 15 miles

F. Inclusion criteria for adult runners with exercise-related lower leg pain (ERLLP)

a. Ages 18-45 years__

b. Male or female

c. Involved in running training at least three times per week over the past three months

d. Current weekly mileage of at least 6 miles

d. Currently experiencing pain during or after running in the anterior or medial aspect of the leg (between the knee and the ankle) of at least one week in duration, with maximum pain levels between 3/10 and 8/10 on the Visual Analogue Scale [11,12]

2. List the criteria for exclusion

A. Exclusion criteria for novice young adult runners and novice middle age adult runners

a. History of distance running experience prior to the past 3 months

b. Current running-related injury that prevents regular running exercise

c. History of lower extremity or spine surgery within the last year

d. Subjects with known pregnancy

e. Subjects with any type of current neuropathy (numbness/tingling) in lower extremity

f. Subject with clinical diagnosis of Parkinson's disease

g. Subject with clinical diagnosis of Multiple Sclerosis (MS)

h. History of a balance disorder

B. Exclusion criteria for ROTC cadet runners, competitive young adult runners and competitive middle age adult runners

a. Current running-related injury that prevents regular running exercise
b. History of lower extremity or spine surgery within the last year
c. Subjects with known pregnancy
d. Subjects with any type of current neuropathy (numbness/tingling) in lower extremity
e. Subject with clinical diagnosis of Parkinson's disease
f. Subject with clinical diagnosis of Multiple Sclerosis (MS)g. History of a balance disorder

C. Exclusion criteria for adult runners with exercise-related lower leg pain (ERLLP)

a. Primary complaint is of pain over the Achilles tendon, popliteal fossa, or lateral or superficial posterior compartment of the lower leg
b. Medical diagnosis of compartment syndrome, tibial or fibular stress fracture, or tibial or fibular fracture within the past 3 months
c. Current running-related pain in the foot, ankle, knee, thigh, hip, or spine
d. Any history of lower extremity or spine surgery
e. Subjects with known pregnancy
f. Subject with any type of neuropathy (numbness/tingling) in lower extremity
g. Subject with clinical diagnosis of Parkinson's disease
h. Subject with clinical diagnosis of Multiple Sclerosis (MS)
i. History of a balance disorder

3. List any restrictions on use of other drugs or treatments. None.

Statistical Considerations

2. Is stratification/randomization involved?
No, stratification/randomization will not be involved in this study.

2. What are the statistical considerations for the protocol?

Study Design: A descriptive study design will be used. Six cohorts of subjects will be recruited: 1) novice young adult runners, 2) competitive young adult runners, 3) ROTC cadet runners, 4) novice middle age adult runners, 5) competitive middle age adult runners, and 6) adult runners with exercise-related lower leg pain (ERLLP). The first 5 cohorts will consist of healthy runners. The last group will consist of runners who have ERLLP but are choosing to continue running. Additionally, all of matched controls will be selected from groups 1-5 to mirror the demographics of subjects in the ERLLP group in regards to age, sex, and weekly running mileage.

Endpoints: Biomechanical data will be collected from each subject over 1 week of the routine runs. For each dependent variable, the mean value across all steps recorded

during the week of running for each subject. Group means and 95% confidence intervals will then be calculated for the groups described above

Primary Specific Aim #1:
Aim: To identify differences in running gait biomechanics (impact g's, braking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors across one week of training in runners with exercise-related lower leg pain (ERLLP) compared to healthy runners. *Research Hypothesis:* Our hypothesis is that runners with ERLLP will have higher impact g's, faster pronation velocity, and longer contact time than healthy runners.
Statistical Approach: For each dependent variable, the mean and 95% confidence intervals will be calculated for the ERLLP group and the healthy group. Measures for which the group confidence intervals do not overlap will be considered statistically significant. Cohen's d effect sizes and associated 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.
Sample Size Estimate: The sample size estimate of 16 subjects per group is based on results of a previous study from our lab group which identified significant differences in many of the same measures between a group of runners with chronic ankle instability and a healthy control group during a 1600 meter run. The previous study had 9 subjects per group. We expect differences associated with ERLLP to be more subtle than those associated with chronic ankle instability; thus the larger sample size in the proposed study.

Primary Specific Aim #2:
Aim: To identify differences in running gait biomechanics (impact g's, braking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors during one week of participants' routine runs between novice young adult runners, competitive young adult runners, ROTC cadet runners, novice middle age adult runners, and competitive middle age adult runners.
Research Hypothesis: Our hypothesis is that novice runners in both age groups will display biomechanical patterns that are associated with increased risk of running-related injury (higher impact g's, faster pronation velocity, longer contact time) than competitive runners. Additionally, we hypothesize that the ROTC group will be most similar to the novice young adult group.
Statistical Approach: For each dependent variable, the mean and 95% confidence intervals will be calculated for each group. Measures for which the group confidence intervals do not overlap will be considered statistically significant. Cohen's d effect sizes and associated 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.
Sample Size Estimate: The sample size estimate of 16 subjects per group is based on results of a previous study from our lab group which identified significant differences in many of the same measures between a group of runners with chronic ankle instability and a healthy control group during a 1600 meter run. The previous study had 9 subjects per group. We expect that differences associated with the various groups in the

proposed study to be more subtle than those associated with chronic ankle instability, thus the larger sample size in the proposed study.

Secondary Specific Aim:
Aim: To identify novel data analysis schemes in an effort to maximize the use of the large volume of biomechanical data to be collected.
Research Hypothesis: Our hypothesis is that advanced data analytics approaches will reveal group differences (same comparisons from Aims 1 & 2) that traditional parametric statistical analyses do not.
Statistical Approach: Possible analysis approaches include, but will not be limited to, principal components analysis, machine learning, and pattern recognition.
Sample Size Estimate: The sample size estimate is based on the two primary aims discussed above.

3. Provide a justification for the sample size used in this protocol.
Aim 1: The sample size estimate of 16 subjects per group is based on results of a previous study from our lab group, which identified significant differences in many of the same measures between a group of runners with chronic ankle instability and a healthy control group during a 1600 meter run. The previous study had 9 subjects per group. We expect that differences associated with ERLLP to be more subtle than those associated with chronic ankle instability, thus the larger sample size in the proposed study.
Aim 2: The sample size estimate of 16 subjects per group is based on results of a previous study from our lab group which identified significant differences in many of the same measures between a group of runners with chronic ankle instability and a healthy control group during a 1600 meter run. The previous study had 9 subjects per group. We expect that differences associated with the various groups in the proposed study to be more subtle than those associated with chronic ankle instability, thus the larger sample size in the proposed study.

4. What is your plan for primary variable analysis?
Aim 1: For each dependent variable, the mean and 95% confidence intervals will be calculated for the ERLLP group and the healthy group. Measures for which the group confidence intervals do not overlap will be considered statistically significant. Cohen's d effect sizes and associated 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.
Aim 2: For each dependent variable, the mean and 95% confidence intervals will be calculated for each group. Measures for which the group confidence intervals do not overlap will be considered statistically significant. Cohen's d effect sizes and associated 95% confidence intervals will also be calculated to estimate the magnitude and precision of group differences.

5. What is your plan for secondary variable analysis?

Possible analysis approaches include, but will not be limited to, principal components analysis, machine learning, and pattern recognition.

6. Have you been working with a statistician in designing this protocol?
No, the PI has considerable experience in designing studies of human biomechanics and performing statistical analyses of biomechanical data sets.

7. Will data from multiple sites be combined during analysis?
No, there will not be multiple sites used during this study.

Study Procedures-Biomedical Research

1. What will be done in this protocol?

Study Procedures:

1. Obtain informed consent for all subjects.
2. Screen all subjects according to inclusion/exclusion criteria to ensure they are eligible to enroll. Subjects in the exercise-related lower leg pain group will be examined by an athletic trainer. A general medical history will be taken.
3. Complete all patient-reported outcome subject questionnaires.
4. Complete a physical exam including measurements of:
    a. Foot posture
    b. Leg length
    c. Pelvic alignment
    d. Lower extremity range of motion
    e. Lower extremity flexibility
    f. Lower extremity strength measures
    g. Ultrasound of the deep posterior compartment of the lower leg
5. Participants will perform a calibration run for the Runscribe.
6. Participants will use the Runscribe sensors during normal training for a one-week period.

Consent & Screening:

Potential subjects will report to the Exercise and Sports Injury Lab (EASIL) in Memorial Gymnasium for all study procedures. Subjects will be asked a series of questions about their health history and running experience prior to consent to ensure that the potential subjects fit the inclusion and exclusion criteria (administered by Study Coordinators).

Once subjects are deemed eligible, informed consent will be obtained for all subjects as outlined in the Recruitment section of the IRB Application. Demographic information will also be collected at this time by the Study Coordinators including age, gender, height, and weight. The study procedures will begin immediately after informed consent is obtained or the subjects may choose to return at a later date to proceed with the study procedures.

Questions asked to determine eligibility included in an included pre-screening form.

Patient Reported Outcomes (Subjective Questionnaires)

1. Visual Analogue Scale[13]
2. Godin Leisure-Time Activity Questionnaire[14]
3. Exercise-Induced Leg Pain Questionnaire – British Version (EILP-BR)[15]
4. Lower Extremity Functional Scale[16]

Physical Examination

All measures listed in this section are non-invasive and are performed in the routine practice of athletic training, physical therapy, and musculoskeletal medicine in the assessment of patients with lower leg injuries.

1. Foot posture
    a. Arch Height Index[17]: measured by an Arch Height Index Measurement System in which subjects place their foot on a platform and an examiner will measure total foot length and truncated foot length in seated and weight-bearing positions.
    b. Foot Posture Index[18]: measured by having subjects march in place and then stand as they normally would as an examiner evaluates foot positioning from multiple views.
2. Leg length with tape measure[19]: measured by having subjects lie supine on a table while an examiner uses a fabric tape measure to determine the leg length from the anterior superior iliac crest of the hip to the medial malleolus of the ankle, repeated on both legs.
3. Pelvic alignment
    a. Pelvic Tilt: measured by having subjects sit on the edge of a treatment table, pull one thigh towards the chest and lay back onto the table to assess if the opposite leg comes up off of the table as a sign of anterior pelvic tilt, also called the Thomas Test.
4. Lower extremity passive range of motion
    a. Hip (flexion, extension, abduction, EROT, IROT)
    b. Knee (flexion, extension)
    c. Ankle (dorsiflexion, plantarflexion, inversion, eversion)
    d. Foot (first ray mobility): measured by having subjects sit or lie on a treatment table while an examiner uses a goniometer of the first ray measurement tool to passively move the respective joints through the available range of motion.
5. Lower extremity flexibility
    a. Straight leg raise test: The subject will be asked to lie supine on a table while an examiner passively flexes the patient's hip while maintaining knee extension until the end range of motion is met.

b. Weight-bearing dorsiflexion test: The subject will be asked to stand facing a wall with feet about 10 cm back from the wall with the other foot back, and bend the front knee until it touches the wall without the heel coming off the ground. If the knee can touch the wall without the heel coming off the ground, the subject will move the foot back progressively until the knee can just touch the wall without the heel coming off the ground.

6. Lower extremity strength measures: measured by having subjects assume different standardized testing positions while an examiner uses a hand-held dynamometer to measure movement forces.
    a. Hip extension with subjects in prone on a treatment table and knee bent
    b. Hip flexion with subjects lying supine on a treatment table
    c. Hip abduction with subjects side-lying on a treatment table
    d. Knee extension with subjects seated on a treatment table
    e. Knee flexion with subjects seated on a treatment table
    f. Plantarflexion with subjects in prone on a treatment table
    g. Dorsiflexion with subjects seated on a treatment table
    h. Inversion with subjects seated on a treatment table
    i. Eversion with subjects seated on a treatment table

7. Ultrasound of the deep posterior compartment of the lower leg to assess muscle belly size[20,21]
8. Balance test: Participants will be required to stand on a single leg on a forceplate with the other knee bent back so the foot is not in contact with the ground, maintain hands on the hips and eyes open for a 15 second balance trial, repeated twice. These same procedures will be repeated with the eyes closed, and done for both legs.

Calibration Run

1. Subjects will be given RunScribe™ sensors and oriented to the use of the wearable sensors and the associated mobile phone application (RunScribe Labs, San Francisco, CA)
2. Sensors will be fitted and mounted on the heel of the participant's left and right shoes.
3. Subjects will run around a 400-meter track once in order to calibrate the RunScribe™ system.

Running Collection

1. Participants will use the calibrated RunScribe™ sensors during all of their normal runs during a one-week period.

2. Participants will be asked to keep a written log of all their runs that will be shared with the research team to verify the RunScribe™ data matches the participant's self-reported mileage and frequency of training.
3. Participants will return to Memorial Gymnasium at the end of the one-week period to return the RunScribe™ sensors and running log.

This protocol is not intended to provide any direct benefits to the enrolled subjects, however subjects will have access to the RunScribe data during the data collection period.

This protocol will allow the researchers to obtain valuable insight into running biomechanics in more natural training environments, in order to provide a generalized benefit to the running populations being studied. Subjects will be informed that the de-identified data and and de-identified ultrasound still images of interest may be maintained in a database for research and/or academic purposes.

2. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study. N/A

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	**Jay Hertel, Ph.D., ATC** Department of Kinesiology PO Box 400407 Charlottesville, VA 22908 (P) (434) 243-8673 (E) jnh7g@virginia.edu
Sponsor:	**Curry School of Education at The University of Virginia**

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

The Dean's Office of the Curry School of Education at the University of Virginia is funding this study.

Why is this research being done?

The purpose of this study is to examine running gait mechanics using wearable sensors during one week of training in six different groups of runners: novice young adult runners, competitive young adult runners, ROTC cadet runners, novice middle age adult runners, competitive adult runners, and adult runners with exercise-related lower leg pain.

All participants will be asked to use small wearable sensors on their training shoes during one week of regular running training. With this study we hope to gain information on running patterns in different types of runners under normal training conditions. Using wearable sensors over a week of running will provide much more information on running mechanics and help us to better understand runners' movement patterns.

You are being asked to be in this study, because you are a runner who fits into one of the six categories we are studying.

Up to 232 people will be in this study at UVA.

What will happen if you are in the study?

CONSENT and SCREENING (will take about 10-15 minutes):

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- Review of your medical history
- Review of your distance running experience
- Review of your current weekly running mileage

If these tests show you are eligible, you will return to the clinic at a later date to begin study treatment, or you may continue with the remainder of testing. The tests and procedures in this study are being done for research purposes only.
If you are a runner in the exercise-related lower leg pain (ERLLP) group, you will be examined by an athletic trainer to confirm your study group.

STUDY PROCEDURES: Visit 1 (will last about 60-90 mins in the lab, and then logging one week of your regular training runs)

If you are eligible and agree to participate in this study, you will be asked to fill out some questionnaires. These questionnaires will ask about:

- General medical history
- Physical activity level
- Exercise-related lower leg pain

It will take about 15-20 minutes to complete all questionnaires.

Physical Exam

Once you have completed the questionnaires, you will be asked to go through a clinical exam. This will include:

1. Measurement of foot posture, by placing your foot on a platform while your foot length is measured, while seated and standing. We will ask you to march in place and then stand as you normally would as your foot is positioned in several different ways.

2. Measurement of leg length while standing. You will lie on a table while a member of the study team measures your legs from your hip bone to your inner ankle bone.
3. Measurement of hip alignment while standing.
4. Measurement of hip, knee, ankle, and foot motion while sitting or lying on a table.
5. Measurement of hip, knee, and ankle flexibility while sitting or lying on a table.
6. Testing of hip, knee, and ankle strength with investigator providing resistance while sitting or lying on a table.
7. Testing of balance while standing on a force plate on one leg for 15 seconds with your eyes open for 2 tests, eyes closed for 2 tests, and repeated for both legs.
8. Examination of lower leg muscles using diagnostic ultrasound imaging while lying on a table. Some clear gel will be applied to your lower leg and a wand will be pressed and moved over the area.

   The physical examination will take approximately 45-50 minutes.

Running with Wearable Sensors

Once you have completed the physical exam, you will complete the running portion of the study.

1. You will need to have access to a smart phone device, and download the RunScribe™ application to keep track of your runs.
2. You will receive a demonstration on how to use the shoe wearable sensors (RunScribe™) and the associated mobile phone application.Your shoes will then be fitted with the RunScribe™ heel sensors.
3. You will then complete a 400-meter run around a track in order to calibrate the sensors.
4. You will keep these calibrated sensors and wear them on the heel of your training shoes during all of your normal runs for one week.
5. You will also keep a written log of all runs you complete so that the research team can make sure the RunScribe™ system data matches your true running information.

Visit 2:

After one week, you will return the sensors to the researchers, and your participation in the study will end.

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety in this study.
These responsibilities are listed below:

- You must attend each visit.
- You must be completely truthful about your health history.

- Follow all instructions given.
- You should tell the study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.

How long will this study take?

Your participation in this study will last one week, and will require 1 laboratory visit, and an additional visit to return the sensors and running log. The physical examination and calibration portions of the study will last about 60-90 minutes total.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks related to the procedures include:

3. Muscle soreness during or after testing/your calibration run may occur infrequently

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Your physical exam results will be shared with you and you may have access to the RunScribe data during the week you are wearing the sensors, which may give you information regarding your gait. The information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only choice is not to be in this study.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.

If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $100.00 for finishing this study by a check through the University of Virginia.
You should get your payment about one month after finishing the study. The income may be reported to the IRS as income.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

The questionnaires, physical examination, imaging, and wearable sensor use in this study will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) You become injured and can no longer participate in the study
b) The study is closed for safety, administrative, or other reasons

If you decide to stop being in the study, we will ask you to return all wearable sensors.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the “Leaving the Study Early” part of this form and return it to the researchers. Then

you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Jay Hertel, Ph.D., ATC
Curry School of Education
Department of Kinesiology
PO Box 400407
Charlottesville, VA 22908
(P) (434) 243-8673
(E) jnh7g@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

ARE YOU A RUNNER?

The UVA Department of Kinesiology is seeking male and female runners, ages 18-45

- The purpose of this research study is to compare ***uninjured runners*** to runners with a variety of running injuries and running backgrounds
- This study will require up to 2 visits. The first visit includes physical assessment and will last up to 90 minutes. The second visit will last 5-10 minutes.
- Study related exam and use of sensors provided free of charge
- You will use shoe sensors and associated app for one week and return to our lab
- You will be paid $100 for completing this study

For more information, please contact:

Alexandra DeJong
afd4au@virginia.edu

Or call the Exercise and Sport Injury Laboratory:
434-924-6184

IRB-HSR # 20501
Principal Investigator: Jay Hertel

Alexandra DeJong Afd4au@virginia.edu 434-924-6184
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Alexandra DeJong Afd4au@virginia.edu 434-924-6184

ARE YOU A RUNNER WITH SHIN SPLINTS?

The UVA Department of Kinesiology is seeking male and female runners, ages 18-45

The purpose of this research study is to compare uninjured runners to runners with leg pain during exercise.

- This study will require up to 2 visits. The first visit includes physical assessment and will last up to 90 minutes. The second visit will last 5-10 minutes.
- Study-related exam and use of sensors provided free of charge
- You will use shoe sensors and associated app for one week and return to our lab
- You will be paid $100 for completing this study

For more information, please contact:

Alexandra DeJong
afd4au@virginia.edu
Or call the Exercise and Sport Injury Laboratory:
434-924-6184
IRB-HSR # 20501
Principal Investigator: Jay Hertel

UVA IRB-HSR
Approval Date: 3/15/18

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Table C2b – Institutional Review Board Documents – Manuscript 2

PROTOCOL

Background

2. Provide the scientific background, rationale and relevance of this project.

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is a FIVE YEAR UPDATE make sure the information throughout the protocol includes the most current information.

Answer/Response:

Running is one of the most popular forms of exercise worldwide, and attracts approximately 18.3 million road-racers annually in the United States.[1] Although running offers extensive physical and mental health benefits, there is a substantial risk for running-related musculoskeletal injuries. Lower limb injuries affect approximately 40% of the running community, with up to 66% diagnosed as chronic exercise-related lower leg pain (ERLLP; known in lay terms as "shin splints").[2,3] Common rehabilitative approaches to ERLLP management such as calf stretching and strengthening appear largely ineffective given the persistently high injury rates. Instead, gait analyses have been used to identify movement patterns associated with injury occurrence and exacerbation to guide clinical gait-training interventions. Traditional gait intervention protocols have utilized instrumented treadmills with motion capture equipment to provide feedback on biomechanical deficits on a finite number of total steps. Given the constrained environment, expensive equipment, and necessary supervision time and technical expertise to conduct these interventions, there is a substantial barrier to generalize controlled setting findings to in-field applications. There are also inherent differences between treadmill and over-ground outdoor running, such as changes in speed, terrain, incline, and environment that may influence biomechanics (Figure 1).[4–6] These limitations highlight the importance of moving beyond the confines of the

laboratory setting to perform gait-training for runners in natural training environments. RunScribe wearable sensors (RunScribe™, Half Moon Bay, CA, USA) are inexpensive, lightweight equipment designed to measure running biomechanics, and have the capacity to collect upwards of 15,000 steps per run in any training environments.[7] These devices have proven reliable against laboratory gold standard equipment and thus offer a valid means to use in the field to facilitate clinical assessments and interventions.[8,9]

We recently conducted a systematic review of gait-training for prevalent lower extremity injuries, and while there are multiple studies on gait-training in healthy populations with injury risk profiles, there is no information to date on gait-training in runners with shin-splints.[10] Further, the majority of interventions have used arbitrary cut-off values to dictate the gait-training programs (i.e. increase step rate by 10-15% or decrease loading by 20-50%). We have conducted a previous descriptive study at UVA using wearable sensors in ERLLP patients, and our results suggest that the previously targeted biomechanics may not be meaningful to outdoor running and instead contact time, or how long the foot is in contact with the ground, is a more important feature to distinguish ERLLP runners from healthy matched comparisons. Thus, we have sufficient resources to support using our current database to guide focused gait-training interventions to maximize runners' responses to interventions. Therefore, the overarching purpose of this project is to use sensor-derived patterns to guide running interventions during in-field training scenarios for runners with ERLLP. We plan to use the RunScribe sensors to facilitate in-field gait-training to determine the effects of real-time gait-training interventions along with a home exercise program (intervention group) on biomechanical and patient-reported outcome measures of pain and function in runners with ERLLP as opposed to receiving a home exercise program alone (control group).

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response:

Aim 1: To evaluate the effects of 4 weeks of field-based gait-training using real-time biomechanical feedback in conjunction with a home exercise plan (intervention) in runners with ERLLP on spatiotemporal, kinetic, and kinematic outcomes compared to baseline and compared to a group of runners with ERLLP who receive home exercises alone (control).

Hypothesis 1a: When performing outdoor gait assessments at 4 weeks, the intervention group will demonstrate decreased contact time, increased cadence, and decreased

loading measures using the RunScribe wearable sensors as compared to baseline measures and to the control group.
Hypothesis 1b: When performing indoor gait assessments at the 4-week timepoint, the intervention group will demonstrate increased sagittal plane lower extremity kinematics measured using motion capture technology as compared to baseline measures and to the control group.

Aim 2: To evaluate the effects of the gait-training intervention in runners with ERLLP on patient-reported outcome measures compared to baseline and the control group.
Hypothesis 2: Runners with ERLLP who receive the intervention will have decreased VAS scores indicative of decreased pain, and increased EILP-Br scores indicative of higher leg function at the 4-week timepoint as compared to baseline measures and compared to the control group.

Aim 3: To evaluate the retention effects of the gait-training intervention 2 weeks post-intervention compared to baseline and 4 weeks in runners with ERLLP for both patient-reported outcomes and biomechanical outcomes.
Hypothesis 3a: At the 2-week post-intervention timepoint, the runners with ERLLP who receive the gait-training intervention will have decreased VAS scores indicative of decreased pain, increased EILP-Br scores indicative of higher leg function compared to baseline and compared to the 4-week timepoint measures.
Hypothesis 3b: At the 2-week post-intervention timepoint, the intervention group will demonstrate decreased contact time, increased cadence, and decreased loading measures using the RunScribe wearable sensors as compared to baseline measures and to the control group at all timepoints. Within the intervention group, there will be comparable measures to the 4-week timepoint suggesting adequate integration of the feedback into their natural running pattern.

Study Design: Biomedical

1. Will controls be used?
Answer/Response:
Yes, controls will be used.

►IF YES, explain the kind of controls to be used.
Answer/Response:
Sex- and experience-matched ERLLP runners will be used as controls. Controls will receive the home exercise protocol alone.

10. What is the study design?

Example: case series, case control study, cohort study, randomized control study, single-blind, double-blind, met-analysis, systematic reviews, other. You may also view the IRB-HSR Learning Shot on this topic to help you answer this question.
(http://www.virginia.edu/vpr/irb/learningshots/Writing_protocol_June09/player.html

Answer/Response:
Randomized control design.

11. Does the study involve a placebo?

Answer/Response:
No placebo will be used.
►IF YES, provide a justification for the use of a placebo
Answer/Response:

Human Participants

Ages: **_18-45 YOA___**
Sex: __Male and Female__
Race: **__All__**

Subjects- see below

INSTRUCTIONS: For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

1. Provide target # of subjects (at all sites) needed to complete protocol.

INSTRUCTIONS: If this is NOT a database protocol, this number should be the same as the number of subjects needed to obtain statistically significant results.

Answer/Response:
An a priori power analysis was performed using published gait-training data[11] that found a mean difference of 4.04 steps/minute following intervention. Based on these data, a total of 40 participants (20 in each group) will be needed to find a minimally detected difference assuming an alpha level of 0.05 and power exceeding 80%.

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.

Answer/Response:
We expect a cumulative 20% rate of screen failure, dropouts, and withdrawals.

3. How many subjects will be enrolled at all sites?

INSTRUCTIONS: This number must be the same or higher than the # from question # 1 in order to account for the # of screen failures, dropouts, withdrawals described in question # 2.

Answer/Response:
46 participants will be enrolled in total.

4. How many subjects will sign a consent form under this UVa protocol?

INSTRUCTIONS: If the protocol does not have a consent form- the number listed here should reflect such things as the number of subjects from whom specimens will be obtained, the number of charts to be reviewed etc.

Answer/Response:
46 participants.

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non-English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.
- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response:
All subjects must be willing to use their own smart phone device (iPhone or Android) to download the RunScribe application for study procedures.

a. Ages 18-45 years

b. Male or female

c. Involved in running training at least two times per week over the past three months

d. Current weekly mileage of at least 6 miles

d. Currently experiencing pain during or after running in the anterior or medial aspect of the leg (between the knee and the ankle) of at least one week in duration, with maximum pain levels between 3/10 and 8/10 on the Visual Analogue Scale [12,13]

2. List the criteria for exclusion

Answer/Response:

a. Primary complaint is of pain over the Achilles tendon, popliteal fossa, or lateral or superficial posterior compartment of the lower leg

b. Medical diagnosis of compartment syndrome, tibial or fibular stress fracture, or tibial or fibular fracture within the past 3 months

c. Current running-related injuries within 3 months at the foot, ankle, knee, thigh, hip, or lower back

d. Any history of lower extremity or lower back surgery

e. Subjects with known pregnancy

f. Subject with any type of neuropathy (numbness/tingling) in lower extremity

g. Subject with clinical diagnosis of Parkinson's disease

h. Subject with clinical diagnosis of Multiple Sclerosis (MS)

i. History of a balance disorder

3. List any restrictions on use of other drugs or treatments.

Answer/Response: None.

Statistical Considerations

4. Is stratification/randomization involved?

Answer/Response: Yes, randomization will be involved.

►IF YES, describe the stratification/ randomization scheme.

INSTRUCTIONS:

The stratification factors and/or the randomization plan should be identified. If there is no randomization component or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

Stratification factors: These are pretreatment patient characteristics which could be balanced across treatment arms by design or may be used to determine starting dose or treatment allocation.

If randomization is going to be used, the details of the randomization plan should be described.

The description should include:
--the method and timing of randomization
--the type of randomization scheme that will be used in the study
--whether or not the randomization masked/blinded/if so, then to whom is it masked/blinded
--who has access to the randomization scheme

Answer/Response:

At baseline prior to collecting any data, ERLLP runners will randomized into intervention (gait-training with home exercise) and control (home-exercise alone) groups using a 1:1 scheme. A random number generator, stratified by sex, will be used to designate groups prior to starting the study. Group allocation will be placed in a sealed, opaque envelope by the Principal Investigator. The Principal Investigator will not be involved in the baseline assessment so there will not be a potential of bias for group allocation. Study Coordinator 1 will conduct all intervention study procedures, and therefore will be blinded to group allocation prior to initiating study procedures to ensure true randomization.

►**IF YES, who will generate the randomization scheme?**

_____ Sponsor
_____ UVa Statistician. Insert name Answer/Response:
_____ UVa Investigational Drug Service (IDS)
__**X**___ Other*:* Specify Answer/Response: Principal Investigator.

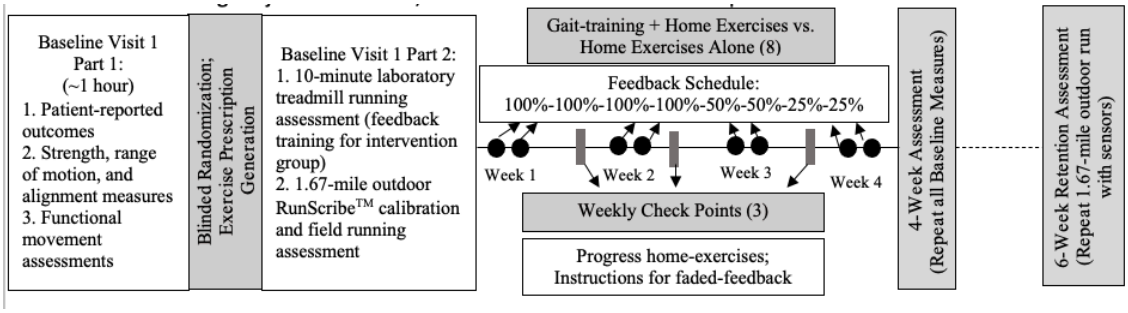
2. What are the statistical considerations for the protocol?

The objectives section and the statistical section should correspond, and any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

The answer to this question should include:
--Study Design/Endpoints
--Recap of study objectives and endpoint definitions. An assessment of how study objectives will be assessed by identifying & defining which endpoints will be used to assess each component of the study objectives.
--The study design should include contingencies for early stopping, interim analyses, stratification factors (If applicable), and any characteristics to be incorporated in analyses.
--The power/precision of the study to address the major study endpoint(s), the assumptions involved in the determination of power/precision.
--If statistical hypothesis testing is included then specify the null and alternative hypotheses, the test statistic, and the type I and II error rates
--If precision of an estimate, then provide a definition for precision
--If other, then specify

Answer/Response:

Study Design: A randomized control study design will be used. An equal number of ERLLP patients will be randomly allocated at a baseline visit to intervention and control groups. Participants will follow study procedures dictated by their group for 8 timepoints over 4 weeks. Following subject recruitment, a schematic of the interventions procedures is as follows:



Endpoints: As depicted in the study schematic, participants will be required to come in for weekly check-in visits to progress the home exercises, and for the intervention group to explain the feedback protocol for the upcoming week) as this is standard clinical practice. All participants will be required to return at 4-week timepoint to repeat all baseline assessment procedures. Finally, all groups will be asked to return at 6 weeks to perform the same running route using the wearable sensors to assess retention of the intervention and repeat patient-reported outcome measures. Statistical analyses will only be conducted by researchers at the final study endpoint at 6 weeks. At this time, repeated-measures ANOVAs will be conducted to compare baseline and follow-up biomechanical and subjective outcomes. Pattern recognition analyses will also be conducted at this time to determine how participants were able to change their biomechanical patterns across the study period.

3. Provide a justification for the sample size used in this protocol.

Include sample size calculations or statistical power estimation. If not applicable, please provide explanation.
Also include the anticipated accrual rate, the accrual goal for the study, including accrual goals by strata if appropriate, adjustments for drop-outs etc. and study duration.

Answer/Response:

The sample size estimation is based off of previously published gait-training data in a healthy population.[11] The authors targeted cadence-based feedback, which we anticipate will be a main factor for our feedback intervention. The authors reported a mean difference of 4.04 steps/minute for a moderate effect (Cohen's d Effect Size=0.39); therefore, we will need a total of 46 participants in each group for a minimally detectable change assuming an alpha level of 0.05 and 80% power, with ~20% attrition.

4. What is your plan for primary variable analysis?

Include primary outcome(s)/predictor variable(s), statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.

Answer/Response:

For primary variable analysis to address our first specific aim, we will use repeated measures ANOVAs to determine the effect of group (intervention vs. control) and time (baseline vs. 4 weeks) on biomechanical running outcomes from (a) the

wearable sensors and (b) the motion capture system. Specifically, we will investigate (a) contact time, step rate, and loading metrics as the primary outcome variables of interest using the output form the RunScribe sensors, and (b) hip, knee, and ankle sagittal plane angles. We will consider adding covariates for running pace and/or BMI if warranted.

For the second aim, we will use repeated measures ANOVAs to determine the effect of group and time on pain and function outcomes. Specifically, we will use the Visual Analog Scale (VAS) for pain, and the exercise-induced lower leg pain British version (EILLP-Br) for leg function.

For the third aim, we will use repeated measures ANOVAs to determine the effect of group (intervention vs. control) and time (baseline, 4 weeks, 6 weeks) on biomechanical and patient-reported outcome measures. Specifically, we will investigate contact time, step rate, and loading metrics as the primary outcome variables of interest using the output from the RunScribe sensors, and the VAS and EILP-Br questionnaires.

5. What is your plan for secondary variable analysis?

Include the following:
--Secondary outcome(s)/predictor variables, statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.
--For phase III studies, the power/precision of the study to address the secondary objective(s).

Answer/Response:
We plan to use repeated measures ANOVAs to investigate additional biomechanical outcomes using the RunScribe sensors and instrumented treadmill to look at the effects of group and time on these secondary outcomes. From the RunScribe sensors, we will investigate step length, pronation excursion, pronation velocity, foot strike, and impact and braking g's during outdoor running. From the treadmill analyses, we will investigate hip, knee, and ankle frontal plane kinematics, electromyography of muscles throughout the lower extremity, and vertical ground reaction force data. Finally, we will investigate additional patient-reported outcome measures, including the Godin Leisure-Time Exercise Questionnaire, the Lower Extremity Functional Scale, the Global Rating of Change questionnaire, and the Running Injury and Recovery Index.

6. Have you been working with a statistician in designing this protocol?

Consultation with a professional statistician is highly recommended to ensure good science of the study and facilitate the review process.

Answer/Response: Yes.

IF YES, what is their name?

Answer/Response:

Jordan Rodu.

7. Will data from multiple sites be combined during analysis?

Answer/Response: No, multiple sites will not be used for this study.

INSTRUCTIONS: IF YES, answer the following questions

7(a). Does the study involve randomization?

Answer/Response:

IF YES, will randomization be done at each site or among sites?

Answer/Response:

7(b). Has the sample size calculation considered the variation among sites?

Answer/Response:

7(c). When combining the data from multiple sites to assess the study results, is the effect of the treatment to be tested (or the association to be tested) assumed to be the same across sites or vary among sites? What is the modelling strategy?

Answer/Response:

7(d). Is there a common protocol used in all sites?

Answer/Response:

IF NO, how will differences among sites, such as those related to the implementation, inclusion criteria, patient characteristics, or other sites characteristics, be considered to assess the study results?

Answer/Response:

Study Procedures-Biomedical Research

1. What will be done in this protocol?

INSTRUCTIONS:

This should include everything that will be done as part of this protocol. Do not repeat information that is included in other sections such as Background or Hypothesis sections.

This section should include an indication of which research interventions if any offer a prospect for direct benefit and which interventions (invasive measurements, collection of blood, tissue, data, surveys, etc.) are being done solely to answer a research question and generate generalizable knowledge. If the interventions done solely for research purposes are associated with greater than minimal risk they need to be justified. Describe and justify any control and experimental arm and include method, dose, and duration of drug administration. Reference any claim of clinical equipoise if applicable.

If you are obtaining specimens or data, provide information regarding the type of specimen/data, amount of specimen needed and how the specimen/data will be obtained and what analysis will be done with the specimen/data.

Special note for studies with waiver of consent/waiver of documentation of consent: Include a statement regarding how subjects will be recruited. For other studies this information is captured in Recruitment does not need to be duplicated in this section.

Answer/Response:

Study Procedures:

Consent & Screening:
Potential subjects will be screened prior to reporting to the Exercise and Sports Injury Lab (EASIL) in Memorial Gymnasium for all study procedures. Subjects will be asked a series of questions about their health history, running experience, and COVID-related history prior to consent to ensure that the potential subjects fit the inclusion and exclusion criteria (administered by Study Coordinators). Once subjects are deemed eligible, informed consent will be obtained for all subjects as outlined in the Recruitment section of the IRB Application. The study procedures will begin immediately after informed consent is obtained or the subjects may choose to return at a later date to proceed with the study procedures.
Questions asked to determine eligibility are included in an attached pre-screening form.

Baseline Visit 1 - Patient-Reported Outcomes (Subjective Questionnaires)
5. Visual Analogue Scale[14]
6. Godin Leisure-Time Activity Questionnaire[15]
7. Exercise-Induced Leg Pain Questionnaire – British Version (EILP-BR)[16]
8. Lower Extremity Functional Scale[16]
9. Global Rating of Change[17,18]
10. University of Wisconsin Running Injury and Recovery Index[19]

Baseline Visit 1 (Part 1)- Physical Examination:
Demographic information will be collected at this time by the Study Coordinators. Additionally, age, sex, height, and weight will be measured.
All measures listed in this section are non-invasive and are performed in the routine practice of athletic training, physical therapy, and musculoskeletal medicine in the assessment of patients.
9. Foot posture
    a. Arch Height Index[17]: measured by an Arch Height Index Measurement System in which subjects place their foot on a platform and an examiner will measure total foot length and truncated foot length in seated and weight-bearing positions.
    b. Foot Posture Index[21]: measured by having subjects march in place and then stand as they normally would as an examiner evaluates foot positioning from multiple views.
10. Leg length with tape measure[22]: measured by having subjects lie supine on a table while an examiner uses a fabric tape measure to determine the leg length from the anterior superior iliac crest of the hip to the medial malleolus of the ankle, repeated on both legs.
11. Pelvic alignment

    a. Pelvic Tilt: measured by having subjects sit on the edge of a treatment table, pull one thigh towards the chest and lay back onto the table to assess if the opposite leg comes up off of the table as a sign of anterior pelvic tilt, also called the Thomas Test.

12. Lower extremity passive range of motion
    a. Hip (flexion, extension, abduction, external rotation, internal rotation)
    b. Knee (flexion, extension)
    c. Ankle (dorsiflexion, plantarflexion, inversion, eversion)
    d. Foot (first ray mobility): measured by having subjects sit or lie on a treatment table while an examiner uses a goniometer of the first ray measurement tool to passively move the respective joints through the available range of motion.
13. Lower extremity flexibility
    a. Straight leg raise test: The subject will be asked to lie supine on a table while an examiner passively flexes the patient's hip while maintaining knee extension until the end range of motion is met.
    b. Weight-bearing dorsiflexion test: The subject will be asked to stand facing a wall with feet about 10 cm back from the wall with the other foot back, and bend the front knee until it touches the wall without the heel coming off the ground. If the knee can touch the wall without the heel coming off the ground, the subject will move the foot back progressively until the knee can just touch the wall without the heel coming off the ground.
14. Lower extremity strength measures: measured by having subjects assume different standardized testing positions while an examiner uses a hand-held dynamometer to measure movement forces.
    a. Hip extension with subjects in prone on a treatment table and knee bent
    b. Hip flexion with subjects lying supine on a treatment table
    c. Hip abduction with subjects side-lying on a treatment table
    d. Knee extension with subjects seated on a treatment table
    e. Knee flexion with subjects seated on a treatment table
    f. Plantarflexion with subjects in prone on a treatment table
    g. Dorsiflexion with subjects seated on a treatment table
    h. Inversion with subjects seated on a treatment table
    i. Eversion with subjects seated on a treatment table

Baseline Visit 1 (Part 1) -Functional Movement Assessment

The functional movement assessments were decided upon based on an expert panel of physical therapists currently assessing runners with leg pain in the clinic. To ensure that an appropriate clinical decision can be made when scoring the movement patterns, video recordings will be obtained from both the front and the side.

1. Star Excursion Balance Test
    a. The tester will first measure the subject's leg length. The test requires

subjects to balance on one foot and reach with the opposite foot as far as they can along a tape measure on the floor then return to standing on both feet. They will reach in eight different directions for three trials each direction for a total of twenty-four repetitions on the tested foot. Fifteen seconds of rest is given between repetitions. The tester measures the total distance reached (cm) of each repetition. This test will be completed for both legs.

2. Single Limb Squat
    a. The tester will first have the participant perform a double-limb squat while measuring the knee flexion angle with a plastic goniometer to assess when the participant reaches 45 degrees of knee flexion. A stool will then be set to the appropriate height such that the participant's gluteal fold will touch the seat when the knee is at 45 degrees of flexion. Participants will then be instructed to stand on one foot and squat down to the seat for two counts and up for two counts to return to the start position, facilitated with a metronome. This will be repeated three times, and then the same procedures will be performed on the opposite limb.
3. Lateral Step-Down
    a. Participants will stand on the edge of a 30-cm wooden box. Participants will then be asked to stand on one limb while keeping their hands on their hips, and squat down for two counts on the stance limb until their other foot just touches the ground, and then up for two counts to return to the start position. Timing will be facilitated with a metronome. This will be repeated three times, and then the same procedures will be performed on the opposite limb.
4. Gait Assessment on Non-Instrumented Treadmill
    a. Participants will be asked to jog at a comfortable speed on a non-instrumented treadmill for approximately 1 minute.

Functional Movement Scoring and Exercise Prescription

1. A blinded assessor will watch the functional movement screening videos to make a clinical judgement about the participants' alignment during the movements. A pre-generated excel spreadsheet will be used to input the data.
2. Based on the inputs, a personalized home exercise plan that was generated by the same expert physical therapist panel will be formulated such that each participant will have 4 home exercises to target their specific deficits during the activities.

Score criteria are listed in the table below.

VALGUS	NEUTRAL	VARUS
SINGLE-LEG SQUAT (CRITERIA 1)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray
LATERAL STEP-DOWN (CRITERIA 2)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray
STAR EXCURSION BALANCE TEST (CRITERIA 3)		
Posterior reach deficits, Medial knee displacement, Contralateral pelvic drop	90%+ of leg length reach performance, Center of patella maintains over first ray, No contralateral hip drop	Medial reach deficits, Center of patella tracks over lateral foot ray
ARCH HEIGHT INDEX/FOOT POSTURE INDEX (CRITERIA 4)		
Arch collapse Pronated foot position	Relatively stable arch, Neutral foot positioning	Immobile arch, Supinated foot positioning
GAIT ASSESSMENT (CRITERIA 5)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray

Baseline Visit 1 (Part 2) - Calibration Run

4. Subjects will be given RunScribe™ sensors and oriented to the use of the wearable sensors and the associated mobile phone application (RunScribe Labs, San Francisco, CA). The sensors consist of tri-axial accelerometers and are capable of measuring contact time, step rate, stride length, pronation excursion, maximum pronation velocity, shock (loading), and foot strike type at a 200 Hz measurement rate.
5. Sensors will be fitted and mounted on the laces of the participant's left and right shoes.
6. Subjects will run a 1.67-mile set running loop around UVA grounds just outside of the study laboratory building in order to calibrate the RunScribe™ system (Please see attached map).
7. Following the run, the data from both sensors will be downloaded onto the phone application, and the distance will be edited to complete the sensor calibration.

Baseline Visit 1 (Part 2) - Laboratory Gait Assessment

Three-dimensional joint kinematics of the ankle, knee, and hip will be measured using the Vicon motion analysis system controlled by Motion Monitor software. A force plate embedded in the treadmill will be used to collect ground reaction forces. A total of 8 clusters of markers will be placed on the upper back, lower back, lateral mid-thigh, lateral mid-shank, and the foot. Participant setup can be seen in image below. Electromyography (EMG) of lower extremity musculature (medial gastrocnemius, anterior tibialis, peroneus longus, and gluteus medius) will also be collected synchronously using wireless surface EMG electrodes. Once sensor set-up is complete, the participant will be instructed to run on the treadmill at their preferred running speed for 5 minutes. Once the subject is familiar with the treadmill and has completed the 5-minute warm-up, we will collect 3 trials of 30 seconds of running at the runners' preferred speed, and at a standardized 6.0mph speed.

Baseline Visit 1 (Part 2) - Participant Randomization

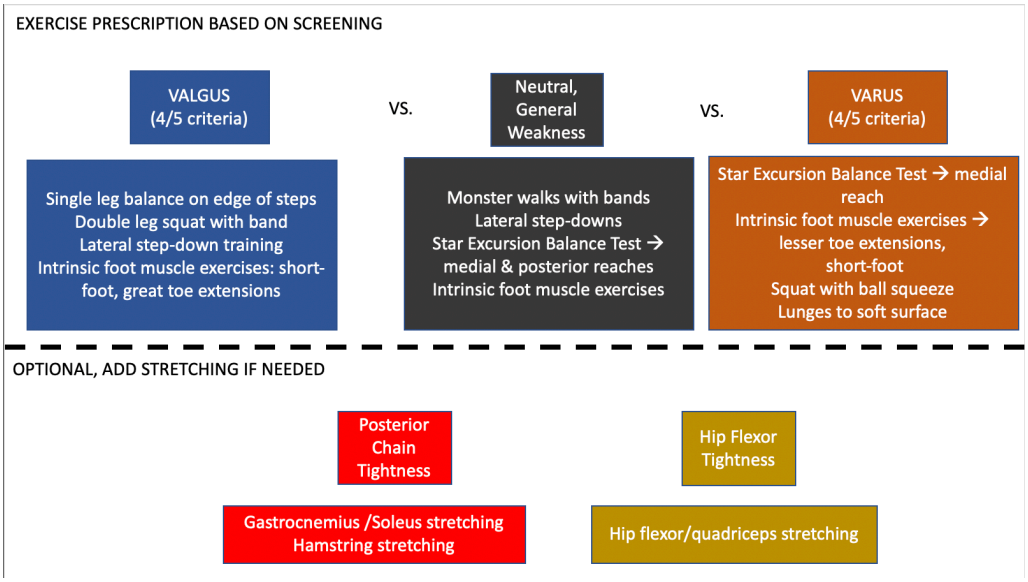
Following all baseline measures, participants will be randomized into either a standard of care home exercise (control) group or gait-training with standard of care (intervention) group using blinded randomization. The randomization sequence will be created *a priori* with a random-number generator, and allocation will be placed in a sealed opaque envelope by the Principal Investigator to blind Study Coordinator I administering the intervention at baseline. At this time, both groups will be given a link (Please copy and paste the link into your browser address bar to view the videos: https://drive.google.com/open?id=1-z3p8oYclRrIawAViB7L2Tyb8mumRLVN) for video instructions on home exercises to complete during the study period, and instructions on how to use the RunScribes with compatible mobile devices. All participants will also be asked to keep notes within the phone application to document the details of the run, as well as pain levels during activity.
At this time, the intervention group will additionally receive a Garmin smart watch. The intervention group will download the RunScribe application onto their Garmin smart watches to facilitate the feedback intervention, and will receive video and verbal instructions on how to perform the gait-training feedback. The participants will also be given the opportunity to practice the feedback on the instrumented treadmill for supervised instruction for 15 minutes or until they feel comfortable with the instructions. The feedback will be focused on the contact time metric. The participants will feel a vibration on their wrist when they exceed an upper limit threshold, and will be instructed to pick their feet up more quickly.

Intervention Procedures

The control and intervention procedures will be administered for 8 sessions over 4 weeks, with weekly check-ins back at the laboratory to progress the home exercises based on specific movement criteria, provide instructions on the feedback, and repeat patient-reported outcome measures. The interventions will appear as follows:

	Intervention	Control
Session 1, Week 1	100% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Session 2, Week 1	100% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Weekly Check-In		
Session 3, Week 2	100% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Session 4, Week 2	100% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Weekly Check-In		
Session 5, Week 3	50% feedback for a run of at least 3 miles with RunScribes and Garmin watch Progressed Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Session 6, Week 3	50% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Weekly Check-In		
Session 7, Week 4	25% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises
Session 8, Week 4	25% feedback for a run of at least 3 miles with RunScribes and Garmin watch Home Exercises	Run of at least 3 miles with RunScribes Home Exercises

The potential list of home exercises is depicted in the figure below:



4-Week Timepoint Procedures

At the end of the 4 weeks, participants will return to the lab to repeat baseline 1 and 2 procedures, including questionnaires, physical examination measures, functional movement assessments, the instrumented treadmill gait analysis, and the 1.67-mile run using the same RunScribe wearable sensors. At this time once all measures have been completed, all participants will return the RunScribe sensors, Garmin watches.

6-Week Timepoint Procedures

At 6 weeks, participants will be contacts once more to return to the laboratory to repeat all questionnaires, and re-run the 1.67-mile run using the RunScribe wearable sensors. At this time, participants will be finished with all study procedures.

8. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.

Example: If the subject will be taking an investigational drug, will they need to be put back on an approved drug when they have completed the study? If yes, explain how this will be accomplished and who will cover the cost. If the subject has a device implanted will it be removed? Again- who will cover the cost of the removal?

Instructions: Answer NA if this study does not involve a study treatment.

Answer/Response: N/A - this is not a treatment study.

Bibliography

INSTRUCTIONS: Provide a current bibliography supporting the hypothesis, background and methodology including references to papers and abstracts that have resulted from previous work by the investigator and references to the work of others.

1. U.S. Road Race Participation Numbers Hold Steady for 2017 - 2018 U.S. Running Trends Report. https://runningusa.org/RUSA/News/2018/U.S._Road_Race_Participation_Numbers_Hold_Steady_for_2017.aspx. Accessed August 31, 2018.
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14. Bijur PE, Silver W, Gallagher J. Reliability of the Visual Analog Scale for Measurement of Acute Pain. *Acad Emerg Med*. 2001;8(12):1153-1157. doi:doi/10.1111/j.1553-2712.2001.tb01132.x/epdf
15. Helmerhorst HHJ, Brage S, Warren J, Besson H, Ekelund U. A systematic review of reliability and objective criterion-related validity of physical activity questionnaires. *Int J Behav Nutr Phys Act*. 2012;9(1):103.
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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study. Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

The Mid-Atlantic Athletic Trainers' Association will be funding this study.

Key Information About This Research Study

Principal Investigator:	Jay Hertel, Ph.D., ATC Department of Kinesiology, University of Virginia PO Box 400407 Charlottesville, VA 22908 (P) (434) 243-8673 **(E) jnh7g@virginia.edu**

You are being asked to take part in a research study. You do not have to take part in this study.

You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

This study is trying to find out if gait-training during running in addition to common home exercises is more beneficial in terms of running patterns and pain levels than home exercises alone for runners with lower leg pain.

You are being asked to take part in this study because you are a runner with lower leg pain, and have been running for at least 3 months.

Why would you want to take part in this study?

You might like to take part in this study because you will have access to all of the data from the sensors during the study which will give you an idea of how you are running. Additionally, your leg pain may decrease from the study procedures. The information researchers get from this study may help other runners with leg pain in the future.

Why would you NOT want to take part in this study?
You might not want to take part in this study because this requires several laboratory visits, remembering to wear the sensors and record runs over the study timeframe. You may have some soreness in your legs from strength testing. Mild muscle soreness during or after home exercises may occur. Muscle soreness during or after testing/your calibration run may occur rarely. Your leg pain may not improve or worsen during the study period.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form.
If you take part in this study you will:

- Complete health and running questionnaires
- Complete squatting, running, and balance assessments
- Complete a physical exam including measurements of foot, leg, and hip alignment, flexibility, and strength
- Run on a treadmill for about 10 minutes, and outdoor running for about 5 minutes
- Download the RunScribe^{TM} application onto your smartphone and use a set of running sensors for each run you do during the study timeframe
- If you are in the intervention group, wear a watch and run with feedback for 8 sessions over 4 weeks and complete rehabilitation exercises at home
- If you are in the control group, complete rehabilitation exercises at home
- Come back into the lab for weekly check-ins
- Come back at 4 weeks to repeat a physical exam, treadmill, and brief outdoor running and return sensors and watches (if applicable)
- Come back 2 weeks later to repeat a brief outdoor run

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

- Running with sensors
- Complete specific rehabilitation exercises
- If you are in the intervention group, wear a watch and change your running form based on the feedback

Up to 46 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require 6 study visits over 6 weeks. The first and the fifth visits will take about 2.5 hours, the third-fifth and seventh visits will take about 20-30 minutes.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

SCREENING (~15 minutes)

Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- COVID-19 screening assessment
- We will ask you questions about your age, running experience and mileage, details about your lower leg pain, and past injuries, surgeries, and other medical history.
- Physical examination of your lower leg
- Height and weight assessment

If these items show you are eligible, you may begin the study immediately, or you may return at a later date to begin the study.

If you are eligible and agree to participate in this study, you will be asked to fill out some questionnaires prior to coming into the lab. These questionnaires will ask about:

- General medical history
- Physical activity level
- Exercise-related lower leg pain
- Running Injury and Recovery Index
    - This will ask you about how your leg pain affects your running, and how much recovery you feel you have made over time

It will take about 15 minutes to complete all questionnaires.

STUDY PROCEDURES

Visit 1 (~2.5 hours)

Physical Exam

Once you have completed the questionnaires and come into the lab for participation, you will have a physical exam. This will include:

9. Measurement of foot posture, by placing your foot on a platform while your foot length is measured, while seated and standing. We will ask you to march in place and then stand as you normally would as your foot is moved in several different ways.

10. Measurement of leg length while lying down. You will lie on a table while a member of the study team measures your legs from your hip bone to your inner ankle bone.
11. Measurement of hip alignment while standing and lying on a table.
12. Measurement of hip, knee, ankle, and foot motion while sitting or lying on a table.
13. Measurement of hip, knee, and ankle flexibility while sitting or lying on a table.
14. Testing of hip, knee, and ankle strength with investigator providing resistance (pushing or pulling) while sitting or lying on a table.

Functional Movement Assessment

1. You will balance on one foot while reaching in different directions.
2. Squat on one leg down from a box.
3. Squat on one leg down to a stool.
4. Run at your own pace for several minutes on a basic treadmill.
5. The functional assessment will be video recorded. The recordings will be used to personalize a home exercise plan.

Running with Wearable Sensors

6. You will need to have access to a smart phone device, and download the RunScribe™ application to keep track of your runs.
7. You will receive a demonstration on how to use the wearable sensors on your shoes and the RunScribe app. Your shoes will be fitted with the RunScribe lace sensors.
8. You will complete a 1.67 mile run outside and the data from the sensors will be downloaded into the app in order to calibrate the sensors.

Running on a Treadmill

You will complete the indoor running portion of the study.

3. You will have sensors attached to your skin that will record how you move and how your muscles turn on during running.
4. With the sensors on, you will run for up to 10 minutes on a treadmill at a pace of 6 miles per hour.

After you complete this visit, you will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups. You cannot choose to which group you are assigned.

GROUP 1: If you are in group 1, you will be given a pair of sensors to wear on your shoes and download the RunScribe application onto your phone during the study. You will also do home exercises during the study. You will be asked to come into the laboratory weekly for about 30 minutes per visit to progress the home exercises (visits 2, 3, and 4).

GROUP 2: If you are in group 2, your will be given a pair or sensors to wear on your shoes and download the RunScribe application onto your phone during the study. You will also be given a Garmin watch to get information from the sensors to the watch for feedback, or information on how you are running. You will also do home exercises during the study. You will be asked to come into the laboratory weekly for about 30 minutes per visit to progress the home exercises and get instructions on feedback for the next week (visits 2, 3, and 4).

FOLLOW UP:

At the end of 4 weeks, you will return to the Exercise and Sport Injury Lab, you will complete the same procedures as you did on Visit 1. At this time, you will return all study equipment (sensors and watch, if applicable). Two (2) weeks later, you will be asked to return to the Exercise and Sport Injury Lab to run 1.67 miles with the RunScribe wearable sensors.

Study Schedule

	Visit 1 (Screening and Baseline)	Study Period	Visit 5 (4-week Follow-up)	Visit 6 (6-week Follow-up)
Study Week	0	1-4	4	6
Informed Consent	X			
Review study eligibility (Screening)	X			
Questionnaires	X	X	X	X
Physical Exam	X		X	
Functional Movement Assessment	X		X	
Treadmill Running	X		X	
Running with Wearable Sensors	X	X	X	X
Home Exercise/ Running Instruction	X	X		
Weekly Check-Ins		X		

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.
These responsibilities are listed below:

h. Attend all study visit time points.
i. You must be completely truthful about your health history.
j. Follow all instructions given.
k. Complete all runs and home exercises over the study period.
l. Keep a running, exercise, and pain log on your RunScribe phone application.
m. Upload all runs to the RunScribe dashboard following exercises.
n. Answer all of the study-related questions completely.
o. You should tell the study staff about any changes in the way you feel.

If you want to know about the results before the study is done:

During the study you are having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you may ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the study include:

5. Mild muscle soreness during or after strength testing may occur rarely
6. Mild muscle soreness during or after home exercises may occur rarely
7. Mild muscle soreness during or after treadmill running/your calibration run may occur rarely
8. Leg pain may not improve or worsen, occurs rarely

Risks of Videotaping/Audio taping:

For part of this study, you will be videotaped so that we can look at your movement patterns during squatting, balance, and running tests. There is a potential your face will be seen on the video. As soon as you complete the visits where you will be videotaped, an assessor will score the videos, and then they will be immediately deleted. No one else will see these videos.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include decreased leg pain and increases in leg strength and/or flexibility. You will have access to all of your running data during the study time. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your leg pain. However, the usual treatment would include the same or similar exercises given to you in this study.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $50 at the half-way point and $50 at the end of the study by check.

You should get your payment about 2 weeks after each payment point. The income may be reported to the IRS as income.

You will not be paid at all if **you** decide not to finish this study. If the study leader says you cannot continue, you will be paid the full amount for the study.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a. You become injured and can no longer participate in the study
b. The study is closed for safety, administrative, or other reasons
c. Your study leader is concerned about your health
d. Your injury gets worse
e. The side effects of the study procedures are too dangerous for you
f. New information shows the study will not work or is not safe for you
g. You do not follow your study team's instructions

If you decide to stop being in the study, we will ask you to return all sensors and, if applicable the Garmin watch, and delete the RunScribe off of your mobile phone.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who evaluate study results
- Tax reporting offices (if you are paid for being in the study)
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study will not be used in future research.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Jay Hertel, Ph.D., ATC
Department of Kinesiology, University of Virginia
PO Box 400407
Charlottesville, VA 22908
Telephone: 434-243-8673
Email: jnh7g@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

_____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.
Health Care Provider Name:
Health Care Provider Address:
Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study or I do not have a health care provider.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by:

1) Sending me questionnaires once
2) In person follow up visit to repeat baseline visit 1 procedures.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

14707 Pre-Screening Form

QUESTIONNAIRE	YES	NO
Are you between 18-45 years old?		
Are you currently involved in running at least two times per week amounting to at least 6 miles?		
Have you been running for at least 3 months?		
Have you had any previous surgeries on either foot, leg, knee, thigh, hip, or for your lower back within the past year?		
Have you had any injuries to either foot, leg, knee, thigh, hip, or to your lower back within the last 3 months?		
Do you have any numbness/tingling in either leg?		
Have you ever been diagnosed with Parkinson's disease, Multiple Sclerosis, or other neurological disorders?		
Are you currently pregnant?		
Do you have any other conditions that are currently preventing you from running?		

Table C2c – Institutional Review Board Documents – Manuscript 3

RESEARCH APPLICATION

Investigators Experience

INSTRUCTIONS:
Provide a brief description of the investigators experience in working with this population in the clinical and research arena.
If this study will be done in a foreign country, add their experience working within the foreign country.

Answer/Response:

Dr. Jay Hertel, PhD, ATC
Dr. Hertel is a certified athletic trainer and is the director of graduate programs in Athletic Training & Sports Medicine and co-director of the Exercise & Sports Injury Lab at the University of Virginia. He has been the primary investigator for numerous studies through the University of Virginia's IRB-HSR, with primary research interests in lateral ankle instability, and additional interests in lower extremity biomechanics during functional tasks.

Study Coordinator I – Alexandra DeJong, MEd, ATC
Ms. DeJong is a certified athletic trainer and graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Ms. DeJong's research focus is in lower extremity biomechanics during gait. Ms. DeJong has participated in a previous descriptive laboratory studies while completing thesis and doctoral requirements at the University of Virginia.

Study Coordinator II – Natalie Kramer, MEd, ATC
Ms. Kramer is a certified athletic trainer and graduate assistant in the PhD program in Sports Medicine at the University of Virginia. Ms. Kramer's research focus is in athlete monitoring using wearable technologies. Ms. Kramer has participated in a previous descriptive laboratory studies while completing thesis and doctoral requirements at the University of Virginia.

Sub-Investigator – Pamela Fish
Ms. Fish is an undergraduate Kinesiology major at the University of Virginia and has previously worked as a research assistant for an IRB-HSR study at the University of Virginia. Ms. Fish will assist with data collections under the direct supervision of a study coordinator.

Sub-Investigator – Miranda Furtado
Ms. Furtado is an undergraduate Kinesiology major at the University of Virginia and has previously worked as a research assistant for an IRB-HSR study at the University of Virginia. Ms. Furtado will assist with data collections under the direct supervision of a study coordinator.

Sub-Investigator – Haoyu Wang
Mr. Wang is a Computer Science doctoeal student who has expertise in working with large datasets and will be an asset in the project for building a database and creating algorithms to interpret de-identified sensor output data. Mr. Wang has experience working as a research assistant at the University of Virginia working with cloud computing, data center networks, and social networks. Mr. Wang will help with data processing and will work with the study coordinators for this study.

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

5. I am not currently debarred by the US FDA from involvement in clinical research studies.
6. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
7. That if this study involves any funding or resources from an outside source or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
8. The protocol will abide by the ethical standards of The Belmont Report
9. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
10. That no personnel will have access to subjects in this protocol or their information until they have completed the human subject research protection on-line training through CITI and the IRB-HSR has been notified.
11. That all personnel working on this protocol will follow all Policies and Procedures of:
    - the UVA Human Research Protection Program (HRPP SOPS)
    - the IRB-HSR http://www.virginia.edu/vprgs/irb/
    - the School of Medicine Clinical Trials Office: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm.
    - and any additional UVA requirements for conducting research.
12. I will ensure that all those personnel delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training, experience or credentialing to undertake those tasks.
13. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.

14. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
15. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
16. That all subjects will give informed consent unless the requirement has been specifically waived by the IRB.
17. That unless written consent has been waived by the IRB all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
18. They will establish and maintain an open line of communication with research subjects within their responsibility.
19. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
20. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
21. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
22. That any serious deviation from the protocol will be reported promptly to the Board in writing.
23. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
24. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
25. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
26. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI leaves UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
27. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
28. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept according to UVA Records Management policies.
29. No data/specimens may be taken from UVa without a signed Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.

30. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

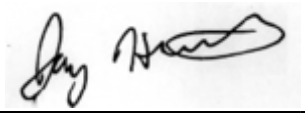
IF THE IRB-HSR WILL BE THE IRB OF RECORD FOR MULTIPLE SITES IN A MULTISITE TRIAL, THE UVA PI AGREES TO CARRY OUT THE FOLLOWING RESPONSIBILITIES:

12. Ensure all UVa personnel designated as Conflict of Interest Investigators complete Reviewing IRB's financial interest disclosure requirements unless the UVa personnel will adhere to the UVa conflict of interest policies that are compliant with DHHS requirements.
13. Promptly provide the Principal Investigator at each site with:
    a. Current approved protocol and consent documents;
    b. Approved modifications, amendments or changes to research protocols; and
    c. Approval of continuing reviews and reviews of unanticipated problems;
14. Notify the Principal Investigator at each site of standards and guidelines for reporting any post approval events such as adverse events, subject injuries, unanticipated problems, and protocol violations. Collect reports from Principal Investigator at each site of any unanticipated problems, deviations, suspensions and terminations, non-compliance, subject complaints, and submit such reports to Reviewing IRB per reporting requirements.
15. Notify the Principal Investigator at each site promptly of any unanticipated problems involving risks to subjects or others as determined by the Reviewing IRB.
16. Collect required information from the Principal Investigator at each site necessary for completing continuing review submissions.
17. Notify the Principal Investigator at each site promptly about any lapses of approval. Forward to the IRB of Record any request from the Principal Investigator of a site for continuation of a specific research subject on a protocol during a lapsed period of approval.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Signatures

Principal Investigator



_____	____Jay Hertel_____	_7/26/2019__
Principal Investigator Signature	Principal Investigator Name Printed	Date

INSTRUCTIONS:
The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

Department Chair or Designee

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

- To work with the investigator and with the board as needed, to maintain compliance with this agreement.
- That the Principal Investigator is qualified to perform this study.
- That the protocol is scientifically relevant and sound.
- He/she is not the Principal Investigator or a sub investigator on this protocol.

_____	___Arthur Weltman____	_7/26/2019___
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

INSTRUCTIONS:
The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
If the Department Chair fills one of these rolls on this protocol, the Department Chair's supervisor must sign here.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

Brief Summary/Abstract

INSTRUCTIONS:
Provide a very brief summary or abstract of this study (500 words or less). Include the purpose or hypothesis, a brief description of the experiment, and plans for data analysis.
DO NOT Reference the sponsors protocol here.
If you plan to deviate from the Sponsor's protocol in any way, such as not doing certain sub-studies, include a description of those deviations in this summary.
For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no sponsors/common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/procedures/data points.

There are two primary purposes of this study. The first aim is to prospectively collect and monitor runners' biomechanics (impact g's, braking g's, pronation excursion, pronation velocity, and spatiotemporal measures) using wearable sensor during typical running training in conjunction with subjective patient-reported outcomes of well-being. These data will be used to form a database of internal and external load metrics as they pertain to performance over time among a representative running cohort. The other primary aim is to measure runners' anthropometrics (strength, flexibility, and alignment) and running biomechanics (lower extremity joint angles, moments, and forces) using traditional indoor laboratory analyses to build a representative database of runners' movement profiles and to contextualize the findings obtained from the wearable sensors.

Sponsor

INSTRUCTIONS:
9. If you have internal funding from your department to conduct this study list the department as the sponsor.
10. If you have external funding, list names of companies, institutes, foundations with which you have a grant or a contract to conduct this study.

Example: This study is funded via a contract with the University of New York, which has a grant from the NIH to conduct this study.

9. Explain the sponsorship for this study.
Answer/Response:
There is no external sponsorship.

Support Source

INSTRUCTIONS:

The support source is any source outside of UVA providing support such as supplies/drug/device's or financial assistance. The entity should NOT be considered a Support Source if they are taking on the responsibilities of a sponsor such as monitoring, safety oversight or data analysis. Do not enter a company/ organization as a supply source unless the support has been secured. The IRB-HSR must be notified and the consent form revised if a support source changes. (Example-the NIH or an investigator-initiated study in which the pharmaceutical company is providing drug free of charge.)

1 .Describe what will be provided and by whom.

Answer/Response:

N/A

Research Involving Students and Employees as Subjects

INSTRUCTIONS: Information on this topic that may be helpful in answering these questions may be found on the IRB-HSR Website at Vulnerable Subjects: Students and Employees.

1. **Explain which study procedure the employees or students will participate in.** (i.e. all procedures, lab controls, MRI dry run)?

   Answer/Response:

   Employees or students may participate in this study based on the specific inclusion criteria, and as such would participate in all procedures.

2. **Provide justification for recruitment of the employee/student in this research proposal**: *You are required to provide a rationale other than convenience for selecting this group.*

   Answer/Response:

   Student participants will be recruited from UVA's varsity cross-country and track teams to obtain a sample of competitive young adult runners, and flyers and advertisements around UVA grounds or local running clubs in the Charlottesville community may attract employees or other student participants to enroll in the study.

3. **Does the Principal Investigator of this study directly supervise/evaluate the Employee/Student within the work or educational setting?** E*mployees and students assigned to a particular investigator or laboratory should not be directly recruited for participation in any study conducted by that investigator or laboratory, although such employees and students may, on their own, volunteer to participate.*

   Answer/Response:

The Principal Investigator will not be in the position of directly supervising or evaluating the participants in this study. All participation by UVA students or employees will be strictly voluntary.

4. **Explain what provisions are implemented to mitigate the risks involved in including employees/students as subjects in the study.** *(e.g., ensuring that participation is voluntary, course grades will not be based on research participation, informed consent will be obtained from the subject by an individual other than the person in a position of power; the researcher will not have access to the data collected until after the class grades have been posted)*

Answer/Response:

Participation in this study is voluntary, and informed consent will be obtained from all participants by an individual who is not in a position of power over the subjects. Salary and course grades will not reflect participation in this study. All participants will be compensated equally for participation in this study.

5. **Describe how students and employees are recruited for this study. (e.g.- verbal scripts, flyers, listservs, and/or web-based systems for student subject pools)** *Recruitment and consent of student/employee subjects are not held to a different standard in the IRB review process, and the researchers must ensure that the recruitment and informed consent processes minimize the possibility of coercion or undue influence and maintain subject confidentiality.*

Answer/Response:

Competitive young adult runners will be recruited from the UVA varsity cross-country and track teams. A member of the study team will attend a practice session for these teams, explain the study methods, and answer any questions that may arise from coaches, athletes, and/or athletic trainers. Additional runners will be recruited from the community through flyers and advertisements placed on the UVA grounds, the Charlottesville community, and local run clubs.

6. **Is there financial or other types of compensation offered for participation in this study for students and employees who are participating?**

Answer/Response:

There will not be a compensation for participating in this study.

If YES, describe the amount and/or nature of this compensation/alternative which should include equal methods for meeting course credit (or extra credit) requirements, such as attending a series of research presentations by faculty, writing a brief paper, conducting one's own research.

Answer/Response:

Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subjects interest in the study.
*The UVa HIPAA covered entity includes the UVa Health System including the School of Medicine& the School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.
PHI may also be shared without tracking disclosures with the following groups as agreements are already in place: VP Office of Research, Nutrition Services (Morrison's) and the UVA Center for Survey Research.

p. How do you plan to <u>identify</u> potential subjects?

- To "identify" a potential subject refers to steps you plan to take to determine which individuals would qualify to participate in your study. This does NOT include steps to actually contact those individuals.
- If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being identified by the given method.
- Check the methods you plan to utilize:

a.____ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project (*e.g. Performance Improvement, Practice Improvement, Quality Improvement*).
<u>If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) please see option b below.</u>

<u>DHHS:</u>
<u>Pre 2018 Common Rule:</u> Study team requests Waiver of Consent to identify prospective subjects.
<u>2018 Common Rule:</u> Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.

<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.

<u>IMPORTANT</u>

Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
--a volunteer approved by the School of Medicine

b____ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research database or use of data from a separate current active research protocol.
If you plan to obtain data from the UVa Enterprise Data Warehouse (EDW) you are required to submit your request to the CDR. The CDR staff will work with the EDW to obtain the data you need.

DHHS:
Pre 2018 Common Rule: Study team requests Waiver of Consent to identify prospective subjects.
2018 Common Rule: Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.

HIPAA: Allowed under Preparatory to Research if PHI to be accessed.

IMPORTANT
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they who meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
--a volunteer approved by the School of Medicine

The information from which you are obtaining potential subjects must also have an IRB protocol approval. If this item is checked, enter the IRB # below.

IRB# _____

If obtaining information from the Clinical Data Repository (CDR) insert IRB # 10797

c. ____ Patients UVa health care provider supplies the UVa study team with the patients contact information without patients' knowledge.

DHHS:
Pre 2018 Common Rule: Study team requests Waiver of Consent to identify prospective subjects.
2018 Common Rule: Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.

HIPAA: Allowed under Preparatory to Research if PHI will be shared by the health care provider.

IMPORTANT
Keep in mind that PHI may only be given to individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
--a volunteer approved by the School of Medicine

d. ____ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be the a member of the study team)

DHHS: NA
HIPAA: Allowed under Health Care Operations

If this choice is checked, check 3d-INDIRECT CONTACT below.

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

If this choice is checked, check 3d- INDIRECT CONTACT below.
DHHS & HIPAA: NA

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.

IRB# of registry/ database: _____

DHHS & HIPAA: NA

g. __X__ Other: Specify Answer/Response: Potential subjects will be identified by virtue of their presence on the UVA XC/Track team.

If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true?

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

Answer/Response:

q. How will potential subjects be contacted?

To "contact" a potential subjects refers to the initial contact you plan to take to reach a potential subject to determine if they would be interested in participating in your study. This may include direct contact by such methods as by letter, phone, email or in-person or indirect contact such as the use of flyers, radio ads etc.

If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being contacted by the given method.

Check the methods below you plan to utilize:

a. ____ Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

Note: Letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

Pre 2018 Common Rule:

DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.

2018 Common Rule:
DHHS:
Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.
HIPAA: Study team requests a Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:
Keep in mind that if PHI was collected during the identification phase that contact with potential subjects may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- a UVa student working in the UVa HIPAA Covered Entity*
- a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
- a volunteer approved by the School of Medicine

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

Pre 2018 Common Rule:
DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.

2018 Common Rule:
DHHS:

Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.
HIPAA: Study team requests a Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:
Keep in mind that contacting individuals in a clinical setting may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
a UVa student working in the UVa HIPAA Covered Entity*
a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*

You should share the following information with the potential subject:

- Your name
  - Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
  - Ask if you have their permission to explain the study to them
- If asked about how you obtained their information use one of the following as an option for response.
  - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN: Your doctor, Dr. insert name wanted you to be aware of this research study and gave us permission to contact you.
  - We obtained your information from your medical records at UVa.
  - Federal regulations allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.
- IF THE PERSON SEEMS ANGRY, HESITANT OR UPSET, THANK THEM FOR THEIR TIME AND DO NOT ENROLL

THEM IN THE STUDY. YOU MAY ALSO REFER THEM TO THE IRB-HSR AT 924-9634.

c.____Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.

Pre 2018 Common Rule:
DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPAA: Allowed under Health Care Operations.

2018 Common Rule:
DHHS:
Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.
HIPAA: Allowed under Health Care Operations.

d.___X_ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

DO NOT UNCHECK THIS BOX EVEN IF YOU DO NOT INTEND TO USE THIS RECRUITMENT METHOD AT THIS TIME.
The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need to review any type of script to use when the potential subject responds to the indirect method.

DHHS & HIPAA: NA

- ○ __X__ Potential subjects are not patients. The study does not include obtaining subjects health information. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

When entering a classroom to recruit students and conduct research, e.g., administer a survey, investigators must do so at the end of the class period to allow non- participating students the option of leaving the classroom, thereby alleviating pressure to participate.

Pre 2018 Common Rule:
DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPAA: NA

2018 Common Rule:
DHHS:
Allowed under Preparatory to Research if the investigator will identify subjects through oral or written communication with prospective subject or LAR OR the investigator will obtain identifiable private information or bio-specimens by accessing records or stored identifiable bio-specimens.
HIPAA: NA

3. Will any information be obtained from a potential subject during "prescreening"?

Pre-screening for IRB purposes is the term used to describe activities PRIOR to obtaining Informed Consent and may not include any research procedures.

The activities may involve pre-screening of potential subjects over the telephone or in person to determine their initial eligibility for, and, interest in a study and is a common strategy in the recruitment process.

Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times.

It is NOT appropriate at this point in the process (i.e. prior to obtaining informed consent/enrollment) to gather information that is not directly related to assessing eligibility and suitability (e.g. obtaining complete medical histories, obtaining blood specimens for lab tests).

An additional telephone script is not required, for this pre-screening process, in addition to any scripts required under Recruitment question # 2.

Answer/Response:
Yes.

IF YES, submit any documents that will be used to collect pre-screening information so that the IRB may confirm what questions will be asked. NOTE: To comply with HIPAA regulations only the minimum necessary information may be collected at this time. This means that only questions pertaining to the Inclusion and Exclusion Criteria may be asked.

IF YES,
DHHS:

Pre 2018 Common Rule: Study team requests a Waiver of Documentation of Consent for Pre-screening questions.

2018 Common Rule: No waiver of documentation of consent required per 45CFR46.116 (g).

45CFR46.116(g) an IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subjects legally authorized representative if either of the following conditions are met:

1. *The investigator will obtain information through oral or written communication with the prospective subject or LAR or*
2. *The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.*

HIPPA:
HIPAA does not apply if:
--no PHI is collected or
--if PHI is collected from a potential subject by an individual from a department that is not part of the HIPAA covered entity.

HIPAA does apply if the collection occurs by individuals* who work in a department that is part of the HIPAA covered entity.

In this case the collection will be covered under Health Care Operations/

These individuals are those that meet one of the following criteria:

--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in an appointment in the UVA HIPAA Covered Entity*
--a volunteer approved by the School of Medicine

IF YES, Will any of the questions involve health information?
Answer/Response:
Yes.

IF YES, will you collect HIPAA identifiers with the health information?
Answer/Response:
Yes.

IF YES, which HIPAA identifiers will be recorded?
Answer/Response:
Name and contact information.

Do you confirm that health information with HIPAA identifiers will not be shared outside of UVa until a consent form is signed or only shared in a de-identified manner?
Answer/Response:
Yes.

r. Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?

For example: come to the first visit fasting, stop taking medications that may be an exclusion criteria, change diet. As this is still part of pre-screening one is not allowed to gather information that is not directly related to inclusion/exclusion criteria or other issues of suitability (e.g. is person able to come to UVa for multiple visits)

NOTE:
Only those members of the study team with a DEA# (license to prescribe drugs) are allowed to determine if a potential subject may be asked/informed to stop taking a drug which is an exclusion criteria.
It is recommended that the potential subject notify their health care provider if they plan to stop a prescription drug.

Answer/Response:
No.

►**IF YES, explain in detail what you will ask them to do**.
Answer/Response:

Tips to Study Team

You must document their verbal consent in the study records.
If a subject is asked to stop taking a drug, document the date and name of the person on the study team giving the verbal order to stop medications (again- must be a person with a DEA#).

DHHS: Study team requests the use of Verbal Consent (Waiver of Documentation of Consent) for minimal risk screening procedures.

HIPPA:
If the individual, obtaining consent, works under the HIPAA Covered Entity this is covered under Health Care Operations
If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

s. How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?

HIPPA:
If the individual, obtaining consent, works under the HIPAA Covered Entity consenting is covered under Health Care Operations.

If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

Describe the setting for the consent process.
If the study is of a sensitive nature and/or includes a reference to a medical condition how will you protect the privacy of the potential subject when they are approached to participate?
Who will discuss the study with the potential subject?
Where will the consenting process take place?
How will you assess subject understanding?
How much time will pass between obtaining written consent and initiation of study procedures?
See Protocol Examples: Consenting Process for examples of how to answer this question.
If recruiting minors, specify how parental /guardian consent will be obtained prior to approaching the minor.

Answer/Response:
Participants will report to the Exercise & Sports Injury Laboratory (EASIL) in Memorial Gymnasium to provide informed consent. One of the study coordinators will discuss the study with the potential participant. Participants will be given the opportunity to ask questions or clarify information to ensure understanding, and written informed consent will

be obtained. The study procedures will begin immediately after eligibility is determined or the subjects could choose to return at a later date to proceed with the study.

6. Will subjects sign a consent form for any part of the study?

Answer/Response:

Yes, written consent will be obtained from all participants.

7. Will the study procedures be started the same day the subject is recruited for the study?

Answer/Response:

Yes, the study procedures may begin immediately after eligibility is determined and informed consent is obtained, or the subjects could choose to return at a later date to proceed with the study.

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.

Answer/Response:

The subject may feel comfortable consenting to the study at the initial screening in which case they can consent immediately, or if they do not feel comfortable, they will be given time to consider consenting.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.

Answer/Response:

The potential participant will be given as much time as they need to make an informed decision. They may come back at a later date if they do not wish to consent immediately.

8. Is there the potential to recruit a vulnerable population? (e.g. economically or educationally disadvantaged subjects, or other vulnerable subjects such as students , employees, investigator is health care provider of potential subject, pregnant women, children or prisoners?

INSTRUCTIONS: If you will be recruiting patients from the UVa Health System, you must answer this question YES as the UVa Health System cares for patients who are economically disadvantaged.

Answer/Response:

Yes, there is the potential to recruit a vulnerable population as flyer and advertisements will be posted around the Charlottesville community, and UVA cross country/track athletes will be included in the study design. Students and employees may participate in this study. See section above, entitled Research Involving Students and Employees as Subjects.

IF YES, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?

Check all applicable options:

____ Consent will be obtained by the CRC rather than the Investigator

__X__ Subjects will be assured that their relationship with their UVA health care providers will not be affected if they decide not to participate

__X__ Subjects will be given all the time needed to make their decision, and will not be pressured for a quick decision. They will be encouraged to seek advice from friends and family before signing consent.

___X_ Employees will be reassured that their decision will not affect their job or benefits.

___X_ Students will be reassured that their decision will not affect their status as a student or their grades.

____ If minors are enrolled, parental permission will be obtained prior to explaining the study to a minor and the minor's assent will be obtained prior to initiation of study procedures.

__X__ all subjects, especially those who are educationally disadvantaged will be asked open ended questions to confirm that they understand the study.

___ Other Explain:

9. Do you need to perform a "dry run" of any procedure outlined in this protocol?

A "dry run" is a procedure done to validate the system used to obtain results. It requires a human "subject" however the results of the dry run are used for system validation and not for the actual research. A common example a "dry run" is the validation or qualification MRI scans required by sponsor to ensure the MRI at UVa is able to perform the study-required scans.

- **If you are doing a sponsored study that involves an MRI for research, you are encouraged to say YES to this question**
- If YES, complete and submit a Consent for a Dry Run Procedure
- A template for a Consent for Dry-Run MRI is located under FORMS on the IRB Website
- IF YES, answer the following questions.

Answer/Response:

No.

9a. List the "dry run" procedure(s) that must be performed.
Answer/Response:

9b. How many "subjects" will be recruited for "dry run" procedures?
These "subjects" should NOT be counted with your total enrollment figures.
Answer/Response:

9c. Describe the recruitment procedures for those participating in the "dry run".
Answer/Response:

9d. Will those participating in the "dry run" be compensated?
IF YES, add the "dry run compensation" as a line item to the payment section of this protocol.
Answer/Response:

9e. Who will pay for the cost of the "dry run" procedure(s)?
Answer/Response:

10. Is the study regulated by the Department of Defense (DoD)?
Answer/Response:
No.

If YES, do you confirm the following protections will be in place for military research participants to minimize undue influence?
Answer/Response:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

If YES, do you also confirm that the following procedures will be in place to require limitations on dual compensation?
Answer/Response:

- Prohibit an individual from receiving pay of compensation for research during duty hours.

- An individual may be compensated for research if the participant is involved in the research when not on duty.
- Federal employees while on duty and non- federal persons may be compensated for blood draws for research up to $50 for each blood draw.
- Non-federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

11. **Non-Monetary Retention Incentives**

If subjects will be provided with non-monetary gifts or tokens of appreciation, such as totes, books, toys, or other such materials, the study team will submit a description and approximate retail value of the item to the IRB.

Study Procedures- Biomedical Research

1. Where will the study procedures be done?

Check One:

____ UVA medical center facilities (In patient or outpatient)

__X__ UVA but not medical center facilities: LIST specific location Answer/Response:

__X__ Other: List specific location Answer/Response: Participants will perform usual training runs throughout the greater Charlottesville or surrounding area using the study's wearable sensors.

2. If the study involves medical risk and study procedures will be done outside of the UVa Medical Center what is your plan to protect the subjects in case of a medical emergency?

__*X*__ *NA*

Check all applicable options:

_____ MD, RN, onsite during procedures

_____ Individual trained in CPR on site during procedures

_____ AED and Individual trained to use it onsite

_____ Call 911

_____ Other: Describe Answer/Response:

3. List the procedures, in bullet form, that will be done for <u>RESEARCH PURPOSES</u> as stipulated in this protocol.

INSTRUCTIONS:
Examples: blood tests, EKG, x-rays, surveys, administration of investigational drug/device, randomization to one of two approved drugs
Do NOT list those procedures which are being ordered for clinical standard of care.
If ALL procedures are being done for the research study, simply write: ALL

Answer/Response:

ALL procedures that will be done are for research purposes. Training runs that occur during study participation are part of the subjects' normal activities- subjects will be

asked to wear the sensors during their usual runs. A laboratory assessment will be performed to analyze anthropometrics and running gait.

4. Do you confirm that, except for blood draws through a peripheral site, that all invasive procedures will be performed by a licensed health care provider under the supervision of an MD?

Answer/Response:

Invasive procedures will not be performed in this study.

5. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?

Answer/Response:

No data or specimens will be used that were previously collected through another research study.

IF YES, will the data/specimens be used in this study without a new consent from the original donor?

Answer/Response:

IF YES, explain how the proposed use is consistent with the use planned in this study and submit a copy of the consent form used to collect the data/specimens.

INSTRUCTIONS: If you are unable to locate the consent form, you must request a Waiver of Consent. Consult with IRB staff to determine additional sections to be added to this protocol.

Answer/Response:

6. Will any of the procedures listed in item # 3 have the potential to identify an incidental finding?

Answer/Response:

INSTRUCTIONS: This includes ALL procedures, assessments and evaluations that are being done for RESEARCH PURPOSES that may or may not be considered investigational. **Examples:** MRI/CT/PET/CXR shows possible tumor, Blood collected and analyzed using an investigational assay and results show possibility of leukemia

No.

►IF YES, check one of the following two options and list the applicable procedures, assessments or evaluations below.

_____The examination(s) utilize(s) the same techniques, equipment, etc., that would be used if the subject were to have the examination(s) performed for clinical care.

Procedures, assessments, evaluations: _____

There exists the potential for the discovery of clinically significant incidental findings.

- The PI takes full responsibility for the identification of incidental findings:
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- If an incidental finding is serious and emergent (e.g. mass on x-ray), the study team will inform the subject and contact the subject's health care provider.
- If applicable a follow-up letter describing the finding should be provided to the subject with instructions to either show the letter to their PC or if the subject has no PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic**.**

____This examination(s) utilizes non-standard/investigational, technique, equipment, etc. It is impossible to determine the significance of such results, therefore abnormalities will not be shared with the subject because the meaning of the exam is not yet proven and is of unknown clinical benefit.

Procedures, assessments, evaluations: _____

7. Do any of the procedures listed above, under question # 3, utilize any imaging procedures for RESEARCH PURPOSES?

Examples: ultrasound, CT scans/ x-rays etc.

Answer/Response:

No.

►IF YES, check one of the following two options:

_____This imaging research examination utilizes the same imaging techniques, equipment, scanning sequences that would be used, if the subject were to have the imaging performed for clinical care. There exists the potential for the discovery of clinically significant incidental findings.

►If checked, answer the following:

List procedures:

Answer/Response:

Will the images be read by a licensed radiologist and the reading placed in the subject's medical record?

Answer/Response:

►IF NO: The PI takes full responsibility for the identification of incidental findings:

- The PI will have all incidental findings reviewed by a radiologist who will advise the PI regarding clinical significance.
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided t**o t**he subject with instructions to either show the letter to their PC or if the subject has **no** PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic.

_____This imaging research examination utilizes non-standard/investigational imaging modality, techniques, equipment, scanning sequences, etc. It is impossible to determine the significance of such images, therefore abnormalities will not be shared with the subject because the meaning of the exam is not yet proven and is of unknown clinical benefit.

L**ist procedures:**

Answer/Response:

8. Will your study involve measures used to screen or assess for depression and/or suicidality for research purposes?

NOTE: Answer this question YES and answer the questions below if any of the following apply:

1) *The protocol has a research purpose to study suicide, suicidal ideation, depression or trauma*
2) *The protocol has a research purpose to study traumatic life events that may evoke powerful emotion or induce mood changes in participants;*
3) *The protocol includes **assessments** or tools (e.g. Surveys, exams, questionnaires, etc.) that can be used to screen or identify **depression (C-SSRS/BID/SCID, questions related to mood, etc.) and/or suicidal ideation** (thoughts of suicide, either active or passive), plan (the means or mechanism) or intent (the expressed desire and willingness to act on the plan).*

No.

a. Which research staff members will be qualified and available to provide a referral for further care or intervention if the subject's responses indicate this need?

Answer by position with study (e.g. PI, sub investigator etc. Do not include names in answer.

Answer/Response:

b. Include specific guidelines for intervention or further assessment based on tools and rating scales used in this study. Include information regarding how soon information from a subject will be reviewed. *(e.g.*

Questionnaire(s) will be reviewed the same day they are administered/submitted. Based on score of xxx or response of X, subject will be assessed further by the PI for suicide risk or referred urgently to an ED, crisis center, or clinic immediately).
Answer/Response:

REMINDER: If your subjects will be patients at UVA Medical Center, you must adhere to **Medical Center Policy 0140 Judicial Treatment Order and 0197 Suicide Risk Assessment and Prevention.**

9. Will any data from this study be submitted to or held for inspection by the FDA?
NOTE: Publication is not equivalent to submission of data to the FDA.
Answer/Response:
No.

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?

Answer/Response:
There are no direct benefits for the participants in this study, however subjects will be able to access the RunScribe data during the collection period. This study will provide information on running gait mechanics in more natural running environments (outside of the laboratory), and will allow for a larger sample of running data to be collected to accrue a sizable amount of data. Additionally, obtaining patient-reported outcome measures will help to contextualize external biomechanical load information to wellness measures. This information would greatly increase the ability to identify risk factors in runners and lead to more effective injury prevention initiatives in the future.

2. Do the anticipated benefits justify asking subjects to undertake the risks?

INSTRUCTIONS: Analyze the risk-benefit ratio and justify your answer.
Analyze the risk- benefit of interventions offering potential health benefit separately from those done solely to answer a research question or generate generalizable knowledge. Clarify risk-benefit for direct benefit to individual participant versus benefit to society.

Answer/Response:
The risks of this study for participants are low; laboratory measures will not pose any risk to the participants, and the only risks present during running are the same as the runners would incur during normal training. Even without direct benefits for participants, the findings that could results from this study can be helpful in better understanding running gait mechanics in natural environments and more successfully identify of running risk factors. The risk benefit ratio is acceptable.

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definitions

1.1 How will you define adverse events (AE)?

Do not change this answer

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring

in human subjects as a result of the collection of identifiable private information under the research**.**

1.2 How will you define an unanticipated problem?

Do not change this answer

An unanticipated problem is any issue that involves increased risk(s)

to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g. serious loss of social status, loss of job, interpersonal conflict.)

1.3 What are the definitions of a protocol deviation and/or noncompliance?

Do not change this answer

A protocol deviation is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol deviations may be major or minor.

Noncompliance can be a protocol deviation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulations**.** Noncompliance may be minor or sporadic, or it may be serious or continuing.

Additional Information: see the IRB-HSR website at
Protocol Deviations, Non-compliance and Protocol Exceptions

2. What risks are expected due to the intervention in this protocol?

INSTRUCTIONS:

2	The risks should be consistent with those in the consent form (if applicable), although they should be written in technical terms in the protocol and in lay terminology in the consent form.
3	List the most serious or most frequent risk first
4	Delete last two rows if no additional risks added.
5	Add additional rows to the table below if needed.

Expected Risks related to study participation	**Pick One**
There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	Occurs rarely
Incidental injury such as falling during calibration run/treadmill analysis	Occurs rarely

3. When will recording and reporting of unanticipated problems/adverse events begin?

___X__After subject signs consent

_____After subject begins study intervention

_____Other Specify Answer/Response:

4. When will the recording/reporting of unanticipated problems/adverse events end?

__X___Subject completes participation in the protocol

_____End of intervention

_____30 days post intervention

_____Subject completes intervention and follow up period of protocol

_____Other: Specify Answer/Response:

5. What is your plan for safety monitoring?

Do not change this answer

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Deviations or Data Breach?

Do not change this answer

Type of Event	**To whom will it be reported:**	Time Frame for Reporting	How reported?
Unanticipated Problems that are not adverse events or protocol deviations This might include a Data Breach.	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Unanticipated Problem report form. Unanticipated Problem Report Form
Protocol Deviations/Noncompliance (*The IRB-HSR only requires that MAJOR deviations be reported, unless otherwise required by your sponsor, if applicable.)*	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Deviation, Noncompliance and Protocol Exception Reporting Form Protocol Deviation Protocol Exception Reporting Form
Data Breach* of Protected Health Information	The UVa Corporate Compliance and Privacy Office ITC: if breach involves electronic data Police if breach includes items that are stolen: Stolen on UVA Grounds OR	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVa Corporate Compliance and Privacy Office- Phone 924-9741 **ITC:** Information Security Incident Reporting procedure, https://security.virginia.edu/report-information-

	Stolen off UVa Grounds- contact police department of jurisdiction of last known location of PHI		security-incident Police: phone- (434) 924-7166

*A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

Additional Information may be found on the IRB-HSR Website: Data Breach

Privacy Plan

The following procedures must be followed.

- The data will be secured per the Data Security Plan of this protocol.
- Only investigators for this study and clinicians caring for the patient will have access to data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*
- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

  If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.
- UVa University Data Protection Standards will be followed.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's Highly Sensitive Data Protection Standard for Individual-Use Electronic Devices or Media Additional requirements may be found in the University's Security of Network-Connected Devices Standard. If identifiable data is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's Electronic Data Removal Standard.
- Data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Standard .
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards (UDPS 3.0).
- Data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.

- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

If you have a question or concerns about the required security standards contact InfoSec at it-security@virginia.edu

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
General Issues	*General Issues*
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know.
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See Encryption Solutions Guidance *Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.*	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the “F” and “O” managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	

Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

Highly Sensitive Data (Identifiable Health Info per HIPAA)	**Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)**
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with InfoSec or Health System Web Development Office: 434-243-6702 • University Side: IT-Security@virginia.edu • Health System: Web Development Center:	
Individual-Use Device	*Individual-Use Device*
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device (e.g. smart phone)	
E Mail	*E Mail*
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	

Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. *NOTE: VPR & IRB staff do not meet this criteria!*	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.**
FAX	*FAX*
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

Highly Sensitive Data (Identifiable Health Info per HIPAA)	Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)
Electronic Data Collection & Sharing	*Electronic Data Collection & Sharing*
(e.g. smart phone app, electronic consent using tablet etc.) MUST consult with InfoSec or Health System Web Development Office: 434-243-6702 • University Side: IT-Security@virginia.edu • Health System: Web Development Center: Contract must include required security measures.	
May be stored in UVA's Qualtrics portal for Highly Sensitive Data (HSD) May NOT be stored in places like UVaBox, UVaCollab or QuestionPro May also NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May be stored in places like UVaBox, UVaCollab, UVA's Qualtrics portal for Moderately Sensitive Data May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*
***The UVa HIPAA covered entity includes the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory, the Exercise Physiology Laboratory and the UVA Center for Survey Research.*

Legal/Regulatory/Ethical Considerations

Recruitment

The following procedures will be followed:

- Finders fees will not be paid to an individual as they are not allowed by UVa Policy.

- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.
- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

Compensation in Case of Injury

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/924-2620) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the UVa Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

Subject Complaints

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/924-2620), the UVa Health System Patient Relations Department (924-8315).

Request for Research Records from Search Warrant or Subpoena

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is important to notify them if information from the study is protected by a Certificate of Confidentiality.

Informed Consent

Unless waived by the IRB, subjects will be fully informed of the:

- purpose of the study,
- reasonably anticipated benefits,
- potential risks or discomfort participation in the study may entail,
- and any alternative treatments.

They will also be informed that their

- consent is voluntary and that they may withdraw their consent to participate at any time, and
- (if applicable) choosing not to participate will not affect the care the subject will receive for the treatment of his or her disease.

The consent documents used to obtain informed consent of the subject must be approved by the IRB prior to use. Any written materials (consent/ short form) will be provided to the potential subject in a language they can read understand. The subjects will be given sufficient time to read the consent form and have the opportunity to ask questions.. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled. After this explanation and before entry into the study, consent should be appropriately recorded. Subjects will be given a copy of the signed consent/ short form.

Institutional Review Board (IRB)

No subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment. Any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

Investigator Responsibilities

The investigator is responsible for ensuring that the study is performed in accordance with the protocol, current ICH guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles that originated in the Declaration of Helsinki, and that the study data are credible.

PROTOCOL

Background

31. Provide the scientific background, rationale and relevance of this project.

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is a FIVE YEAR UPDATE make sure the information throughout the protocol includes the most current information.

Answer/Response:

Distance running is the most popular means of exercise undertaken by adults in the United States. While there are several profound health benefits associated with running, musculoskeletal injuries have been identified as a substantial barrier to participation.[1] Running-related injuries are common in runners of varying experience levels.[2] Despite the recognition of the high prevalence of running-related injuries since the 1970's, injury rates among runners are essentially unchanged in the past 40 years.[1]

Assessment of running biomechanics has been a common mode of inquiry in the study of running-related injuries; however, traditionally it has been confined to laboratory settings. This is typically done by having runners fitted with dozens of reflective markers which are tracked with high speed cameras around instrumented treadmills which have force plates embedded beneath the treadmill belts. This allows for continuous data collection while subjects run on a treadmill; however, there are documented biomechanical differences between treadmill and overground running.[3–5] Additionally, most research articles only report biomechanical analysis of less than a few dozen strides per subject at a single timepoint. Thus, the running injury biomechanics literature predominantly consists of studies that have analyzed a small number of strides per subject at one time, with data collection occurring in highly controlled laboratory environments that do not reflect the conditions under which running related injuries occur (track, road, trail, etc.). This additionally hinders the ability to

prospectively monitor changes in biomechanics as they related to performance and well-being outcomes.

The advent of wearable sensors allows for biomechanical data to be collected in a runner's natural training environment while collecting thousands of steps in a single run. Our lab group has recently collected biomechanical data using commercially available sensors (RunScribe Labs, San Francisco, CA) that are mounted on a runner's shoes and transmit data after a run to a mobile phone app via Bluetooth technology. We have presented multiple research abstracts at national conferences demonstrating aspects of validity of these sensors in measuring common biomechanical measures during continuous running.[6–8] The ability to capture thousands of steps per day over weeks or even months for an individual runner should greatly increase the ability to identify injury risk factors in runners and lead to more effective injury prevention initiatives. Further, these data can be used to inform running decision-making in regards to training load, especially if considered in conjunction with subjective outcomes of well-being for internal training load measures.

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response:

Primary Specific Aims:

1) To prospectively collect and monitor runners' biomechanics (impact g's, baking g's, pronation excursion, pronation velocity, spatiotemporal measures) using wearable sensors during typical running training in conjunction with subjective patient-reported outcomes of well-being to form a database of internal and external load metrics as they pertain to performance and injury over time among a representative running cohort.
2) To measure runners' anthropometrics (strength, flexibility, and alignment) and running biomechanics (lower extremity joint angles, moments, and forces) using traditional indoor laboratory analyses to build a representative database of runners' movement profiles and determine associations to performance and injury over time.

Hypotheses:

1) Measures of highest internal and external loads will be associated with altered biomechanics related to decreased performance and higher injury risk, such as decreased step rates and increased loading.

2) Decreased strength and flexibility as well as stiffer movement patterns identified on the treadmill will be associated with decreased performance and higher injury risk.

Study Design: Biomedical

1. Will controls be used?

Answer/Response:

No.

►IF YES, explain the kind of controls to be used.

Answer/Response:

18. What is the study design?

Example: case series, case control study, cohort study, randomized control study, single-blind, double-blind, met-analysis, systematic reviews, other. You may also view the IRB-HSR Learning Shot on this topic to help you answer this question.
(http://www.virginia.edu/vpr/irb/learningshots/Writing_protocol_June09/player.html

Answer/Response:

Prospective cohort study.

19. Does the study involve a placebo?

Answer/Response:

No.

►IF YES, provide a justification for the use of a placebo

Answer/Response:

Human Participants

Ages: _18-45 years___

Sex: __**Males and Females**__

Race: __All races__

Subjects- see below

INSTRUCTIONS: **For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.**

1. Provide target # of subjects (at all sites) needed to complete protocol.

INSTRUCTIONS: If this is NOT a database protocol, this number should be the same as the number of subjects needed to obtain statistically significant results.

Answer/Response:
400 subjects will be recruited to build a representative running database.

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.

Answer/Response:
We expect a 25% cumulative drop-out rate of runners over time.

3. How many subjects will be enrolled at all sites?

INSTRUCTIONS: **This number must be the same or higher than the # from question # 1 in order to account for the # of screen failures, dropouts, withdrawals described in question # 2.**

Answer/Response:
500 total subjects.

4. How many subjects will sign a consent form under this UVa protocol?

INSTRUCTIONS: If the protocol does not have a consent form- the number listed here should reflect such things as the number of subjects from whom specimens will be obtained, the number of charts to be reviewed etc.

Answer/Response:
500.

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non-English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.

- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response:

- All subjects must be willing to use their own smart phone device (iPhone or Android) to download the RunScribe™ application, and to respond to questionnaires for study procedures.
- Ages 18-45
- Male or female
- Participating in distance running at least 3 times per week with a weekly mileage of at least 6 miles
- Running experience of at least 3 months

2. List the criteria for exclusion

Answer/Response:

- Acute fractures within 3 months of the study procedures
- Surgery within 1 year of the study procedures
- Subjects with known pregnancy
- Subjects with any type of current neuropathy (numbness/tingling) in lower extremity
- Subject with clinical diagnosis of Parkinson's disease
- Subject with clinical diagnosis of Multiple Sclerosis (MS). History of a balance disorder
- Any other condition that prevents current running training

3. List any restrictions on use of other drugs or treatments.

INSTRUCTIONS: List only those drugs or treatments that are prohibited while on study, not those listed as an exclusion criteria.

Answer/Response:

None.

Statistical Considerations

11. Is stratification/randomization involved?

Answer/Response:

No.

►IF YES, describe the stratification/ randomization scheme.

INSTRUCTIONS:
The stratification factors and/or the randomization plan should be identified. If there is no randomization component or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

Stratification factors: These are pretreatment patient characteristics which could be balanced across treatment arms by design or may be used to determine starting dose or treatment allocation.

If randomization is going to be used, the details of the randomization plan should be described.

The description should include:
--the method and timing of randomization
--the type of randomization scheme that will be used in the study
--whether or not the randomization masked/blinded/if so, then to whom is it masked/blinded
--who has access to the randomization scheme

Answer/Response:

►**IF YES, who will generate the randomization scheme?**

_____ Sponsor
_____ UVa Statistician. Insert name Answer/Response:
_____ UVa Investigational Drug Service (IDS)
_____ Other: Specify Answer/Response:

2. What are the statistical considerations for the protocol?

The objectives section and the statistical section should correspond, and any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

The answer to this question should include:
--Study Design/Endpoints
--Recap of study objectives and endpoint definitions. An assessment of how study objectives will be assessed by identifying & defining which endpoints will be used to assess each component of the study objectives.
--The study design should include contingencies for early stopping, interim analyses, stratification factors (If applicable), and any characteristics to be incorporated in analyses.
--The power/precision of the study to address the major study endpoint(s), the assumptions involved in the determination of power/precision.
--If statistical hypothesis testing is included then specify the null and alternative hypotheses, the test statistic, and the type I and II error rates
--If precision of an estimate, then provide a definition for precision
--If other, then specify

Answer/Response:

400 subjects will be recruited to build a representative running database (for use in this study only).

3. Provide a justification for the sample size used in this protocol.

Include sample size calculations or statistical power estimation. If not applicable, please provide explanation.
Also include the anticipated accrual rate, the accrual goal for the study, including accrual goals by strata if appropriate, adjustments for drop-outs etc. and study duration.

Answer/Response:

As the goal of this study is to build a representative database of runners and to capture running performance and injury over time, a substantial sample size is necessary for this study. Previous prospective cohort studies evaluating running injuries over time using only survey-based data have recruited 330 participants to detect trends associated with training volume and lower extremity injuries.[9] However, since we will also be measuring runners' biomechanics in conjunction with survey data, we anticipate needing a larger sample size to detect subtle changes in movement patterns over time in conjunction with training volume and patient-reported outcome measures.

4. What is your plan for primary variable analysis?

Include primary outcome(s)/predictor variable(s), statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.

Answer/Response:

Aim 1: Biomechanical measures obtained from the RunScribe™ sensors will be assessed using pattern recognition algorithms to determine changes in movement patterns and patient-reported outcome measures over time within study participants. Discriminatory analyses will also be used to assess likelihood of injury and changes in performance based on internal and external factors. Descriptive summaries will be used to characterize runners' biomechanics and patient-reported outcomes based on similarities among training volume.

Aim 2: Anthropometric laboratory measures and gait biomechanics will be assessed using discriminatory analyses to assess likelihood of injury and changes in performance based on baseline characteristics. Descriptive summaries will also be used to generate a database of runners' characteristics.

5. What is your plan for secondary variable analysis?

Include the following:
--Secondary outcome(s)/predictor variables, statistical methods/models/tests to be employed, or descriptive summaries as appropriate. If not applicable, please provide explanation.
--For phase III studies, the power/precision of the study to address the secondary objective(s).

Answer/Response:
Possible analysis approaches include, but will not be limited to, principal components analysis, machine learning, and pattern recognition.

6. Have you been working with a statistician in designing this protocol?

Consultation with a professional statistician is highly recommended to ensure good science of the study and facilitate the review process.

Answer/Response:
No, the PI has considerable experience in designing studies of human biomechanics and performing statistical analyses of biomechanical data sets, and a sub-investigator has considerable experience building pattern recognition and machine-learning algorithms.

IF YES, what is their name?
Answer/Response:

7. Will data from multiple sites be combined during analysis?
Answer/Response:
No.

INSTRUCTIONS: IF YES, answer the following questions

7(a). Does the study involve randomization?
Answer/Response:
IF YES, will randomization be done at each site or among sites?
Answer/Response:

7(b). Has the sample size calculation considered the variation among sites?
Answer/Response:

7(c). When combining the data from multiple sites to assess the study results, is the effect of the treatment to be tested (or the association to be tested) assumed to be the same across sites or vary among sites? What is the modelling strategy?
Answer/Response:

7(d). Is there a common protocol used in all sites?
Answer/Response:
IF NO, how will differences among sites, such as those related to the implementation, inclusion criteria, patient characteristics, or other sites characteristics, be considered to assess the study results?
Answer/Response:

Study Procedures-Biomedical Research

1. What will be done in this protocol?

INSTRUCTIONS:

This should include everything that will be done as part of this protocol. Do not repeat information that is included in other sections such as Background or Hypothesis sections.
This section should include an indication of which research interventions if any offer a prospect for direct benefit and which interventions (invasive measurements, collection of blood, tissue, data, surveys, etc.) are being done solely to answer a research question and generate generalizable knowledge. If the interventions done solely for research purposes are associated with greater than minimal risk they need to be justified. Describe and justify any control and experimental arm and include method, dose, and duration of drug administration. Reference any claim of clinical equipoise if applicable.

If you are obtaining specimens or data, provide information regarding the type of specimen/data, amount of specimen needed and how the specimen/data will be obtained and what analysis will be done with the specimen/data.

Special note for studies with waiver of consent/waiver of documentation of consent: Include a statement regarding how subjects will be recruited. For other studies this information is captured in Recruitment does not need to be duplicated in this section.

Answer/Response:

Study Procedures:

1. Obtain informed consent for all subjects.
2. Ensure all subjects meet inclusion/exclusion criteria to ensure they are eligible to enroll.
3. Complete all patient-reported outcome subject questionnaires.
4. Complete a physical exam including measurements of:
    a. Foot posture
    b. Leg length
    c. Pelvic alignment
    d. Lower extremity range of motion
    e. Lower extremity flexibility
    f. Lower extremity strength measures
5. Complete a running gait analysis examination on an instrumented laboratory treadmill
    a. 5-minute warm-up
    b. 5-minute running collection
6. Participants will perform a calibration run for the RunScribe™.
7. Participants will use the RunScribe™ sensors during normal training for at least one year and respond to patient-reported questionnaires sent to mobile phones weekly.
8. Complete check-ins (in person or electronically) from the study coordinator on a weekly basis to record injury data.

a. In the case of the UVA varsity cross-country and track athletes, the team's athletic trainers will be asked to report injury data on the participating athletes at these time-points.

Consent & Screening:

Potential subjects will report to the Exercise and Sports Injury Lab (EASIL) in Memorial Gymnasium for all study procedures. Subjects will only be asked a series of questions about their health history and running experience on a pre-screening form prior to consent to ensure that the potential subjects fit the inclusion and exclusion criteria (administered by Study Coordinators). At this time, subjects that fit the criteria will sign an informed consent before performing any other questionnaires and/or surveys. Questions asked to determine eligibility are included in an attached pre-screening form.
Once subjects are deemed eligible, informed consent will be obtained for all subjects as outlined in the Recruitment section of the IRB Application. The study procedures will begin immediately after informed consent is obtained or the subjects may choose to return at a later date to proceed with the study procedures. Demographic information will be collected by the Study Coordinators including age, sex, height, and weight after informed consent.

Patient-Reported Outcomes (Subjective Questionnaires)

11. Visual Analogue Scale[10]
12. Godin Leisure-Time Activity Questionnaire[11]
13. Exercise-Induced Leg Pain Questionnaire – British Version (EILP-BR)[12]
14. Lower Extremity Functional Scale[16]
15. Foot and Ankle Ability Measure (FAAM) Activities of Daily Living and Sport Scale[13]

Physical Examination:

All measures listed in this section are non-invasive and are performed in the routine practice of athletic training, physical therapy, and musculoskeletal medicine in the assessment of patients.

15. Foot posture
    a. Arch Height Index[17]: measured by an Arch Height Index Measurement System in which subjects place their foot on a platform and an examiner will measure total foot length and truncated foot length in seated and weight-bearing positions.
    b. Foot Posture Index[15]: measured by having subjects march in place and then stand as they normally would as an examiner evaluates foot positioning from multiple views.
16. Leg length with tape measure[16]: measured by having subjects lie supine on a table while an examiner uses a fabric tape measure to determine the leg length from the anterior superior iliac crest of the hip to the medial malleolus of the ankle, repeated on both legs.

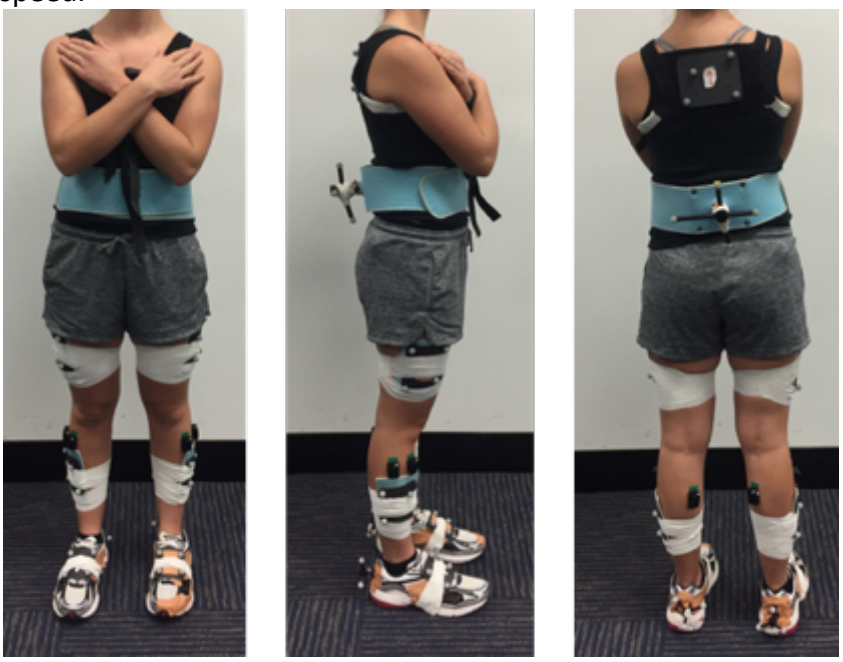
17. Pelvic alignment
    a. Pelvic Tilt: measured by having subjects sit on the edge of a treatment table, pull one thigh towards the chest and lay back onto the table to assess if the opposite leg comes up off of the table as a sign of anterior pelvic tilt, also called the Thomas Test.
18. Lower extremity passive range of motion
    a. Hip (flexion, extension, abduction, EROT, IROT)
    b. Knee (flexion, extension)
    c. Ankle (dorsiflexion, plantarflexion, inversion, eversion)
    d. Foot (first ray mobility): measured by having subjects sit or lie on a treatment table while an examiner uses a goniometer of the first ray measurement tool to passively move the respective joints through the available range of motion.
19. Lower extremity flexibility
    a. Straight leg raise test: The subject will be asked to lie supine on a table while an examiner passively flexes the patient's hip while maintaining knee extension until the end range of motion is met.
    b. Weight-bearing dorsiflexion test: The subject will be asked to stand facing a wall with feet about 10 cm back from the wall with the other foot back, and bend the front knee until it touches the wall without the heel coming off the ground. If the knee can touch the wall without the heel coming off the ground, the subject will move the foot back progressively until the knee can just touch the wall without the heel coming off the ground.

20. Lower extremity strength measures: measured by having subjects assume different standardized testing positions while an examiner uses a hand-held dynamometer to measure movement forces.
    a. Hip extension with subjects in prone on a treatment table and knee bent
    b. Hip flexion with subjects lying supine on a treatment table
    c. Hip abduction with subjects side-lying on a treatment table
    d. Knee extension with subjects seated on a treatment table
    e. Knee flexion with subjects seated on a treatment table
    f. Plantarflexion with subjects in prone on a treatment table
    g. Dorsiflexion with subjects seated on a treatment table
    h. Inversion with subjects seated on a treatment table
    i. Eversion with subjects seated on a treatment table

Laboratory Gait Assessment

Participants will wear standard laboratory shoes (Brooks) during motion analysis. Three-dimensional joint kinematics of the ankle, knee, and hip will be measured using the Vicon motion analysis system controlled by Motion Monitor software. A force plate embedded in the treadmill will be used to collect ground reaction forces. A total of 10 clusters of markers (38 markers) will be placed on the upper

back, lower back, lateral mid-thigh, lateral mid-shank, posterior calcaneus, and the foot. Participant setup can be seen in image below. Electromyography (EMG) of lower extremity musculature (medial gastrocnemius, anterior tibialis, vastus lateralis, biceps femoris, and gluteus medius) will also be collected synchronously using wireless surface EMG electrodes. Once sensor set-up is complete, the participant will be instructed to run on the treadmill at their preferred running speed for 5 minutes. Once the subject is familiar with the treadmill and has completed the 5-minute warm-up, we will collect 2 trials of 60 seconds of running at the runners' preferred speed, and at a standardized 6.0mph speed.



Calibration Run

8. Subjects will be given RunScribe™ sensors and oriented to the use of the wearable sensors and the associated mobile phone application (RunScribe Labs, San Francisco, CA)
9. Sensors will be fitted and mounted on the laces of the participant's left and right shoes.
10. Subjects will run around a 400-meter track once in order to calibrate the RunScribe™ system.

Running Collection

4. Participants will use the calibrated RunScribe™ sensors at least twice per week during their normal runs during the study period.
5. Participants will be asked to respond to phone-based surveys through the Qualtrics smart phone application as follows:
    a. Mileage this week?
    b. Hours of sleep?

c. Sleep quality? (1-5 scale)
    i. Insomnia, restless sleep, difficulty falling asleep, good, very restful
d. Energy level? (1-5)
    i. Always tired, more tired than normal, normal, fresh, very fresh
e. Stress level? (1-5)
    i. Highly stressed, feeling stressed, normal, relaxed, very relaxed
f. Mood? (1-5)
    i. Highly annoyed/irritated, snappiness at others, less interested in others/activities than usual, generally good mood, very positive mood
g. Soreness level? (1-5)
    i. Very sore, increase in tightness/soreness, normal, feeling good, feeling great
    If respond with "very sore" or "increase in tightness/soreness", will be asked to indicate which body part(s):
        1. Foot
        2. Ankle joint
        3. Shin/low leg
        4. Knee joint
        5. Quadriceps
        6. Hamstrings
        7. Groin
        8. IT Band
        9. Hip joint
        10. Low back

6. Participants (or athletic trainers, see above) will be asked weekly by the investigators about injury occurrence.
7. At the end of the study time period, participants will return the sensors to the investigators at Memorial Gymnasium. The study aims to have the subjects wear the sensors and respond to surveys for as much time as possible to get longitudinal data.

10. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.

Example: If the subject will be taking an investigational drug, will they need to be put back on an approved drug when they have completed the study? If yes, explain how this will be accomplished and who will cover the cost. If the subject has a device implanted will it be removed? Again- who will cover the cost of the removal?
Instructions: Answer NA if this study does not involve a study treatment.

Answer/Response:
N/A.

Bibliography

INSTRUCTIONS: Provide a current bibliography supporting the hypothesis, background and methodology including references to papers and abstracts that have resulted from previous work by the investigator and references to the work of others.

1. Videbæk S, Bueno AM, Nielsen RO, Rasmussen S. Incidence of Running-Related Injuries Per 1000 h of running in Different Types of Runners: A Systematic Review and Meta-Analysis. *Sports Med*. 2015;45(7):1017-1026. doi:10.1007/s40279-015-0333-8
2. Molloy JM. Factors Influencing Running-Related Musculoskeletal Injury Risk Among U.S. Military Recruits. *Mil Med*. 2016;181(6):512-523. doi:10.7205/MILMED-D-15-00143
3. Tessutti V, Ribeiro AP, Trombini-Souza F, Sacco ICN. Attenuation of foot pressure during running on four different surfaces: asphalt, concrete, rubber, and natural grass. *J Sports Sci*. 2012;30(14):1545-1550. doi:10.1080/02640414.2012.713975
4. McIntosh AS, Beatty KT, Dwan LN, Vickers DR. Gait dynamics on an inclined walkway. *J Biomech*. 2006;39(13):2491-2502. doi:10.1016/j.jbiomech.2005.07.025
5. Schache AG, Blanch PD, Dorn TW, Brown NAT, Rosemond D, Pandy MG. Effect of Running Speed on Lower Limb Joint Kinetics: *Med Sci Sports Exerc*. 2011;43(7):1260-1271. doi:10.1249/MSS.0b013e3182084929
6. Colapietro M, Fraser JJ, Resch JE, Hertel J. Running mechanics during 1600-meter track runs in young adults with and without chronic ankle instability. Free Communications presented at the: National Athletic Trainers' Association Annual Meeting; June 2017; Houston, TX.
7. Hollis C. Gait mechanics as measured by a wearable sensor during running at two speeds on different surfaces. Free Communications presented at the: National Athletic Trainers' Association Annual Meeting; June 2017; Houston, TX.
8. Koldenhoven RM. Validation of a wearable sensor for measuring running biomechanics. Free Communications presented at the: National Athletic Trainers' Association Annual Meeting; June 2017; Houston, TX.
9. Hollander K, Baumann A, Zech A, Verhagen E. Prospective monitoring of health problems among recreational runners preparing for a half marathon. *BMJ Open Sport Exerc Med*. 2018;4(1):e000308. doi:10.1136/bmjsem-2017-000308
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11. Helmerhorst HHJ, Brage S, Warren J, Besson H, Ekelund U. A systematic review of reliability and objective criterion-related validity of physical activity questionnaires. *Int J Behav Nutr Phys Act*. 2012;9(1):103.
12. 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(6):485-496. doi:10.2519/jospt.2015.5428
13. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Swearingen JMV. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). *Foot Ankle Int*. 2005;26(11):968–983.

14. Butler RJ, Hillstrom H, Song J, Richards CJ, Davis IS. Arch height index measurement system: establishment of reliability and normative values. *J Am Podiatr Med Assoc*. 2008;98(2):102-106.
15. Evans AM, Copper AW, Scharfbillig RW, Scutter SD, Williams MT. Reliability of the Foot Posture Index and Traditional Measures of Foot Position. *J Am Podiatr Med Assoc*. 2003;93(3):203-213. doi:10.7547/87507315-93-3-203
16. Neelly K, Wallmann HW, Backus CJ. Validity of measuring leg length with a tape measure compared to a computed tomography scan. *Physiother Theory Pract*. 2013;29(6):487-492. doi:10.3109/09593985.2012.755589

DATA SECURITY PLAN

Do not complete this document if this study will be submitted via Clinical Research Connect.

Version Date: 07/26/19
IRB HSR Submission # 14797
IRB-HSR #21756: Using Wearable Sensors To Prospectively Monitor Runners' Biomechanics

General Information

You should consult with InfoSec during the development phase of this protocol if your protocol will involve highly technical issues such as the creation of a website to collect data, software application development, the use of a smart phone app, or if you plan to store identifiable data ONTO an individual use device such as a tablet/laptop/camera. Otherwise submit the protocol and this Data Security Plan to the IRB-HSR for pre-review. The IRB-HSR will notify the study team and InfoSec if InfoSec approval is required. .

InfoSec CONTACT INFORMATION:
UVa Office of Information Security, Policy & Records Office (InfoSec)
EMAIL: IT-Security@Virginia.edu

Glossary of terms located at end of document.

Completion Instructions

1. Read questions carefully and answer questions as indicated.
2. For questions, contact InfoSec IT-Security@Virginia.edu

3. Use the following instructions to provide the server name. **INSTRUCTIONS:**

- You may locate the server/drive name and path by taking the following steps :
  - In Windows under computer, right click on the Drive icon (e.g. F). Then click on Properties. The server/drive name and path will appear at the very top of the box.
  - If you need additional assistance contact your department computer support or system administrator for assistance.

Submission Instructions

The IRB-HSR will submit the protocol to InfoSec after the pre-review is completed if their review is required.

DATA COLLECTION

1A. Will any HIPAA identifiers (as identified in Table 1 below) be collected or received by the UVa study team?

INSTRUCTIONS:

- Answer YES if you are collecting, recording or receiving any of these items for a potential subject, an enrolled subject, a subject's relative, household member or employer.
- Answer YES even if you are recording any item below temporarily while the information is being collected.
- Keep in mind that the information below includes data collected via photographs, video, audiotapes, and systems like IVRS (Interactive Voice Response System)
- If you answer NO to all items it means you would never be able to go back and obtain any additional information about an individual.

TABLE 1: Limited Data Set criteria per HIPAA under 164.514(e)

NOTE: you will refer to this table throughout the document

YES	NO	HIPAA Identifier
☒	☐	1. Name
☐	☒	2. Postal address information, other than town or city, state, and zip code (e.g. street name or GPS information.)
☒	☐	3. Telephone numbers
☐	☒	4. Fax numbers
☒	☐	5. Electronic mail addresses
☐	☒	6. Social Security number- *Must be checked if you are collecting SS# for compensation.*
☐	☒	7. Medical Record number
☐	☒	8. Health plan beneficiary numbers
☐	☒	9. Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
☐	☒	10. Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)
☐	☒	11. Vehicle identifiers and serial numbers, including license plate numbers
☐	☒	12. Device identifiers and serial numbers
☐	☒	13. Web Universal Resource Locators (URLs)
☐	☒	14. Internet Protocol (IP) address numbers
☐	☒	15. Biometric identifiers, including finger and voice prints
☐	☒	16. Full face photographic images and any comparable images

INSTRUCTIONS:

If you checked NO to all HIPAA Identifiers above your data is considered to be MODERATELY SENSITIVE. Follow

The requirements for handling moderately sensitive data in the Privacy Plan of the protocol.

Do not answer any additional questions. No review by InfoSec is required.

If you checked YES to any item above, continue to question 1B.

1B. Check ALL applicable items below to describe HOW DATA will be COLLECTED:

►IMPORTANT: If you check any of the items 1B(1) through 1B(3) below and you will be collecting HIPAA identifiers with the information (as noted in table 1 on previous page), the protocol may require review and approval by InfoSec. The IRB-HSR office staff will notify InfoSec if their review is required.

1B(1). ☐

Collection of data ONTO* an individual-use device (examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, video or audio recorder)

*ONTO means the data will reside on OR will be stored on the device even if temporarily.

Do not check this box if the device will simply be used to access a server.

IF CHECKED:

i. **Describe the individual use device: (e.g., smart phone)**

LIST all HIPAA identifiers to be collected (see table 1 on previous page):

ii. **AND COMPLETE APPENDIX 1B(1) later in this document.**

1B(2.) ☒

Collection of data via web-based format or cloud storage (e.g., UVaBox, UVa-Collab or other cloud service OR online consent, online surveys)

DO NOT check if data will be collected directly to a server/drive managed by the sponsor or CRO (use item 1B(5) below if server managed by sponsor or CRO).

IF CHECKED:

i. **List the web address (URL): https://dashboard.runscribe.com;**

ii. **LIST all HIPAA identifiers to be collected: none, this information will be de-identified**

AND COMPLETE APPENDIX 1B(2) later in this document.

1B(3). ☐

Collection of data directly to a server at UVa NOT listed under 1B(4) below.

IF CHECKED:

i. *List the name of the server (e.g. name.virginia.edu\project name):* _____

ii. *LIST all HIPAA identifiers to be collected*:_____

AND COMPLETE APPENDIX 1B(3) later in this document.

►IMPORTANT: If you check any of the items 1B(1) through 1B(3) above and you will be collecting HIPAA identifiers with the information (as noted in table 1 on previous page), the protocol may require review and approval by InfoSec.

The IRB-HSR office staff will notify InfoSec if their review is required.

1B(4). ☒

Collection of data directly to one or more of the UVa servers checked below.

IF CHECKED:

i. **LIST all HIPAA identifiers to be collected onto this device: none**

AND COMPLETE APPENDIX 1B(4) later in this document.

- ☐ Dropbox with Sookasa
- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☒ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsartredc1.hscs.virginia.edu/ UVA Bioinformatics REDCap
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☒ Qualtrics HSD
- ☐ School of Nursing SECURE NETf
- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

1B(5). ☐

Collection of data directly to a server/drive managed by the sponsor or CRO.
Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

IF CHECKED:

i. **List the name of the server (e.g. remote.sponsor.com\project name):** _____

ii. **LIST all HIPAA identifiers to be collected onto this server:** _____

AND COMPLETE APPENDIX 1B(5) later in this document

1B(6). ☒ Paper -

IF CHECKED:

i. List ALL the HIPAA identifiers to be stored in paper file(s): Name, initials, telephone number, email

Remember: Initials are considered a HIPAA identifier!

►If health information with HIPAA identifiers are stored in a paper file, where will the paper files be housed?

☒ Signed consent forms or documentation regarding obtaining verbal consent will be stored in a *secure area with limited access.*

☒ Case report forms will be stored in a *secure area with limited access.*

☒ Questionnaires/surveys will be stored in a *secure area with limited access.*

☐ Other - *Specify* _____

NOTE: "*in a secure area with limited access*" means access to data is limited to study personnel only and there must be two forms of security. Example: 1) in a locked office in a building with swipe locks when unattended or 2) in a locked file cabinet in a locked room when unattended or 3) study personnel present in room at all times located in a building with swipe locks or a room with a lock,

DATA STORAGE

1C. Will any data be stored electronically either at UVA or with an outside entity (e.g. during data analysis and/or beyond)?

Yes ☒ No ☐ *IF NO, skip to item 1C(1)b.*

1C(1)►IF YES, will it include storage of any health information or other sensitive data?

Yes ☒ No ☐

1C(1)a If YES, which HIPAA identifiers as noted in table 1, will be kept with highly sensitive data in the same location (e.g. on the same electronic drive, server or file). none

NOTE: If you checked YES to any HIPAA Identifier, your data is considered to be HIGHLY SENSITIVE.
Follow requirements for handling Highly Sensitive data in the Privacy Plan of the protocol

1C(1)b. Will you store any of the following HIPAA identifiers electronically in a different location from the data?

YES	NO	HIPAA Identifier
☐	☒	Social Security number- *Must be checked if you are collecting SSN for compensation.*

☐	☒	Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
☐	☒	Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)

IF YOU CHECKED YES to SSN, Account # or Certificate/License as noted above:

ii. List the name of the server (e.g. name.virginia.edu\project name):_____

INSTRUCTIONS: If you checked YES to any HIPAA Identifier above your data is considered to be HIGHLY SENSITIVE. Follow requirements for handling Highly Sensitive data in the Privacy Plan of the protocol.

1C(2). WHERE will the data be stored long term by UVA and/or the sponsor (e.g. during data analysis and beyond)?

☒ Data will be stored in the same location to which it was collected or transferred as noted in 1B *(Skip to Transferring Data)*

You may check 1C(2) above and also add a new place where data will be stored that was not a location where it was collected. For example, you may have checked 1B(2) for collection of data, and plan to store it both in same location as 1B(2) as well as store on HSCS server. So you could check 1C(2) above and just fill out 1C(1)d below.

If you did not answer the option above, check an applicable option below.

1C(2)a. ☒

*ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer)*
**ONTO means the data will reside or be stored on the device even if temporarily. Do not check this box if the device will simply be used to access a server.*

IF CHECKED:

i. Describe the individual use device: (e.g., smart phone) run scribe app

ii. LIST all HIPAA identifiers to be stored: none

AND COMPLETE APPENDIX 1C(2)a later in this document

InfoSec approval may be required. The IRB-HSR staff will send the protocol and Data Security Plan to InfoSec after pre-review is completed if InfoSec approval is required.

1C(2)b. ☐

Web-based or cloud storage (e.g., UVaBox, UVa-Collab or other cloud service)

IF CHECKED:

i. LIST the web address (URL):_____

ii. LIST all HIPAA identifiers to be stored:_____

AND COMPLETE APPENDIX 1C (2)b later in this document.

InfoSec approval may be required. The IRB-HSR staff will send the protocol and Data Security Plan to InfoSec after pre-review is completed if InfoSec approval is required.

1C (2)c. ☐

On a server at UVa NOT listed under 1C(2)d below.

IF CHECKED:

i. List the name of the server/drive (e.g. name.virginia.edu\project name): _____

ii. LIST all HIPAA identifiers to be stored:_____

AND COMPLETE APPENDIX 1C2(c) later in this document.

InfoSec approval may be required. The IRB-HSR staff will send the protocol and Data Security Plan to InfoSec after pre-review is completed if InfoSec approval is required.

1C(2)d. ☐

Directly to one or more of the UVa servers listed below.

IF CHECKED:

i. LIST all HIPAA identifiers to be stored:_____

AND COMPLETE APPENDIX 1C(2)d later in this consent.

- ☐ Dropbox with Sookasa
- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☐ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsartredc1.hscs.virginia.edu/UVA Bioinformatics REDCap
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud

☐ musicvpn01.med.virginia.edu
☐ Oncore (oncore.med.virginia.edu)
☐ Qualtrics HSD
☐ School of Nursing SECURE NETf
☐ \\radshare\
☐ upgusers.hscs.virginia.edu

1C(2)e. ☐
A server/drive managed by the sponsor or CRO. The data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) onto a server/drive that is configured to store data regulated by HIPAA.
IF CHECKED:
i. **List the name of the server (e.g. remote.sponsor.com\project name):** _____
ii. **LIST all HIPAA identifiers to be stored:** _____
AND COMPLETE APPENDIX 1C(2)e.

DATA TRANSFER

1E(1) Will you be sharing/transferring data outside of UVa? Yes ☐ No ☒
If YES, Will any of the following HIPAA identifiers be shared/transported with the data outside of UVa?

Limited Data Set criteria per HIPAA under 164.514(e)

☐Yes ☐ No	1. Name
☐Yes ☐ No	2. Postal address information, other than town or city, state, and zip code (e.g. street mane or GPS information.)
☐Yes ☐ No	3. Telephone numbers
☐Yes ☐ No	4. Fax numbers
☐Yes ☐ No	5. Electronic mail addresses
☐Yes ☐ No	6. Social Security number
☐Yes ☐ No	7. Medical Record number
☐Yes ☐ No	8. Health plan beneficiary numbers
☐Yes ☐ No	9. Account numbers
☐Yes ☐ No	10. Certificate/license numbers
☐Yes ☐ No	11. Vehicle identifiers and serial numbers, including license plate numbers
☐Yes ☐ No	12. Device identifiers and serial numbers
☐Yes ☐ No	13. Web Universal Resource Locators (URLs)
☐Yes ☐ No	14. Internet Protocol (IP) address numbers
☐Yes ☐ No	15. Biometric identifiers, including finger and voice prints
☐Yes ☐ No	16. Full face photographic images and any comparable images

1E(2).If you checked YES to any item above have you obtained verbal or written HIPAA authorization to share the data with the specific group outside of UVa?
Yes ☐ No ☐

If NO: Data collected may not be shared with any of the HIPAA identifiers checked above unless the IRB has approved the disclosure and the study team tracks the disclosure in EPIC.

1E(3). How will the data be shared/transported?

☐ **Paper forms**

If shipped outside of UVa must be shipped with tracking (FedEx, UPS, certified mail etc.)
Messenger mail not allowed if you have answered YES to any item above

☐ **Email:**

Not allowed if you have answered YES to any item above unless *the data will only be sent to and from an individual with a *HS in their email address*

☐ **Secure Email:**

Not allowed if you have answered YES to any item above UNLESS you use the HSC Mail System and follow the steps listed at:
https://www.hsts.virginia.edu/services/it-security/how-tos/encrypted-email

☐ **FAX:**

Not allowed unless receiving fax machine is in a restricted-access location, the intended recipient is clearly indicated, and that recipient has been alerted to the pending transmission and is available to pick it up immediately. Also verify FAX numbers before faxing and use FAX cover sheet with a confidentiality statement.

☐ **Devices such as flash-drive/ CD etc.:**

Not allowed if you have answered YES to any item in 1E(1) unless you written approval from a VP/ Dean. The request for their written approval should be obtained using the Highly Sensitive Data Storage Request Form. You may also contact the UVa Office of Information, Security, Policy and Records Management at IT-Security@Virginia.edu for assistance in completing this form.

☐ **Web Based Data Entry (e.g. website, database, registry): NOT Encrypted and Password Protected;**

Not allowed if you have answered YES to any item 1E(1).

☐ **Web Based Data Entry (e.g. website, database, registry): Encrypted and Password Protected;**

If checked, do you confirm that you have verified with host site that the data will be sent and stored in an encrypted fashion (e.g. via Secure FX, Secure FTP, HTTPS, PGP)? Yes ☐ No ☐

IF CHECKED COMPLETE DATA SECURITY PLAN APPENDIX 1B(5) if not already completed.

INSTRUCTIONS: Do not complete the questions below if the only data being shared/transported are being sent with specimens. See Specimens Section of the IRB application or Research Protocol

1E(4) If sharing data with anyone outside of UVa do you confirm that you will obtain a contract/ material transfer agreement with them via the School of Medicine Grants and Contracts Office or the Office of Sponsored Programs (OSP) ospnoa@virginia.edu**?** Yes ☐ No ☐

1E(5) Will any data be sent outside of UVa to any person at another institution other than the sponsor or the FDA (e.g. researcher outside of UVa, funding source)? Yes ☐ No ☐

INSTRUCTIONS:
If NO, skip questions 1E(5))a-d below, If YES, complete below.

1E(5)a. What will be shared?
*List the data to be shared, including any HIPAA identifiers:*_____

1E(5)b. Who will the data be shared with?

_____

1E(5)c. What will they do with the data?

_____

1E(5)d. Will information be sent back to UVa? Yes ☐ No ☐
If yes, *LIST the data to be sent back, including any HIPAA identifiers:*_____
If yes, *how it will sent back (see the list under 1E(3) for possible methods)*?

_____

****COMPLETE THE APPENDIX SECTIONS THAT FOLLOW ONLY IF APPLICABLE****

Data Security Plan: APPENDIX 1B(1)

1B(1). Collection of data *ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, audio or video recorder)*

- What kind of device is it (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, audio or video recorder)*

- Who manages / supports the device (e.g., Health Systems Computing Services (HS/CS), local computer support partner (LSP), self)?

  INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

- Will the data be transferred elsewhere? Yes ☐ No ☐

  - INSTRUCTIONS:
  - *If NO, you must complete Appendix 1C(2)a below and if you will store health information with any of the identifiers check in the table 1A on page 2 you must also complete and have signed a* ***Highly Sensitive Data Storage Request form available at:***
    www.virginia.edu/informationsecurity/highlysensitivedata/approvalform.doc
  - *If YES, answer the following four questions*

  1. Will the data be transferred in an encrypted secure manner such as the use of SFTP or HTTPS? Yes ☐ No ☐
     - Describe transfer method: _____

  2. How long will the data remain on the individual-use device before being transferred? _____

  3. Please provide the location the data are transferred to:_____

  4. After the information is transferred elsewhere will you securely delete all data from the website/server? Yes ☐ No ☐

  INSTRUCTIONS: For computers not using Windows 8 or newer, download and use the Secure Delete Program from ITS. If using Windows 8 or newer, click on Secure Delete when deleting a file. For Macintosh computers, select "Secure Empty Trash" from the Finder menu.

- Will anyone other than study team members have access to data on the device?
  Yes ☐ No ☐ If yes, describe:

- Are any backups made of the information on the device? Yes ☐ No ☐
  - If yes, explain how backups are made and where they are stored:

- Does the owner of the device (e.g. phone service provider/ app developer) have any rights to use or access data either individually or in aggregate? Yes ☐ No ☐

- Are you doing any audio or videotaping (recording)? Yes ☐ No ☐ N/A ☐
    - If yes, have you completed the Taping/Photography section in the protocol? Yes ☐ No ☐ N/A ☐

- If you are using an individual use device such as a camera or video recorder do you confirm the photos will not include the full face. Yes ☐ No ☐ N/A ☐

- If you are using a video or audio recorder, do you confirm the data will not include HIPAA identifiers? Yes ☐ No ☐ N/A ☐

END OF APPENDIX 1B(1)

Data Security Plan: APPENDIX 1B(2)

1B(2.) Collection of data via web-based or cloud storage (e.g. UVaCollab, UVaBox, or online consent, online surveys or any cloud service)

- Provide the name of the website or cloud storage (e.g.,URL): **dashboard.runscribe.com**

> **NOTE:** No research data of any kind may be stored in a non-UVa licensed cloud provider such as Dropbox, Google Drive, SkyDrive, Survey Monkey etc.
> **INSTRUCTIONS:** (e.g., https://name1.name2.org/mystudy/login.html)
> The URL is in the address bar of your web browser (e.g., Internet Explorer (IE), Firefox, Chrome)
> If you need additional assistance contact your department computer support or system administrator for assistance in answering this question.

  - Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS),ITS, third party)? **third party**
    - List how you contact this support (e.g., name, email, phone number): **Tim Clark, contact@runscribe.com**
  - What kind of device will be used to connect to this website/server? (*examples include non-UVA desktop computer, smart phone app, drive, tablet, laptop,*)? **smart phone app**

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? **self**

  - List how you contact this support (e.g., name, email, phone number): _____

> **INSTRUCTIONS:** If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

  - Will the data be transferred elsewhere? Yes ☐ No ☒
    If yes, answer the following four questions.

    1. Will the data be transferred in an **encrypted** secure manner such as the use of SFTP or HTTPS? Yes ☐ No ☐
       1a. Describe the transfer method: _____

    2. How long will the data remain on the website/server before being transferred?_____

    3. Please provide the location the data are transferred to:_____

    4. After information is transferred elsewhere will all the data be **securely** delete from the website/server? Yes ☐ No ☐

- **NOTE: Securely** deleted means the data are overwritten with zeros and ones and then deleted. You may need to check with the website/server administrator about their deletion method.

- Will anyone other than study team members have access to data on the server/website? Yes ☒ No ☐
  - If yes, describe: **RunScribe personnel will have access to de-identified data on the dashboard website.**

- Are any backups made of the information on the secure server/website? Yes ☐ No ☒
  If yes, explain how backups are made and where they are stored: _____

- Do the owners of the website/server have any rights to use or access data either individually or in aggregate? Yes ☐ No ☐
  If yes, please explain: _____

- If the website/server is not hosted at UVa, is there a Business Associates Agreement (BAA) with the provider of the non-UVa website? Yes ☐ No ☒ N/A ☐

END OF APPENDIX 1B(2)

Data Security Plan: APPENDIX 1B(3)

1B(3). To a UVa server NOT listed under 1B(4) below.

- Provide the name of the server/drive:_____

- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS),ITS, your department, third party)? _____

- List how you contact this support (e.g., name, email, phone number): _____

- What kind of device will be used to connect to this server/drive? _____
  (*examples include desktop computer, smart phone app, tablet, laptop,*?

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? _____

- List how you contact this support (e.g., name, email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(3)

Data Security Plan: APPENDIX 1B(4)

1B(4). Directly to one or more of the UVa servers listed below.

- ☐ Dropbox with Sookasa
- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☒ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsartredc1.hscs.virginia.edu/ UVA Bioinformatics REDCap
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☒ Qualtrics HSD
- ☐ School of Nursing SECURE NETf
- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop)* **desktop computer**

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? **LSP**

- List how you contact this support (e.g., name, email, phone number): IT Support for Educational Technologies Office at UVA Curry, edtech-support@virginia.edu, 434-924-7086.

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(4)

Data Security Plan: APPENDIX 1B(5)

1B(5).

Directly to a server/drive managed by the sponsor or CRO. Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

- Provide the name of the server/drive: _____
- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop,)*)? _____
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? _____
- List how you contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(5)

Data Security Plan: APPENDIX 1C(2)a

1C(2)a. Storage of data *ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer)*)

> **INSTRUCTIONS:** *If you will store health information with any of the identifiers checked in the table 1C(1)a (around page 5) you must also complete and have signed a* ***Highly Sensitive Data Storage Request form available at:***
> www.virginia.edu/informationsecurity/highlysensitivedata/approvalform.doc

- What kind of device is it (e.g. desktop computer, smart phone app, flash (thumb) drive, tablet, laptop, CD, C drive of your computer) **smart phone app**

- Who manages / supports the device (e.g., Health Systems Computing Services (HS/CS), local computer support partner (LSP), self)? **self**

  > **INSTRUCTIONS:** If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

- Will anyone other than study team members have access to data on the device?
  Yes ☒ No ☐ If yes, describe: **data will be stored in a de-identified fashion on the RunScribe**

- Are any backups made of the information on the device? Yes ☒ No ☐
  - If yes, explain how backups are made and where they are stored: **on the RunScribe**

- Does the owner of the device (e.g. phone service provider/ app developer) have any rights to use or access data either individually or in aggregate? Yes ☒ No ☐

- Are you storing audio- or video-recordings or pictures? Yes ☐ No ☒ N/A ☐
  - If yes, have you completed the Taping/Photography section in the protocol?
    Yes ☐ No ☐ N/A ☐

- If you are storing pictures or video recordings, do you confirm they will not include the full face? Yes ☐ No ☐ N/A ☒

- If you are storing audio- or video-recordings or pictures, do you confirm the data will not include HIPAA identifiers? Yes ☐ No ☐ N/A ☒

END OF APPENDIX 1C(2)a

Data Security Plan: APPENDIX 1C(2)b

1C(2)b. Storage of data on web-based or cloud storage (e.g., UVaBox, UVaCollab, online surveys or any cloud service)

- Provide the name of the website or cloud storage (e.g., URL): _____

NOTE: Not allowed if you have answered YES to any HIPAA identifier (the use of a unique subject ID (e.g. Subject # 1) is acceptable).

NOTE: No research data of any kind may be stored in a non-UVa licensed cloud provider such as Dropbox, Google Drive, SkyDrive, Survey Monkey etc.

INSTRUCTIONS: (e.g., https://name1.name2.org/mystudy/login.html)
The URL is in the address bar of your web browser (e.g., Internet Explorer (IE), Firefox, Chrome)
If you need additional assistance contact your department computer support or system administrator for assistance in answering this question.

- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS), ITS, third party)? _____
- List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/website? (*examples include desktop computer, smart phone app, tablet, laptop,*)? _____
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? _____
  - List how you contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage:
http://www.virginia.edu/informationsecurity/device-requirements.html

- Will anyone other than study team members have access to data on the server/drive? Yes ☐ No ☐
  - If yes, please describe: _____

- Are any backups made of the information on the secure server/drive? Yes ☐ No ☐
  If yes, explain how backups are made and where they are stored: _____

- Do the owners of the website/server have any rights to use or access data either individually or in aggregate? Yes ☒ No ☐
  If yes, please explain: **The owners of the website/server may individually access de-identifiable data.**

- If the website/server is not hosted at UVa, is there a Business Associates Agreement (BAA) with the provider of the non-UVa website? Yes ☐ No ☐ N/A ☐

END OF APPENDIX 1C(2)b

Data Security Plan: APPENDIX 1C(2)c

1C(2)c. To a UVa server NOT listed in 1C(2)d below.

- Provide the name of the server/drive: _____
- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS), ITS, third party)? _____
  - List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop)*? _____
- Who manages / supports this individual-use device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? _____
  - List how to contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)c

Data Security Plan: APPENDIX 1C(2)d

1C(2)d. Directly to one or more of the UVa servers listed below.

- ☐ Dropbox with Sookasa
- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☒ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsartredc1.hscs.virginia.edu/ UVA Bioinformatics REDCap
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☐ Qualtrics HSD
- ☐ School of Nursing SECURE NETf
- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop.)* **desktop computer**

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? _____

  - List how to contact this support (e.g., name, email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)d

Data Security Plan: APPENDIX 1C(2)e

1C(2)e. Directly to a server/drive managed by the sponsor or CRO. Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

- Provide the name of the server/drive: _____
- Who manages / supports this server or website? _____
- List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/drive? _____
  (*examples include desktop computer, smart phone app, tablet, laptop,)*)?
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group,, self)? _____
- List how to contact this support (e.g., name, email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (InfoSec) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)e

Data Security Plan Glossary:

Data Collected or Received: Where you put any kind of data recorded or gathered from another source for purposes of research. The data can come from any source, electronic, paper or voice. You may be sent these individual data points by paper, subject/patient interview or electronically. You may be manually extracting these data points from EPIC. You may be collecting these data with devices (camera, heart monitor, etc.)

Data Stored Long Term (Data storage) is different from data collected as it implies a longer-term non-volatile storage. It may be the same location as collected, (such as paper or HSCS server) or it may be a new location (computer drive or paper). It is where it is located for further analysis, manipulation, and access.

Highly Sensitive Data: includes personal information that can lead to identity theft if exposed and/or health information that reveals an individual's health condition and/or history of health services use. Electronic data storage policy: http://uvapolicy.virginia.edu/policy/IRM-015 Three HIPAA-identifiers are considered highly sensitive data by themselves (without being connected to PHI). These are #7-Social Security Number, #10-Account numbers, if it's a financial account number such as credit card or bank card number and #11 – Certificate/license number if it's a passport number, driver's license number, board license number, etc.). If these are in a file or on paper without any personal health information (PHI) it is still highly sensitive data (HSD).

Moderately Sensitive Data: includes information that is not highly sensitive nor is intentionally made public. So this category includes most of the data and information we work with. All research data that is not intentionally made public (e.g., published) is considered moderately sensitive data (MSD).

Individual Use Device: any kind of technology that has persistent memory. Flash memory, solid state drives, traditional hard drives, SD cards, USB thumb drives (sticks) allow for data to be kept long term. This means that any smartphones, laptops, tablets, biometric fitness devices and digital cameras and MP3 recorders (digital audio) qualify as individual use devices that could store potential data and must be protected.

Web based or Cloud storage: generally implies a storage server where a web browser is the main way to login and manipulate files. Sometimes a smartphone app is created to interface to these cloud storage containers. Examples include UVaBox, Box.com Google Drive, Google Docs, DropBox. Use of any Google Drive, Doc, Email, etc. for any UVa data or files is against UVa data protection policies.

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

There is no funding for this study.

Key Information About This Research Study

Principal Investigator:	**Jay Hertel, Ph.D., ATC** Department of Kinesiology PO Box 400407 Charlottesville, VA 22908 (P) (434) 243-8673 **(E) jnh7g@virginia.edu**

You are being asked to take part in a research study. You do not have to take part in this study.

You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

This study is trying to examine running gait mechanics using wearable sensors during regular running training over time along with self-reported measures of running mileage, soreness and injury, mood, and sleep and tiredness. All participants will be asked to use small wearable sensors on their training shoes during regular running training. With this study we hope to gain information on running patterns as they relate to wellness under normal training conditions. You are being asked to take part in this study because you are currently a runner with at least 3 months of running experience.

Why would you want to take part in this study?
You might like to take part in this study because your physical exam results will be shared with you and you may have access to the RunScribe data during the time you are wearing the sensors, which may give you information regarding your gait. The information researchers get from this study may help others in the future.

Why would you NOT want to take part in this study?
You might not want to take part in this study because this requires responding to surveys on a regular basis and remember to wear the sensors for each run during the time that you are participating in the study.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form.
If you take part in this study you will:

- Complete health and running questionnaires
- Complete a physical exam including measurements of foot, leg, and hip alignment, flexibility, and strength
- Run on a treadmill for approximately 10 minutes
- Download the RunScribe™ application onto your smartphone and use a set of running sensors at least twice per week during your normal runs in the study timeframe
- Respond to surveys on your smartphone about your well-being

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

- You will be asked to wear the sensors during your regular running training
- You will be asked to respond to weekly surveys

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- Review of your medical history
- Review of your distance running experience
- Review of your current weekly running mileage

If you are eligible, you will return to the clinic at a later date to begin study treatment, or you may continue with the remainder of testing. The tests and procedures in this study are being done for research purposes only.

STUDY PROCEDURES

Visit 1

If you are eligible and agree to participate in this study, you will be asked to fill out some questionnaires. These questionnaires will ask about:

- General medical history
- Physical activity level
- Exercise-related lower leg pain
- Foot and Ankle Ability Measures

It will take about 15-20 minutes to complete all questionnaires.

Physical Exam

Once you have completed the questionnaires, you will be asked to go through a clinical exam. This will include:

15. Measurement of foot posture, by placing your foot on a platform while your foot length is measured, while seated and standing. We will ask you to march in place and then stand as you normally would as your foot is positioned in several different ways.
16. Measurement of leg length while standing. You will lie on a table while a member of the study team measures your legs from your hip bone to your inner ankle bone.
17. Measurement of hip alignment while standing.
18. Measurement of hip, knee, ankle, and foot motion while sitting or lying on a table.
19. Measurement of hip, knee, and ankle flexibility while sitting or lying on a table.
20. Testing of hip, knee, and ankle strength with investigator providing resistance while sitting or lying on a table.

Running on a Treadmill

Once you have completed the physical exam, you will complete the indoor running portion of the study.

32. You will have sensors attached (with adhesive tape) to your skin that will passively record how you move and how your muscles turn on during running.
33. With the sensors on, you will run for up to 10 minutes on a treadmill.

Running with Wearable Sensors

9. You will need to have access to a smart phone device, and download the RunScribe™ application to keep track of your runs.

10. You will receive a demonstration on how to use the shoe wearable sensors (RunScribe™) and the associated mobile phone application. Your shoes will then be fitted with the RunScribe™ lace sensors.
11. You will then complete a 400-meter run around a track in order to calibrate the sensors.
12. You will keep these calibrated sensors and wear them on the laces of your training shoes at least two times per week during normal runs during the study period.

Surveys

1. You will need to respond to weekly surveys sent to your smart phone device.
2. Questions in the survey will ask you about your:
    a. Running mileage
    b. Hours and quality of sleep, and your energy level
    c. Stress and mood levels
    d. Body soreness level

Weekly Check-Ins

1. A study team member will either ask you in person or electronically weekly asking about any injuries that might have occurred during the week, and ensure the sensors are working properly.
2. If you are a member of the UVA varsity track or cross-country team, your athletic trainer may be contacted for injury information.

How long will this study take?

Your participation in this study will require ***1*** study visit. The visit will last about **2** hours. Additionally, at the end of the study time period, you will be asked to return the sensors to the investigators at Memorial Gymnasium.

What are the risks of being in this study?

Risks related to the procedures include:

12. Muscle soreness during or after testing/your calibration run may occur rarely

13. Incidental injury during the treadmill running/calibration run

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. Your physical exam results will be shared with you and you may have access to the RunScribe data during the week you are wearing the sensors, which may give you information regarding your gait. The information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only choice is not to be in this study.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study. If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

The questionnaires, physical examination, gait analysis, and wearable sensor use in this study will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) You become injured and can no longer participate in the study
b) The study is closed for safety, administrative, or other reasons

If you decide to stop being in the study, we will ask you to return all wearable sensors.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

Information obtained from you during this study will not be used in future research.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Tax reporting offices (if you are paid for being in the study)
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Jay Hertel
Curry School of Education, Department of Kinesiology PO Box 400407 Charlottesville, VA 22908, Telephone:(434)243-8673

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483, Charlottesville, Virginia 22908, Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and

all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

Signature From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Signature

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING SIGNATURE (SIGNATURE)	PERSON OBTAINING SIGNATURE (PRINT)	DATE

Table C3a – Running and Health History Questionnaire

1. How long have you been running regularly? (# of years/ months)_____
2. Why do you run? (check all that apply)
   ___ fitness ____recreation ____competition
3. How many days a week do you run?
   _____
4. How many miles per week do you average?
   _____
5. What is your average pace per mile?
   _____
6. What level of runner do you consider yourself?
   ____beginner ____intermediate ____advanced ____competitive
7. What shoes are you currently running in?
   _____
8. How many miles have you run in the shoes that you are wearing currently?
   _____
9. Do you wear orthotics in your running shoes? _____ Yes _____ No

   If yes, why do you wear orthotics?_____
10. Do you currently have a running-related injury? _____ Yes _____ No
    If yes, explain:_____
    Have you sustained any previous running-related injuries? _____ Yes _____ No

    If yes, explain:_____
    _____
11. Have you had any surgeries? _____ Yes _____ No
    If yes, explain:_____
    _____

Table C3b – Exercise-Induced Leg Pain Questionnaire – British Version

EXERCISE-INDUCED LEG PAIN QUESTIONNAIRE-BRITISH VERSION (EILP-BR)

	No Difficulty	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to Perform	NA
When beginning to run						
Running after about 10 minutes						
Running after about 15 minutes						
Running after 30 minutes or longer						
Jumping						
Landing						
Starting and stopping quickly						
Sideward cutting movements						
Low-impact activities						
Ability to participate in your desired sport as long as you like						

Table C3c – Lower Extremity Functional Scale

The Lower Extremity Functional Scale

We are interested in knowing whether you are having any difficulty at all with the activities listed below **because of your lower limb problem** for which you are currently seeking attention. Please provide an answer for **each** activity.

Today, *do you* or *would you* have any difficulty at all with:

	Activities	Extreme Difficulty or Unable to Perform Activity	Quite a Bit of Difficulty	Moderate Difficulty	A Little Bit of Difficulty	No Difficulty
1	Any of your usual work, housework, or school activities.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
2	Your usual hobbies, re creational or sporting activities.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
3	Getting into or out of the bath.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
4	Walking between rooms.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
5	Putting on your shoes or socks.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
6	Squatting.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
7	Lifting an object, like a bag of groceries from the floor.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
8	Performing light activities around your home.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
9	Performing heavy activities around your home.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
10	Getting into or out of a car.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
11	Walking 2 blocks.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
12	Walking a mile.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
13	Going up or down 10 stairs (about 1 flight of stairs).	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
14	Standing for 1 hour.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
15	Sitting for 1 hour.	0 ☐	1 ☐	2 ☐	3 ☐	4
16	Running on even ground.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
17	Running on uneven ground.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
18	Making sharp turns while running fast.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
19	Hopping.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
20	Rolling over in bed.	0 ☐	1 ☐	2 ☐	3 ☐	4 ☐
	Column Totals:		0	0	0	0

Minimum Level of Detectable Change (90% Confidence): 9 points **SCORE: 0 / 80 (fill in the blank with the sum of your responses)**

Source: Binkley et al (1999): The Lower Extremity Functional Scale (LEFS): Scale development, measurement properties, and clinical application. Physical Therapy. 79:371-383.

Table C3d – 100-mm Visual Analog Pain Scale

12. Please rate your **highest pain in the last week** on the line below, with the farthest left being no pain, and the farthest right being the worst pain possible.

No Pain Worst Pain Possible

13. Please rate your **pain at rest** on the line below, with the farthest left being no pain, and the farthest right being the worst pain possible.

No Pain Worst Pain Possible

14. Please rate your **pain during a typical run** on the line below, with the farthest left being no pain, and the farthest right being the worst pain possible.

No Pain Worst Pain Possible

15. Please rate your **pain after a typical run** on the line below, with the farthest left being no pain, and the farthest right being the worst pain possible.

No Pain Worst Pain Possible

Table C3e – Godin Leisure-Time Exercise Questionnaire

Godin Leisure-Time Exercise Questionnaire

INSTRUCTIONS

In this excerpt from the Godin Leisure-Time Exercise Questionnaire, the individual is asked to complete a self-explanatory, brief four-item query of usual leisure-time exercise habits.

CALCULATIONS

For the first question, weekly frequencies of strenuous, moderate, and light activities are multiplied by nine, five, and three, respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components, as shown in the following formula:

Weekly leisure activity score = (9 × Strenuous) + (5 × Moderate) + (3 × Light)

The second question is used to calculate the frequency of weekly leisure-time activities pursued "long enough to work up a sweat" (see questionnaire).

EXAMPLE

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

Total leisure activity score = (9 × 3) + (5 × 6) + (3 × 14) = 27 + 30 + 42 = 99

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

	Times Per Week
a) **STRENUOUS EXERCISE** **(HEART BEATS RAPIDLY)** (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	_____
b) **MODERATE EXERCISE** **(NOT EXHAUSTING)** (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	_____
c) **MILD EXERCISE** **(MINIMAL EFFORT)** (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	_____

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. |_|	2. |_|	3. |_|

Table C3f – Global Rating of Change Score

Global Rating of Change

Please rate the overall condition of your injured body part or region from the **time that you began treatment until now**. (Select only one)

(+7) A very great deal better		(-7) A very great deal worse
(+6) A great deal better		(-6) A great deal worse
(+5) Quite a bit better		(-5) Quite a bit worse
(+4) Moderately better	About the same	(-4) Moderately worse
(+3) Somewhat better	(0)	(-3) Somewhat worse
(+2) A little bit better		(-2) A little bit worse
(+1) A tiny bit better		(-1) A tiny bit worse

Table C3g – University of Wisconsin Running Injury and Recovery Index

APPENDIX

APPENDIX A. University of Wisconsin Running Injury and Recovery Index

Instructions: Consider your current running injury over the **past 7 days** when answering each question; check (☒) the appropriate box.

1.	How does your running injury impact your ability to perform daily activities?	☐ No impact	☐ Slightly impact	☐ Moderately impact	☐ Significantly impact	☐ Unable to perform
2.	How frustrated are you by your running injury?	☐ Not frustrated	☐ Mildly frustrated	☐ Moderately frustrated	☐ Significantly frustrated	☐ Extremely frustrated
3.	How much recovery have you made from your running injury?	☐ Complete recovery	☐ Significant recovery	☐ Moderate recovery	☐ Minimal recovery	☐ No recovery
4.	How much pain do you experience while running?	☐ No pain	☐ Minimal pain	☐ Moderate pain	☐ Significant pain	☐ Unable to run
5.	How much pain do you experience during the 24 hours following a run?	☐ No pain	☐ Minimal pain	☐ Moderate pain	☐ Significant pain	☐ Unable to run
6.	How has your weekly mileage or weekly running time changed as a result of your injury?	☐ Same or greater than before my injury	☐ Minimally reduced	☐ Moderately reduced	☐ Significantly reduced	☐ Unable to run
7.	How has the distance of your longest weekly run changed as a result of your injury?	☐ Same or longer than before my injury	☐ Minimally reduced	☐ Moderately reduced	☐ Significantly reduced	☐ Unable to run
8.	How has your running pace or speed changed as a result of your injury?	☐ Same or faster than before my injury	☐ Minimally reduced	☐ Moderately reduced	☐ Significantly reduced	☐ Unable to run
9.	How does your injury affect your confidence to increase the duration or intensity of your running?	☐ Confident to increase my running	☐ If I increase I might be fine	☐ Neutral	☐ If I increase I might get worse	☐ I cannot increase my running

Table C3h – Rating of Perceived Exertion 10-point scale

"How would you rate your effort?" Thirty minutes post workout subjects were again shown the scale and asked, "How would you rate your entire workout?"

Rating	Descriptor
0	**Rest**
1	**Very, Very Easy**
2	**Easy**
3	**Moderate**
4	**Somewhat Hard**
5	**Hard**
6	*
7	**Very Hard**
8	*
9	*
10	**Maximal**

Table C3i – Custom Running and Wellness Questionnaire

Start of Block: Default Question Block

Q12 What is your RunScribe Sensor #?

_____

Q1 What is your current distance logged this week (in miles)?

_____

Q2 How many hours of sleep did you get last night?

_____

Q3 How would you rate the quality of your sleep?

- 1 - insomnia (1)
- 2 - restless sleep (2)
- 3 - difficulty falling asleep (3)
- 4 - good (4)
- 5 - very restful (5)

Q4 What is your energy level today?

- ○ 1 - exhausted (1)
- ○ 2 - more tired than normal (2)
- ○ 3 - normal (3)
- ○ 4 - fresh (4)
- ○ 5 - very fresh (5)

Q5 What is your stress level today?

- ○ 1 - highly stressed (1)
- ○ 2 - feeling stressed (2)
- ○ 3 - normal (3)
- ○ 4 - relaxed (4)
- ○ 5 - very relaxed (5)

Q6 How would you rate your mood today?

- ○ 1 - highly annoyed (1)
- ○ 2 - snappiness at others (2)
- ○ 3 - less interested in activities than usual (3)
- ○ 4 - generally good mood (4)
- ○ 5 - very positive mood (5)

Q13 How would you rate your entire workout in terms of effort?

	Rest	Very, Very Easy	Easy	Moderate	Somewhat Hard	Hard	Very Hard	Maximal
	0	1	2	3	4	5	6	7	8	9	10
Workout Rating ()											

Q7 How would you rate your soreness level today?

- 1 - very sore (1)
- 2 - increase in tightness/soreness (2)
- 3 - normal (3)
- 4 - feeling good (4)
- 5 - feeling great (5)

Display This Question:

If How would you rate your soreness level today? = 1 - very sore

Or How would you rate your soreness level today? = 2 - increase in tightness/soreness

Q9 Where are you experiencing your soreness?

- [ ] Right Foot (1)
- [ ] Left Foot (2)
- [ ] Right Ankle (3)
- [ ] Left Ankle (4)
- [ ] Right Calf (5)
- [ ] Left Calf (6)
- [ ] Right Shin (7)
- [ ] Left Shin (8)
- [ ] Right Knee (9)
- [ ] Left Knee (10)
- [ ] Right Quad (11)
- [ ] Left Quad (12)
- [ ] Right Hamstring (13)
- [ ] Left Hamstring (14)
- [ ] Right Groin (20)
- [ ] Left Groin (21)

- [ ] Right Hip (15)
- [ ] Left Hip (16)
- [ ] Lower Back (17)
- [ ] Shoulders/Upper Body (19)
- [ ] Other (22) _____

Display This Question:
If How would you rate your soreness level today? = 1 - very sore
Or How would you rate your soreness level today? = 2 - increase in tightness/soreness

Q10 Is your soreness progressing to pain?

- ○ Yes (1)
- ○ No (2)

Display This Question:
If Is your soreness progressing to pain? = Yes

Q11 Have you seen your athletic trainer or another healthcare contact about your pain?

- ○ Yes (1)
- ○ No (2)

End of Block: Default Question Block

Table C4a. Data Collection & Procedures – Instrumentation & Procedures

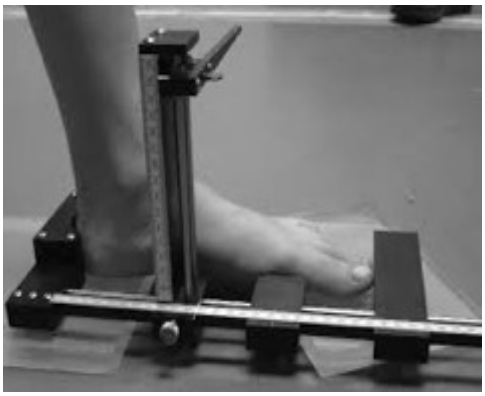
Foot Posture Index

Visual inspection and palpation of the foot from an anterior and posterior clinician view. The participant will be asked to take several steps in place to obtain a natural foot positioning, and then the assessor will use the objective criteria below to form a clinical impression of foot posture (Redmond 2006).

	COMPONENT	PLANE	SCORE 1 Date_____ Comment_____	
			Left *(-2 to +2)*	***Right*** *(-2 to +2)*
Rearfoot	Talar head palpation	Transverse		
Rearfoot	Curves above and below lateral malleoli.	Frontal/ Sagittal		
Rearfoot	Inversion/eversion of the calcaneus	Frontal		
Forefoot	Bulge in the region of the TNJ	Transverse		
Forefoot	Congruence of the medial longitudinal arch	Sagittal		
Forefoot	Abduction/adduction of the forefoot on the rear foot (too-many-toes).	Transverse		
	TOTAL			

Arch Height Index

A left and right Jaktool will be used to measure the foot length and truncated foot length (foot length from the heel until the first metatarsophalangeal joint). The arch height is then measured from 1/2 the foot length with a free-falling bar. These measurements are recorded and the patient is then asked to stand. From a standing position the measurements are taken again. With this data arch height index in sitting and standing, arch rigidity index, and arch drop are measured for each foot.

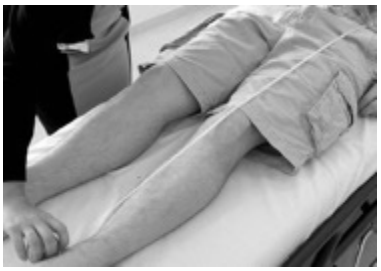


Ankle Weight Bearing Dorsiflexion

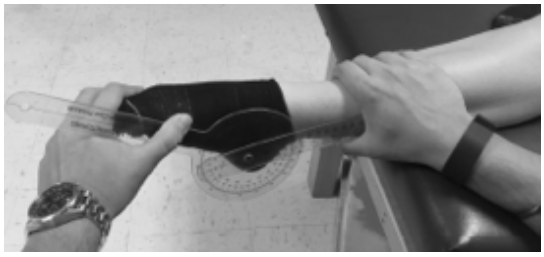
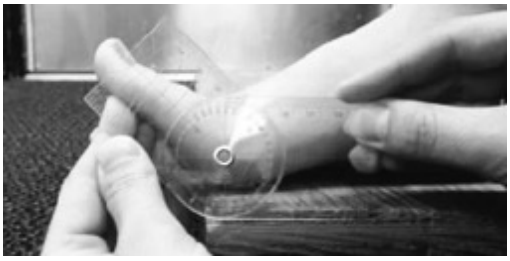
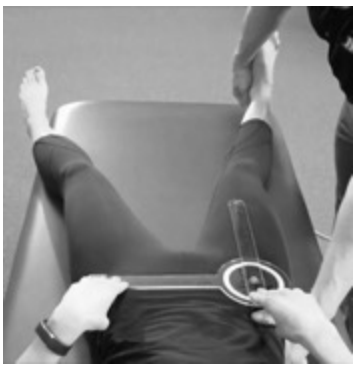
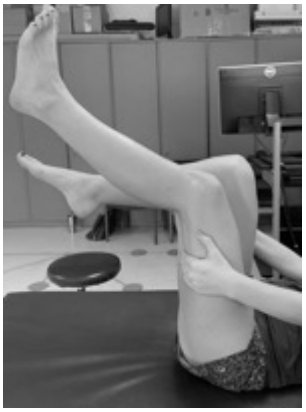
The participant will align their foot on a tape measure that is flush against a wall, such that their foot is flat on the floor and their knee touches the wall. The participant will be asked to move their foot further back along the tape measure while the heel maintains contact on the ground and their knee on the wall, until either is about to come off. The assessor will measure the furthest point from the great toe to the wall for the weight-bearing dorsiflexion measure.

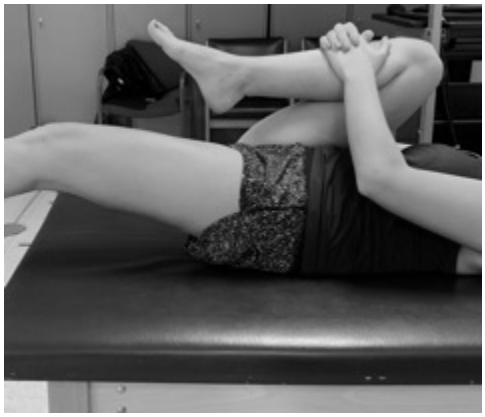
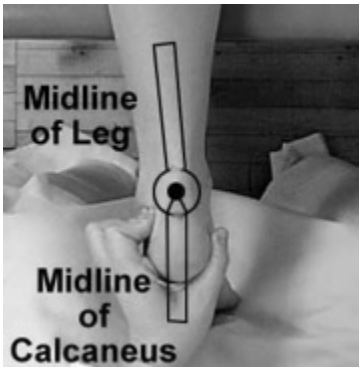
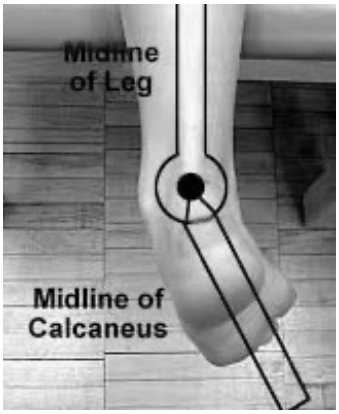
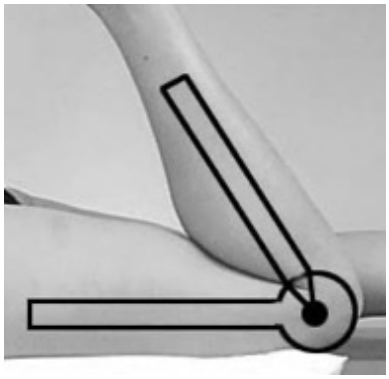
Leg Length

With the patient in supine, the assessor will measure the distance from the anterior superior iliac spine to the tip of the medial malleolus in centimeters for anatomical leg length.



Standard goniometry measures will be taken to assess lower extremity motion as follows:

Q Angle	Knee Extension
	
Ankle Dorsiflexion	**Ankle Plantarflexion**
	
First MTP Flexion	**First MTP Extension**
	
Hip Abduction	**90°/90° Straight Leg Raise**
	

Thomas Test	Ankle Inversion
	
Ankle Eversion	**Knee Flexion**
	
Hip Anteversion	**Tibial Torsion**
	

Standard hand-held dynamometry measures for lower extremity strength will be as follows (Fraser et al. 2017; Thornberg et al. 2010):

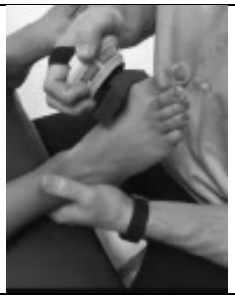
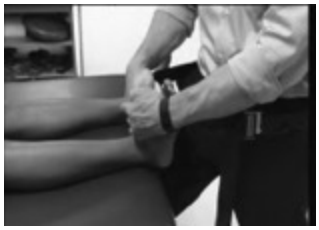
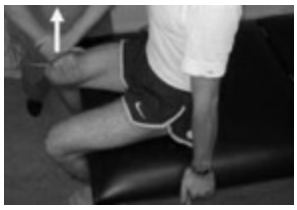
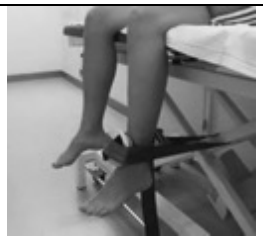
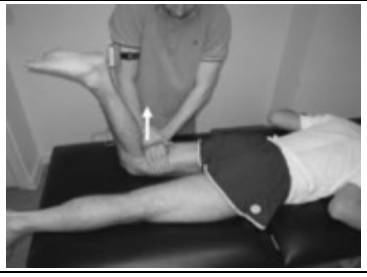
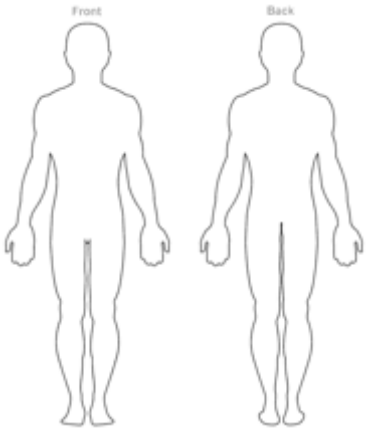
1st MTP Flexion	**Ankle Inversion**
	
Ankle Eversion	**Ankle Dorsiflexion**
	
Hip Flexion	**Knee Extension**
	
Ankle Plantarflexion	**Hip Extension**
	
Knee Flexion	**Hip Abduction**
	

Table C4b. Data Collection Forms
Participant ID _____
Date_____

BASELINE I DATA COLLECTION SHEET

Sex: ____ Age: ____



PHYSICAL EXAM

R	L	
____	____	Pain along the proximal 2/3 of tibia
____	____	Pain along the distal 1/3 of the posteromedial tibia
____	____	Pain with palpation of tibialis anterior?
____	____	Pain with MMT of tibialis anterior?
____	____	Pain with palpation of tibialis posterior?
____	____	Pain with MMT of tibialis posterior?
____	____	Pain with palpation of the evertors/lat. compartment?
____	____	Pain with MMT of peroneals?
____	____	Thompson test +?
____	____	Diffuse tenderness?
____	____	Diffuse muscle weakness?
____	____	Paresthesia with touch or sensations of tension/fullness in anterior leg?

Notes:

FOOT POSTURE INDEX

	FACTOR	PLANE	LEFT (-2 to +2)	RIGHT (-2 to +2)
Rearfoot	Talar head palpation	*Transverse*		
	Curves above and below lateral malleoli	*Frontal/Trans*		
	Inversion/eversion of the calcaneus	*Frontal*		
	Bulge in the region of the TNJ	*Transverse*		
Forefoot	Congruence of the medial longitudinal arch	*Sagittal*		
	Abd/Adduction of the forefoot on rearfoot (too many toes)	*Transverse*		
	TOTAL			

-12 to -5	-4 to -1	0 to 5	+6 to +9	10+
Highly Supinated	Supinated	Normal	Pronated	Highly Pronated

ARCH HEIGHT INDEX (JAKTOOL)

(R)Arch Height Index	Unloaded	Loaded
Total foot length (cm)		
Truncated foot length (cm)		
Foot width (mm)		
Dorsal Arch Height (50% total length, cm)		
(L)Arch Height Index	Unloaded	Loaded
Total foot length (cm)		
Truncated foot length (cm)		
Foot width (mm)		
Dorsal Arch Height (50% total length, cm)		

Passive Range of Motion

Patient Position	Motion	Left	Right
Standing	Ankle Weight Bearing Dorsiflexion (Knee-to-Wall, cm)		
Supine	Leg Length (cm)		
	Q-Angle		
	Knee Extension (bolster)		
	Ankle Plantarflexion		
	Ankle Dorsiflexion		
	1st MTP Flexion		
	1st MTP Extension		
	Hip Abduction		
	90°/90° Straight Leg Raise		
	Thomas Test (cm)		
Prone	Ankle Inversion		
	Ankle Eversion		
	Knee Flexion		
	Tibial Torsion		
	Hip Anteversion		

Strength Measures

Patient Position	Strength Measure	Left	Right
Supine	1st MTP Flexion		
	Ankle Inversion		
	Ankle Eversion		
	Ankle Dorsiflexion		
Short Sit	Hip Flexion		
	Knee Extension		

Prone	Ankle Plantarflexion		
	Hip Extension		
	Knee Flexion		
Side Lying	Hip Abduction		

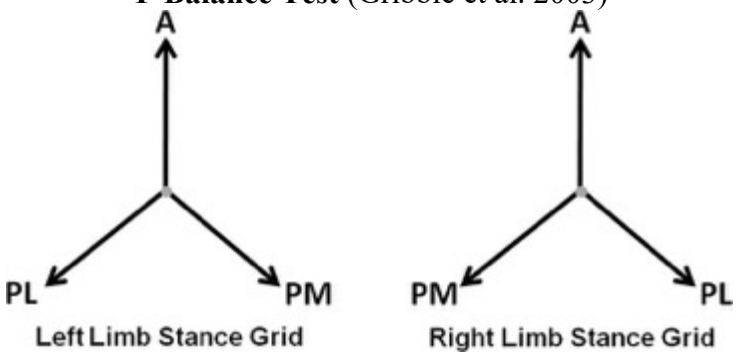
Functional Movement Assessments – *ALL RECORDED*

SEBT (cm)	Left	Right
Medial		
Anteromedial		
Anterior		
Anterolateral		
Lateral		
Posterolateral		
Posterior		
Posteromedial		

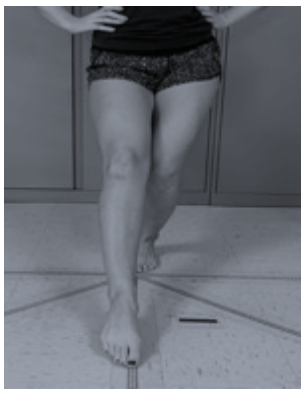
□ Lateral Step-Down
□ Single Leg Squat
□ Gait Assessment
(5 min warm-up, 30 sec recording)

Table C5a. Functional Movement Assessments – Instrumentation & Procedures

Y-Balance Test (Gribble et al. 2003)



a. Anterior



b. Posterolateral

c. Posteromedial

Single Leg Squat to 45° Knee Flexion

Lateral Step-Downs

Table C5b. Functional Movement Assessments – Assessment Criteria Sheets

PARTICIPANT ID	

AFFECTED LIMB?	

STAR EXCURSION BALANCE TEST

AFFECTED LIMB

AFFECTED LIMB LEG LENGTH (cm)		*Video Impression (put a "1" under the appropriate criteria)*			
	Reach Distance	Medial Knee Displacement / Hip Drop / Ipsilateral Trunk Lean	Neutral Hip and Knee	Lateral Patellar Displacement / Hip Hike / Contralateral Trunk Lean	*Normalized Reach Distance*
ANTERIOR					#DIV/0!
ANTEROLATERAL					#DIV/0!
LATERAL					#DIV/0!
POSTEROLATERAL					#DIV/0!
POSTERIOR					#DIV/0!
POSTEROMEDIAL					#DIV/0!
MEDIAL					#DIV/0!
ANTEROMEDIAL					#DIV/0!
OVERALL IMPRESSION		0	0	0	

SINGLE LEG SQUAT

AFFECTED LIMB	*Video Impression (put a "1" under the appropriate criteria)*		
	Medial Knee Displacement / Hip Drop / Ipsilateral Trunk Lean	Neutral Hip, Knee, and Trunk	Lateral Patellar Displacement / Hip Hike / Contralateral Trunk Lean
Frontal View			
	Anterior Knee Displacement / Forward Trunk Lean	Neutral Hip, Knee, and Trunk	Posterior Trunk Lean
Sagittal View			
Overall Impression	0	0	0

LATERAL STEP-DOWN

AFFECTED LIMB	*Video Impression (put a "1" under the appropriate criteria)*		
	Medial Knee Displacement / Hip Drop / Ipsilateral Trunk Lean	Neutral Hip, Knee, and Trunk	Lateral Patellar Displacement / Hip Hike / Contralateral Trunk Lean
Frontal View			
	Anterior Knee Displacement / Forward Trunk Lean	Neutral Hip, Knee, and Trunk	Posterior Trunk Lean
Sagittal View			
Overall Impression	0	0	0

GAIT ASSESSMENT

	Video Impression (put a "1" under the appropriate criteria)		
	Medial Knee Displacement / Hip Drop / Ipsilateral Trunk Lean	Neutral Hip, Knee, and Trunk	Lateral Patellar Displacement / Hip Hike / Contralateral Trunk Lean
Frontal View			
	Medial Knee Displacement / Hip Drop / Ipsilateral Trunk Lean	Neutral Hip, Knee, and Trunk	Posterior Trunk Lean
Sagittal View			
Overall Impression	0	0	0

FOOT ALIGNMENT

AFFECTED LIMB

FOOT POSTURE INDEX (SUM)	
UNLOADED TOTAL	
UNLOADED TRUNCATED	
UNLOADED WIDTH	
UNLOADED ARCH	
LOADED TOTAL	
LOADED TRUNCATED	
LOADED WIDTH	
LOADED ARCH	

Unloaded Arch Height Index
#DIV/0!
Loaded Arch Height Index
#DIV/0!
Arch Rigidity Index
#DIV/0!
Arch Drop
0

KEY	AHI ratios	Drop
Varus	0.356	0
Normal	0.316	0.6
Valgus	0.275	1

FLEXIBILITY

AFFECTED LIMB

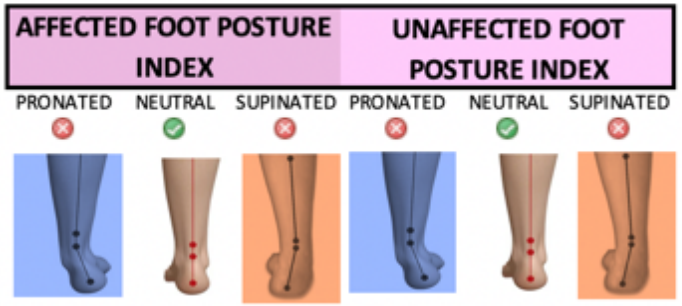
Weight-Bearing Dorsiflexion	
90-90 Straight Leg Raise	
Thomas Test	


AFFECTED SINGLE LEG SQUAT
VALGUS
NEUTRAL
VARUS


AFFECTED LATERAL STEP DOWN
VALGUS
NEUTRAL
VARUS


STAR EXCURSION BALANCE TEST - AFFECTED
VALGUS
NEUTRAL
VARUS


GAIT ASSESSMENT
VALGUS
NEUTRAL
VARUS


AFFECTED FOOT POSTURE INDEX
UNAFFECTED FOOT POSTURE INDEX
PRONATED
NEUTRAL
SUPINATED
PRONATED
NEUTRAL
SUPINATED


SEBT PERFORMANCE
ANTERIOR
ANTEROLATERAL
LATERAL
POSTEROLATERAL
POSTERIOR
POSTEROMEDIAL
MEDIAL
ANTEROMEDIAL
90
80
70
60
50
40
30
20
10
0
AFFECTED LIMB
Target Performance

FUNCTIONAL MOVEMENT TESTING

VALGUS	NEUTRAL	VARUS
SINGLE-LEG SQUAT (CRITERIA 1)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray
LATERAL STEP-DOWN (CRITERIA 2)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray
STAR EXCURSION BALANCE TEST (CRITERIA 3)		
Posterior reach deficits, Medial knee displacement, Contralateral pelvic drop	90%* of leg length reach performance, Center of patella maintains over first ray, No contralateral hip drop	Medial reach deficits, Center of patella tracks over lateral foot ray
ARCH HEIGHT INDEX/FOOT POSTURE INDEX (CRITERIA 4)		
Arch collapse Pronated foot position	Relatively stable arch, Neutral foot positioning	Immobile arch, Supinated foot positioning
GAIT ASSESSMENT (CRITERIA 5)		
Medial knee displacement, Contralateral pelvic drop	Center of patella maintains over first ray, No contralateral hip drop	Center of patella tracks over lateral foot ray

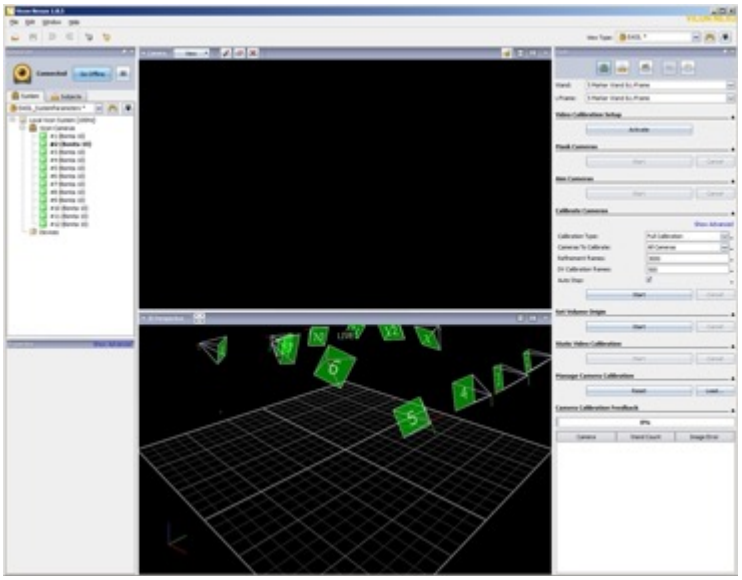
FLEXIBILITY TESTING

HYPERMOBILE	NEUTRAL	HYPOMOBILE
WEIGHT-BEARING LUNGE TEST		
Distance > 1-SD above normative database, no stretching needed	Distance within 1-SD of normative database, no stretching needed	Distance < 1-SD below normative database, gastrocnemius/soleus stretching needed
90º/90º STRAIGHT LEG RAISE		
Within 10º full extension, no stretching needed	Between 10-20º full extension, no stretching needed	Above 20º away from full extension, hamstring stretching needed
THOMAS TEST		
No leg lift off table, no stretching needed	Leg lift less than 3 cm off table, no stretching needed	Leg lift > 3cm off table, hip flexor stretching needed

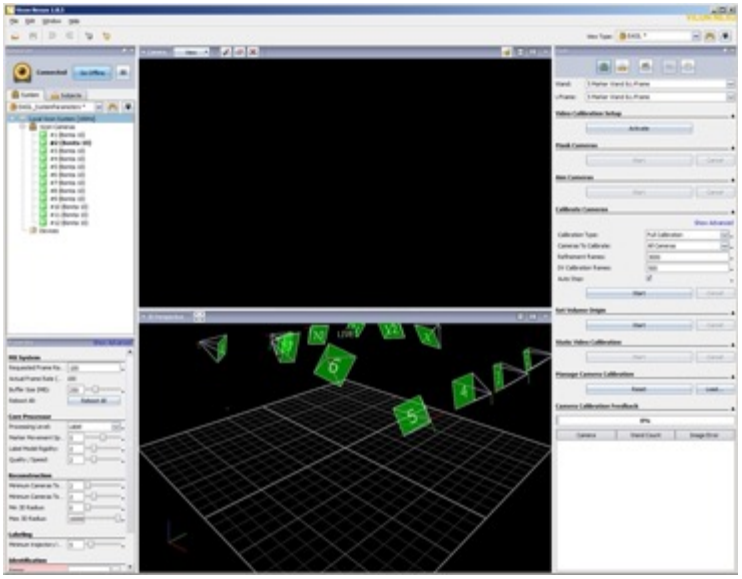
Table C6a. Laboratory Gait Assessments –Instrumentation & Procedures

Vicon and MotionMonitor Setup Using the Cluster Markers

1. Turn on computer and open Vicon Nexus
    a. Make sure all cameras are green
    b. If any cameras are not green, unplug and reinsert corresponding camera cable



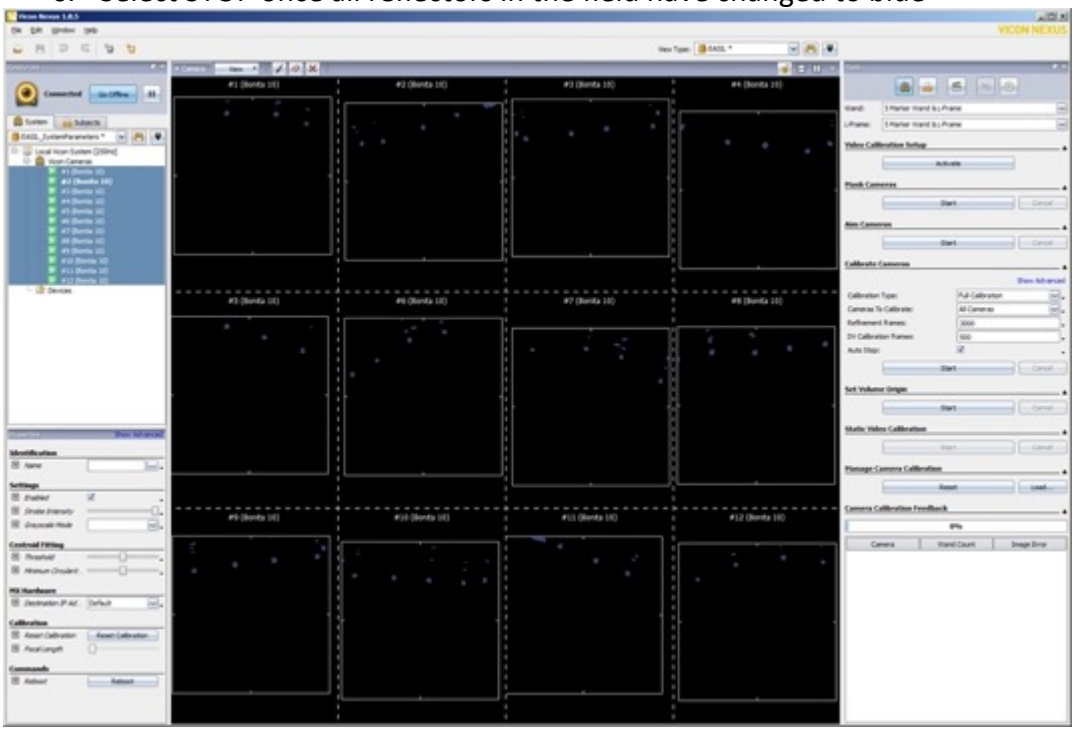
2. Change frame rate to 250 Hz.



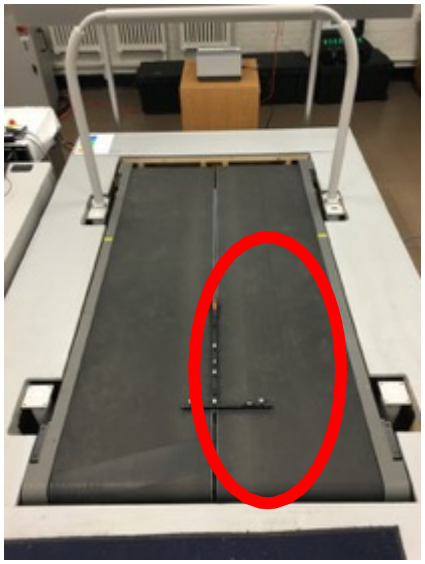
3. Select all cameras and change view to camera view
4. Remove all markers from the field

a. If an unknown marker is in the field, try to locate it before masking cameras

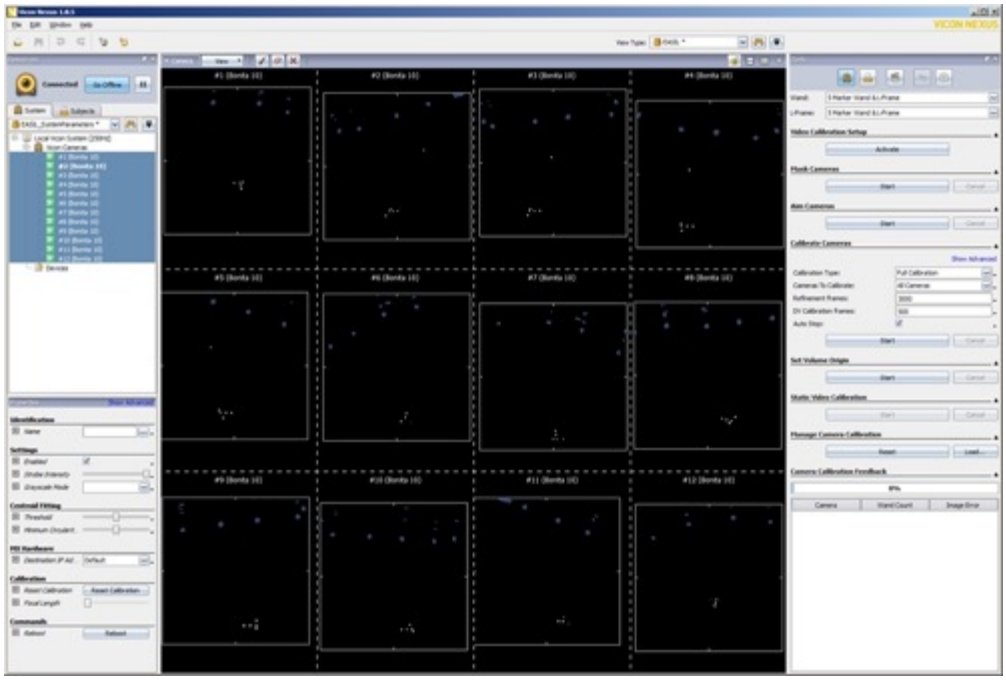
5. Mask cameras
6. Select STOP once all reflectors in the field have changed to blue



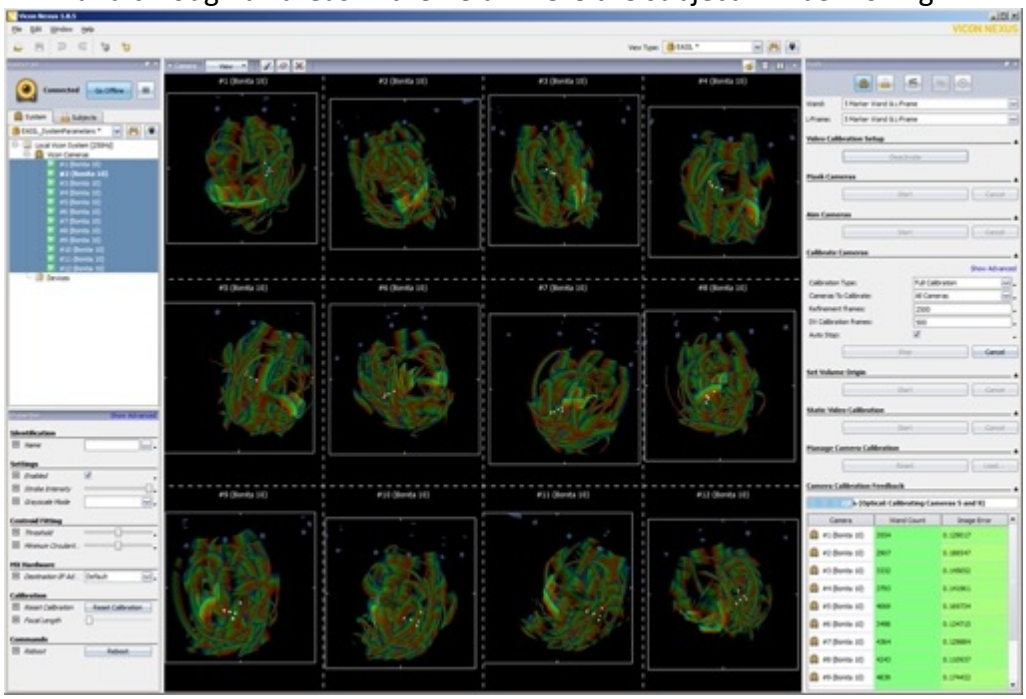
7. Place the L-shaped wand in the field at the edge of the force plates



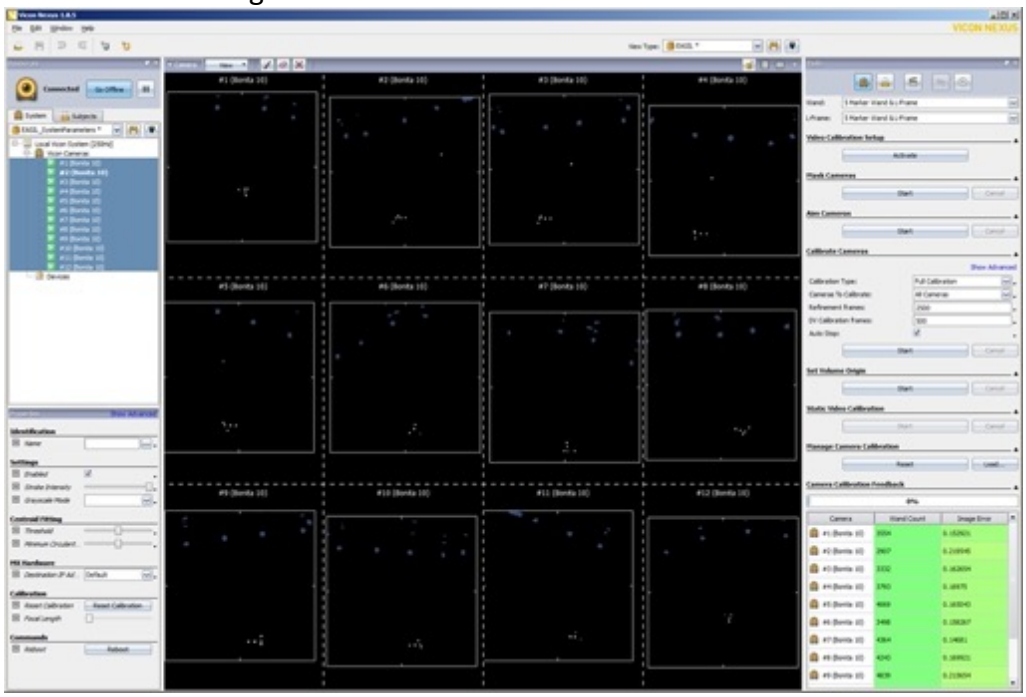
8. Aim Cameras



9. Calibrate cameras using 2500 refinement frames. Make sure to move the wand through all areas in the field where the subject will be moving.

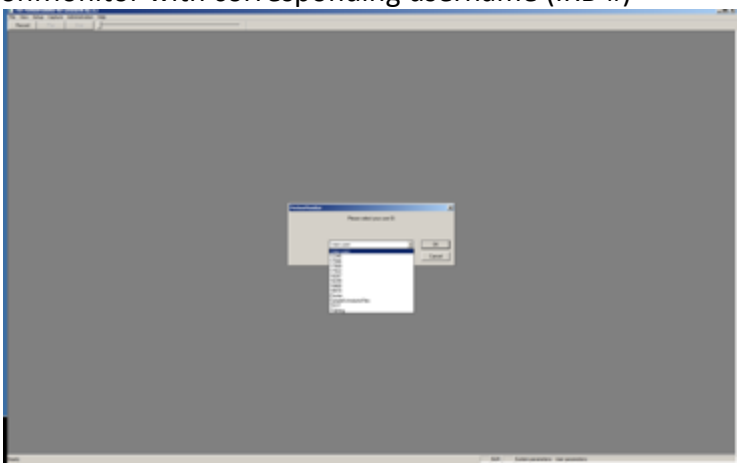


10. Check Image Error for any error greater than 0.25 – this may require recalibration
11. Replace the wand in the field (see picture in Step 7)
12. Set Volume Origin

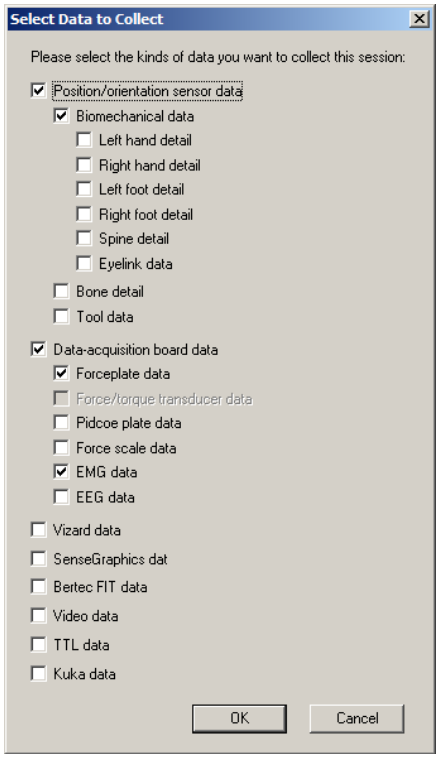


13. Select “Subjects’ tab to verify cluster files have loaded.
    a. Select the appropriate subject markers. (Uncheck Eyelink and TMM_Head)
    b. Press Control-R and markers on participant will be recognized to create model.

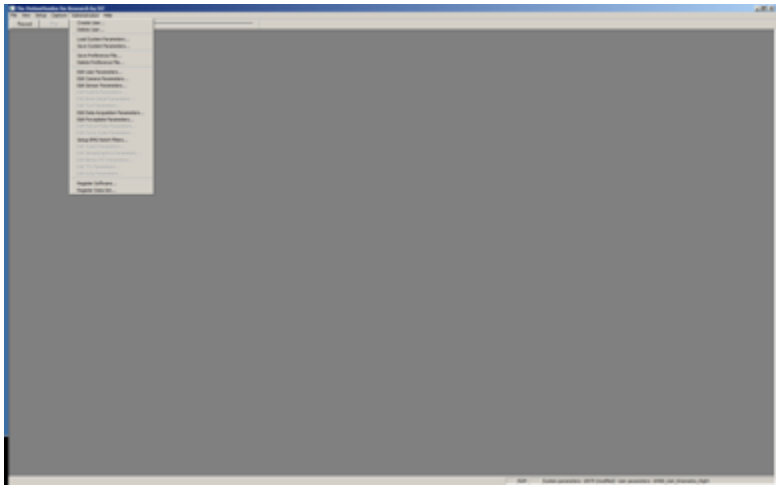
14. Open MotionMonitor with corresponding username (IRB #)



15. Select data to collect: Make sure Position/orientation sensor data, Biomechanical data, Data-acquisition data, forceplate data, and EMG data are checked.



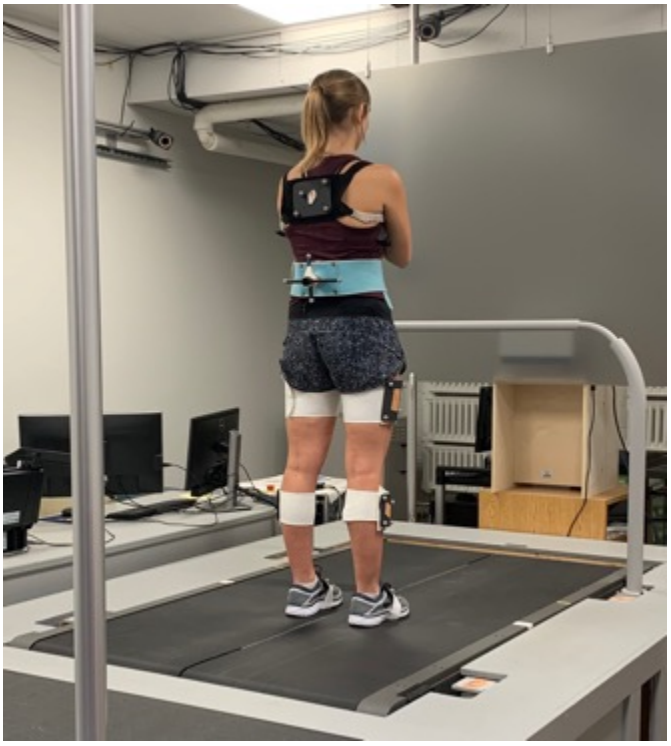
16. Go to the top menu and select Administration and Load System Parameters.



Load corresponding system parameters (IRB #).

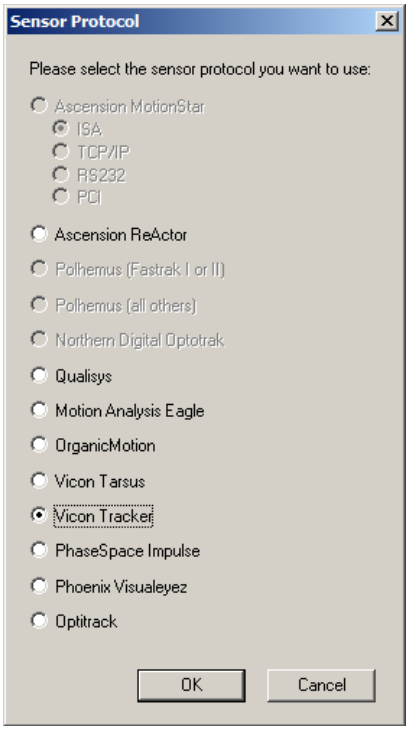
17. Go to the top menu and select File and Preference File. Load appropriate preference file.
18. Subject should enter the field (stand on the treadmill) with all clusters attached and the stylus placed within the view of the cameras.

a. Press Control-R to refresh the view of the markers in Vicon

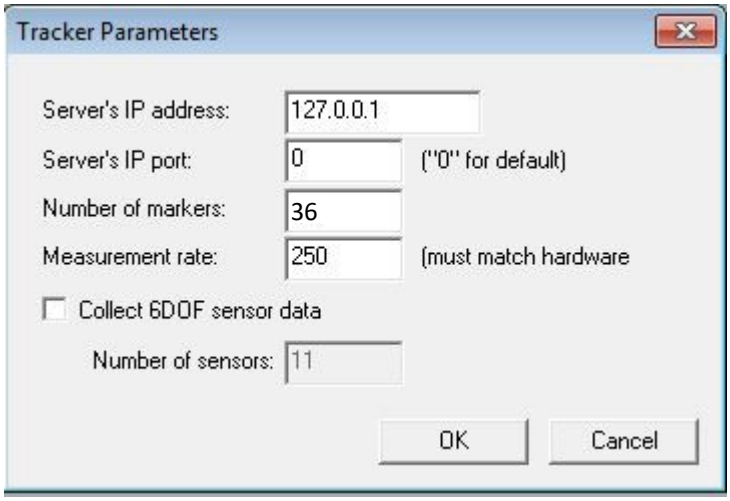


19. Go to the top menu and select Administration then select Edit Sensor Parameters.

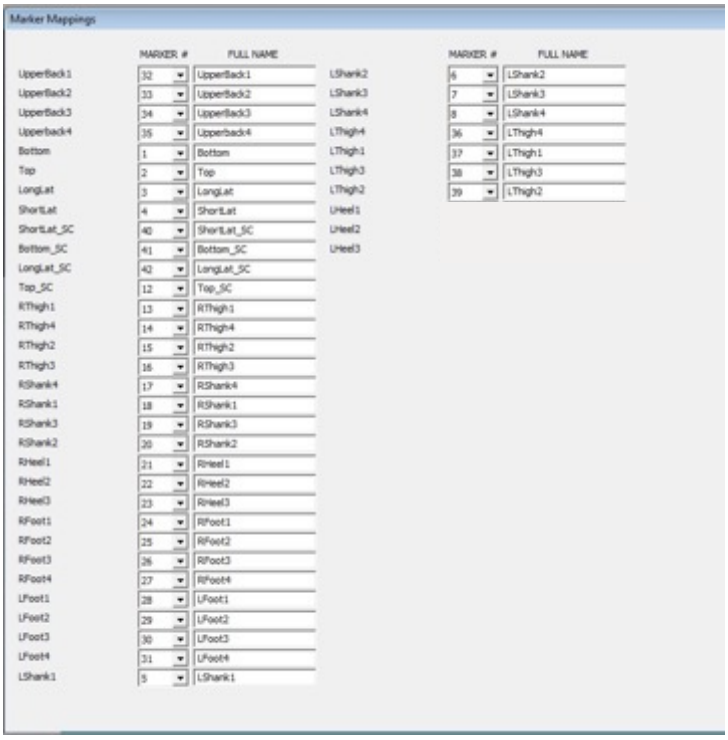
20. Select Vicon Tracker

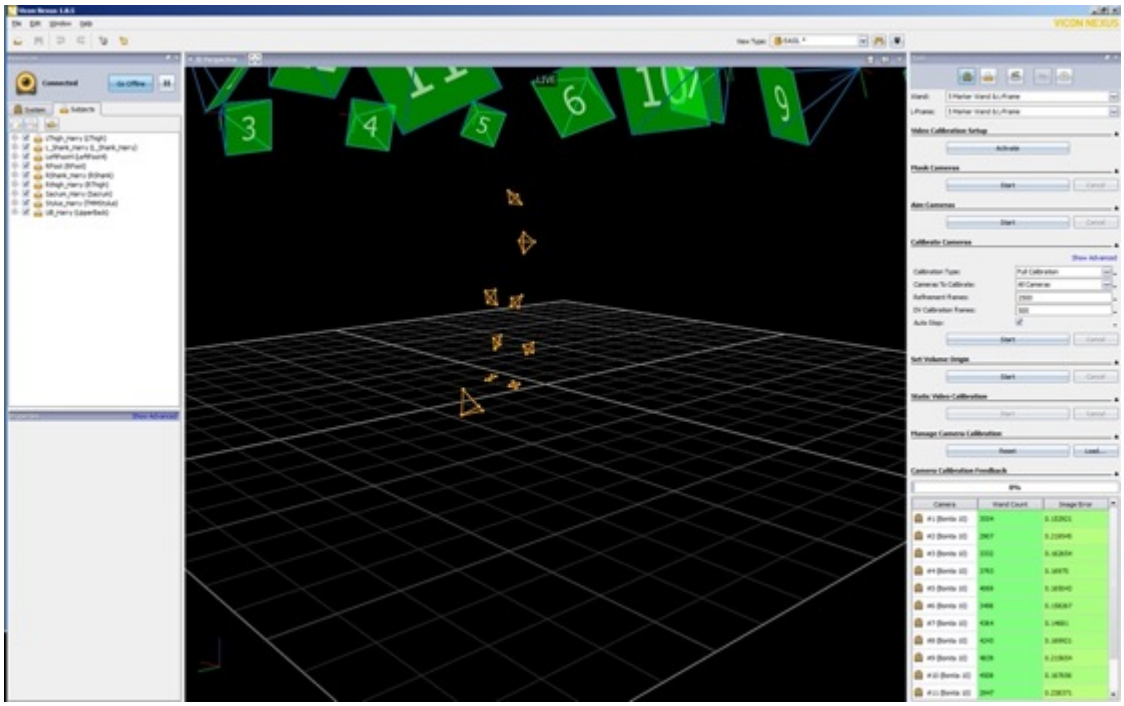


21. Confirm that number of markers = 36 and measurement rate = 250Hz

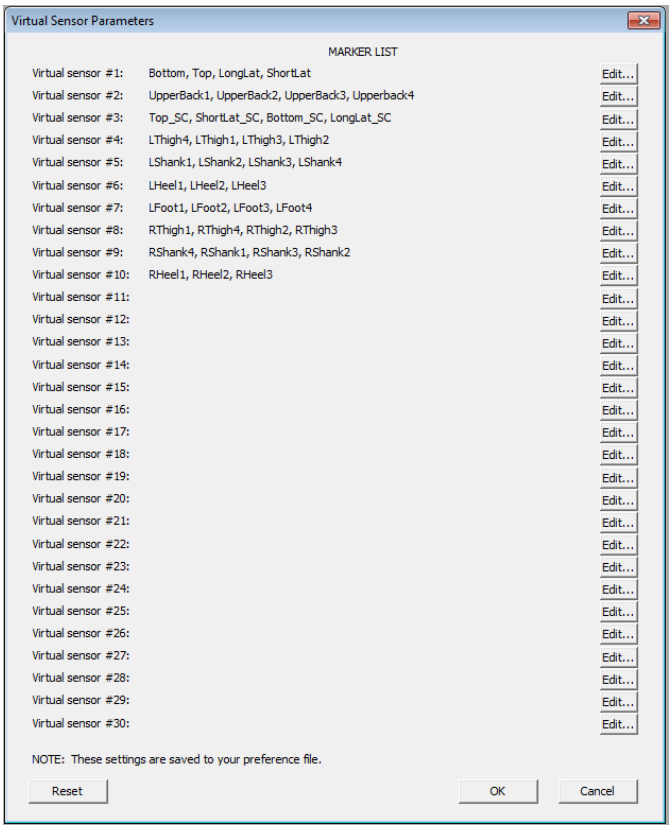


22. Confirm that all 42 markers are recognized

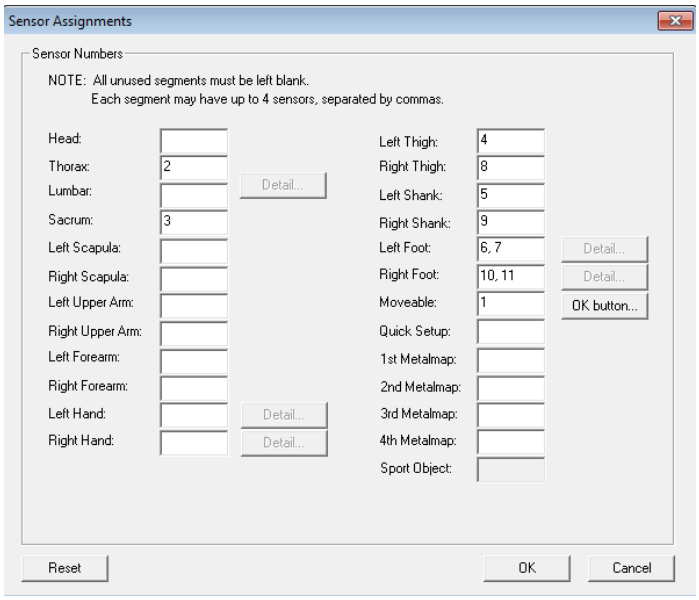

Marker Mappings
MARKER #
FULL NAME
UpperBack1 32 UpperBack1
UpperBack2 33 UpperBack2
UpperBack3 34 UpperBack3
UpperBack4 35 UpperBack4
Bottom 1 Bottom
Top 2 Top
LongLat 3 LongLat
ShortLat 4 ShortLat
ShortLat_SC 40 ShortLat_SC
Bottom_SC 41 Bottom_SC
LongLat_SC 42 LongLat_SC
Top_SC 12 Top_SC
RThigh1 13 RThigh1
RThigh4 14 RThigh4
RThigh2 15 RThigh2
RThigh3 16 RThigh3
RShank4 17 RShank4
RShank1 18 RShank1
RShank3 19 RShank3
RShank2 20 RShank2
RHeel1 21 RHeel1
RHeel2 22 RHeel2
RHeel3 23 RHeel3
RFoot1 24 RFoot1
RFoot2 25 RFoot2
RFoot3 26 RFoot3
RFoot4 27 RFoot4
LFoot1 28 LFoot1
LFoot2 29 LFoot2
LFoot3 30 LFoot3
LFoot4 31 LFoot4
LShank1 5 LShank1
LShank2 6 LShank2
LShank3 7 LShank3
LShank4 8 LShank4
LThigh4 36 LThigh4
LThigh1 37 LThigh1
LThigh3 38 LThigh3
LThigh2 39 LThigh2
LHeel1
LHeel2
LHeel3



23. Confirm all clusters are assigned to appropriate virtual sensor.

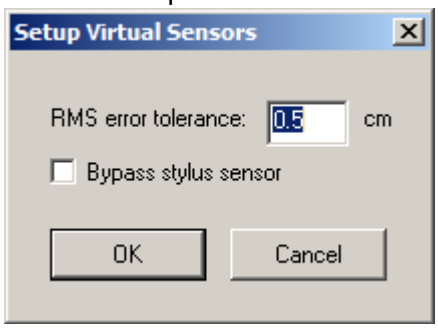


24. Go to the top menu and select setup and Edit Sensor Assignments. Sensor assignments listed should match assignments in virtual sensor parameters

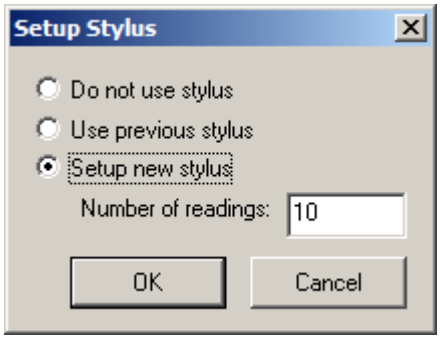


(see previous step).

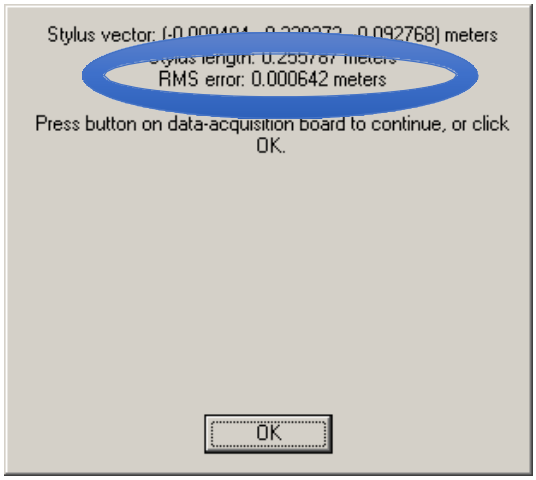
25. Ask the subject to stand still with hands crossed on the shoulders
26. Go to Vicon Nexus window and press Control-R
27. Return to MotionMonitor window and go to the top menu and select Setup and Setup Virtual Sensors



28. If you DO NOT receive an error, continue to step 30. If you DO receive an error, go back to step 20.
    a. Be sure to double check which subject sensors are marked in Vicon
29. Ask Subject to step onto the mat behind the treadmill.
30. Select Setup and Select Data to Collect. **Uncheck EMG data.**
31. Select Setup and Setup Stylus. Setup a new stylus with 10 readings.



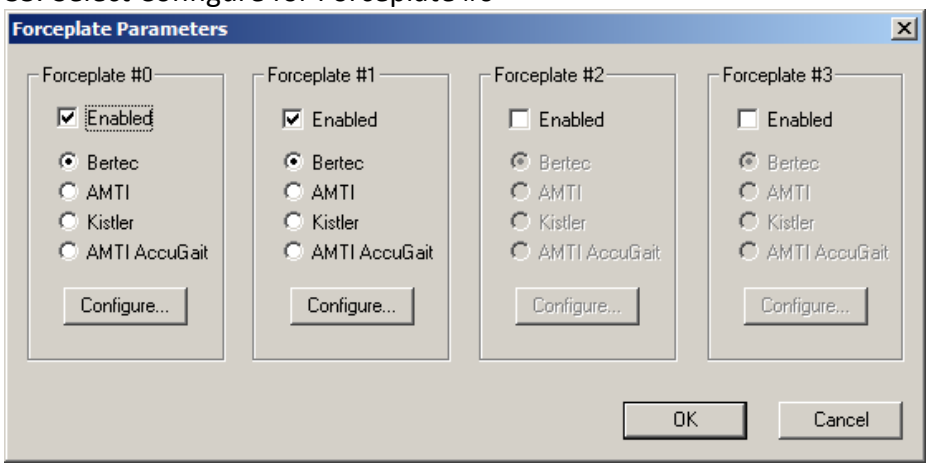
32. Calibrate stylus.
    a. RMS error should be less than 0.001



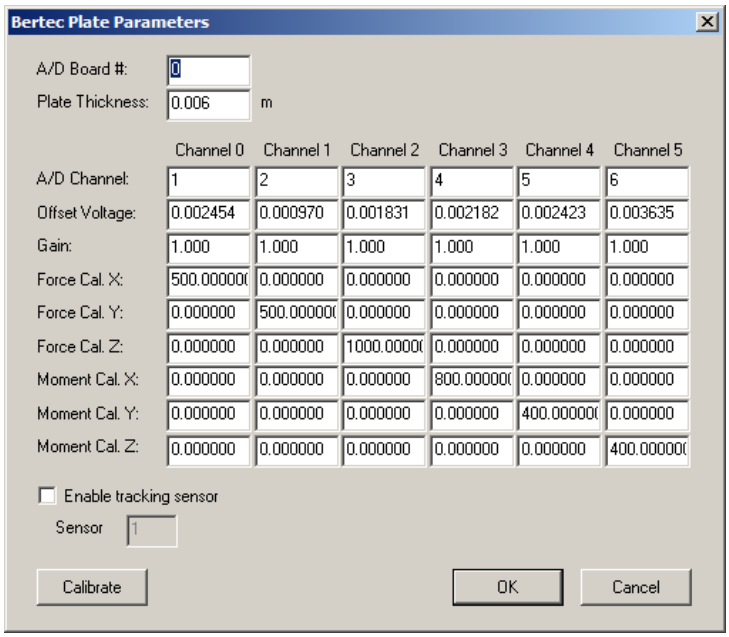
33. Remove all weight from forceplates. Zero the forceplates on the hardware.

34. Go to Administration and Edit Forceplate Parameters.

35. Select Configure for Forceplate #0

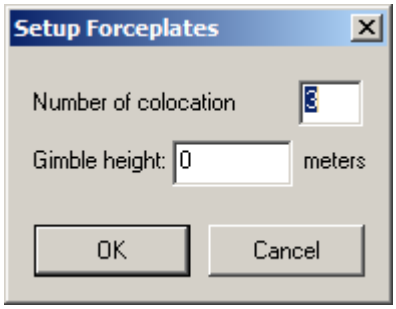


36. Select Calibrate

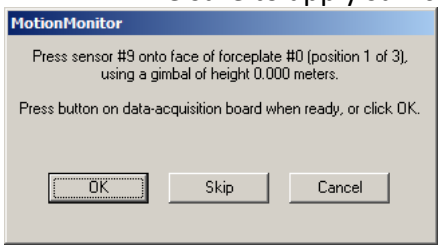


37. Select OK and repeat steps for Forceplate #1

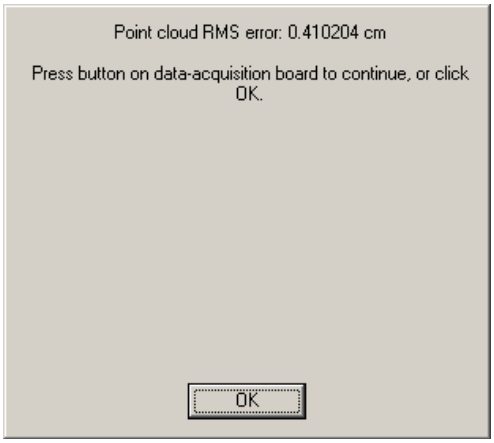
38. Go to the top menu and select Setup and Setup Forceplates



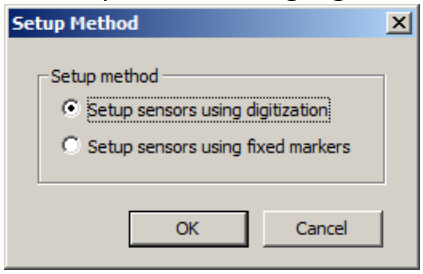
39. Using the stylus, press into the forceplate at three non-linear locations.
    a. Be sure to apply sufficient force

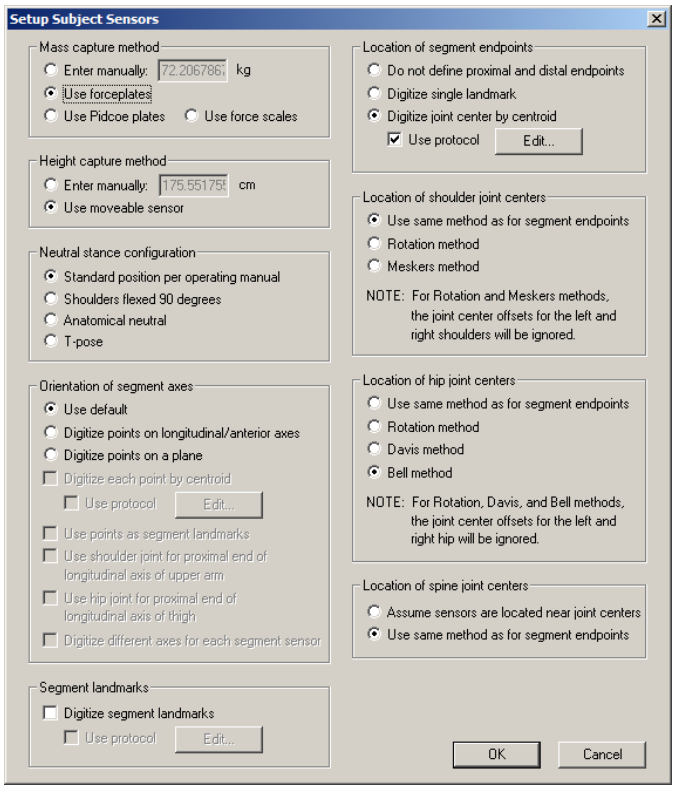


40. RMS error should be less than 1 cm. If it is greater than 1.0, repeat steps 34-40.

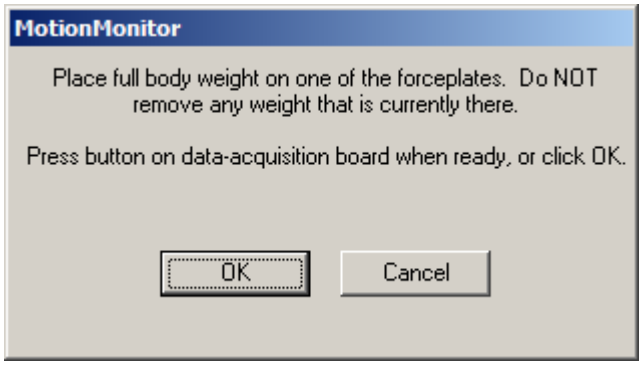


41. Go to the top menu and select Setup and Setup Subject Sensors. Select setup sensors using digitization.

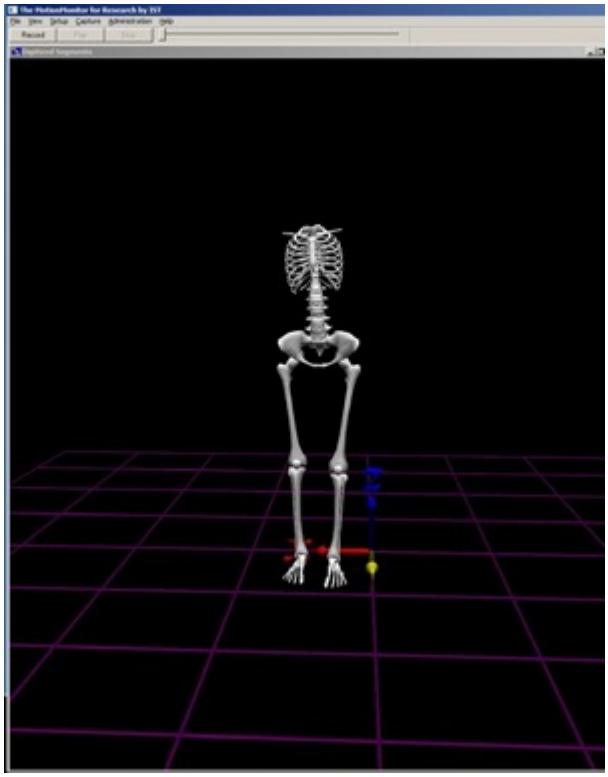




42. With below image on screen, ask subject to step onto **ONE** of the forceplates (one treadmill belt) with both feet. Once subject is in place, click "OK" to record body weight.



43. Place the tip of the stylus on top of the subject's head when prompted by MotionMonitor. Make sure height and weight are accurate (around what you would expect). Hold still with stylus to don sensors.
44. Point out the following landmarks on the subject in the following order (hitting Control-R on Vicon Nexus screen as appropriate):
    a. Left ASIS
    b. Right ASIS (hold still to get final hip reading)
    c. C7/T1
    d. T12/L1
    e. L5/S1
    f. Left Lateral Knee Joint Line
    g. Left Medial Knee Joint Line
    h. Left Lateral Malleolus
    i. Left Medial Malleolus
    j. Left Tip of 2nd Phalanx
    k. Right Lateral Knee Joint Line
    l. Right Medial Knee Joint Line
    m. Right Lateral Malleolus
    n. Right Medial Malleolus
    o. Right Tip of 2nd Phalanx
45. If skeleton looks appropriate, continue with collection. If anything does not look right, re-digitize the skeleton (redo steps 42-45).

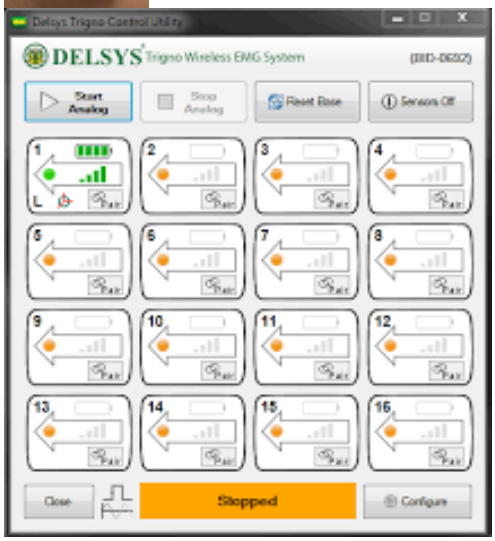


46. Go to the top menu and select Setup and Select Data to Collect**. Recheck EMG Data.**

Electromyography Set Up for Trigno Wireless System

1. Open Trigno Control Utility window

2. Turn electrodes on (green light illuminates)



3. Set up the subject
    a. Shave
    b. Abrade
    c. Cleanse
    d. Place electrodes over muscle belly
4. Collect maximal voluntary isometric contraction by Selecting Record on the **MotionMonitor** window (DO NOT press START on the Control Utility Window)

Table C6b. Laboratory Gait Assessments – Data Collection Sheet

Participant ID _____
Date_____

BASELINE II DATA COLLECTION SHEET

Rehabilitation Prescription and Explanation □

Group Allocation? _____
RS Number? _____
Garmin Number? _____

Height: _____ (cm)
Mass: _____(kg)

5 Minute Warm-Up □

Standard Running Speed: 2.68 m/s
3 x 30 second recordings □

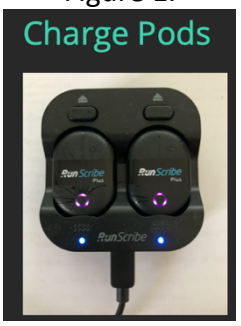
Preferred Running Speed: _____
3 x 30 second recordings □

Feedback practice as needed □

Table C7a. RunScribe™ Assessments - Set-up, Sensor Designations, and Calibration

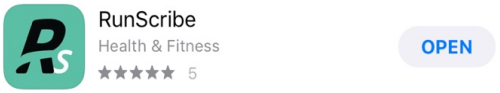
1.) Charge the RunScribe foot pods in the dual charger - the indicator light on the charger will turn green when fully charged (Figure 1).

Figure 1.



2.) Download the RunScribe app from the Apple App Store or Google Play (Figure 2).

Figure 2.



3.) Launch the RunScribe account and enter in one of the EaSIL account emails and passwords

a. Once logged in, be sure to toggle Bluetooth on for the electronic device that is being used to access the RunScribe application. This is how the sensors connect to the application.

Figure 3.

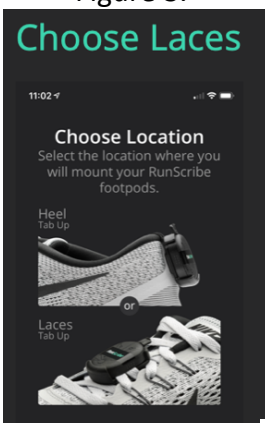
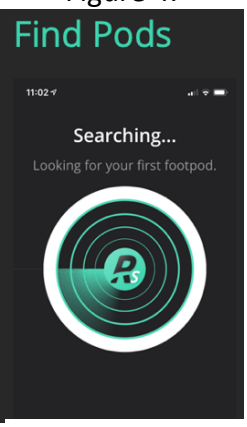


Figure 4.



4.) The app will prompt you to set up new sensors:

a. Choose sensor location → Select Laces (Figure 3).

b. The application will then search for available foot pods that are on and charged to connect (Figure 4).

c. Once a sensor is found, the app will indicate which foot the sensor should be worn on (in this example, the LEFT foot. The app will then prompt for a color designation so that the footpod will be distinguished for the limb. For the left, indicate BLUE (Figure 5).

Figure 5.

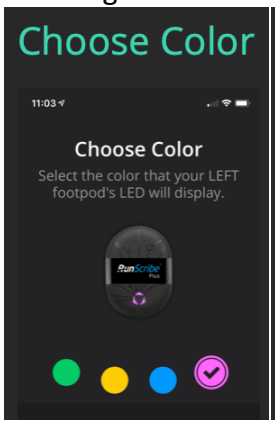
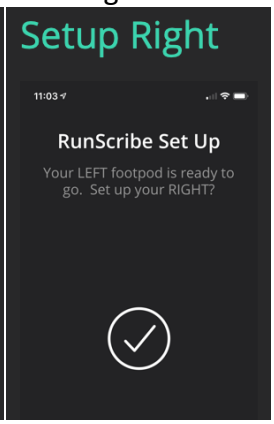


Figure 6.



d. The app will prompt that set-up for the LEFT footpod is complete (Figure 6). Repeat steps 4a-c for the RIGHT footpod, this time designating the color as PINK.

5.) Following sensor set-up, the footpods will now need to be updated to ensure the most recent firmware is installed.
   a. Click on the three bars in the upper left-hand corner of the application home screen.
   b. If the footpods need to be updated, they will appear with an orange exclamation point by the pod (Figure 7). Click on the LEFT footpod, and then click the large orange "Install Update" button.
   c. The footpod will download the update, and then will indicate when the process is completed (Figure 8).
   d. Repeat steps 5a-c for the RIGHT footpod if an update is available.

Figure 7.

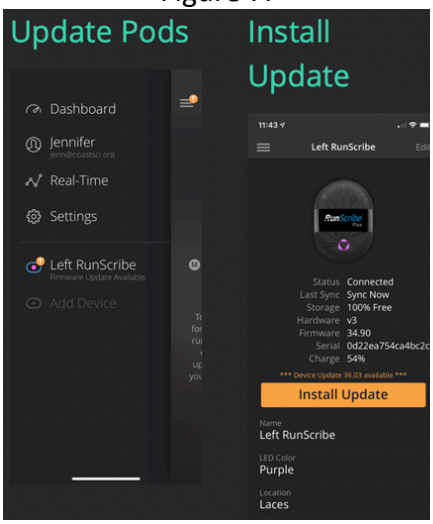
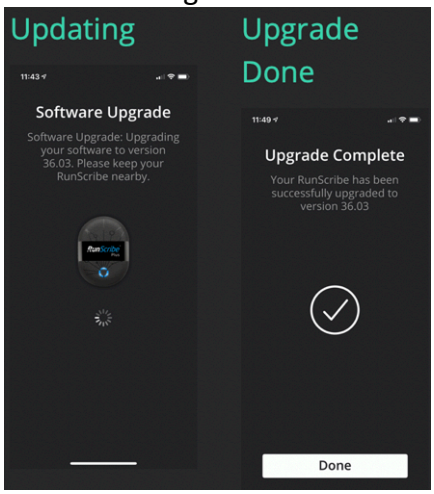


Figure 8.



6.) The final step in the calibration process is to calibrate the footpod mounting so that the accelerometer can detect the positioning when the sensors are situated in the cradles on the shoe laces.
   a. Lace in the sensor cradles onto the LEFT running shoe that will be used during the collection period. To do so, unlace the shoes to the midfoot region, and then thread the laces through the middle of the clip so that the tab of the cradle is facing up (Figure 9a).
   b. Clip in the LEFT footpod into the cradle, such that the light is facing out and the hole at the top aligns with the tab of the clip (Figure 9b).
   c. Repeat steps a-b for the RIGHT footpod.

d. On the RunScribe application dashboard, press on the middle icon at the top of the screen to calibrate the sensors (Figure 10).
e. The app will prompt to ensure that the footpods are on and connected. Select the large orange "They Light Up" button on the app if the footpods are successfully on and connected (Figure 11).
f. Stand upright with the shoes on and the sensors clipped into the cradles when prompted by the application. Select the large orange "Calibrate Mounting" button and stand still during the process (Figure 12).

7.) Additional settings
   a. For the purposes of the cross-sectional and prospective studies (MI, MIII), the sensors should be set to auto stop/start recording.
      i. Click the three bars in the upper left corner of the application home screen, and select "Settings".
      ii. Ensure that the toggle bar is on and green for "Auto Start/Stop Recording" (Figure 13).
      iii. To make sure that the start/stop threshold is not too high to miss

Figure 9.

a b

Figure 10.

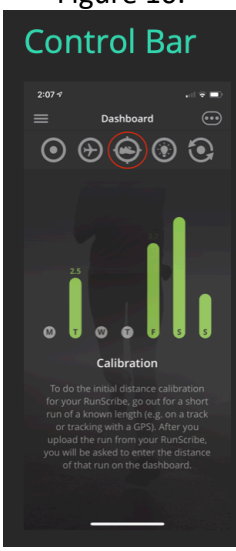


Figure 11.

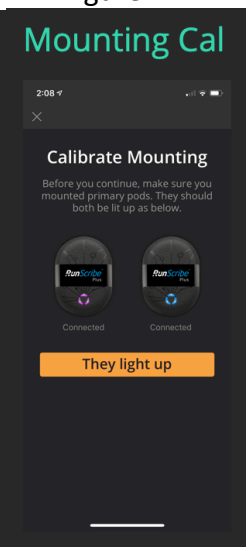


Figure 12.

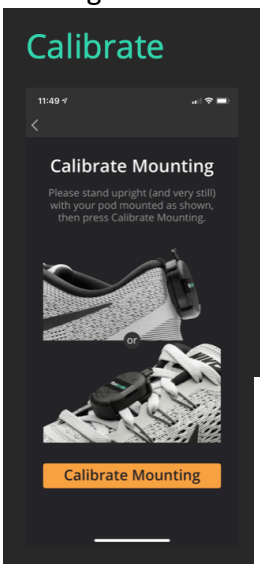
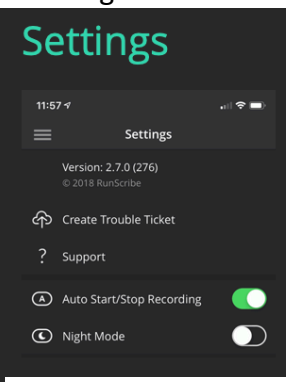


Figure 13.



a recording, click the three bars in the upper left corner of the application home screen and select the Profile (second from the top, below Dashboard). Under “AutoStart Stride Rate Threshold”, enter in 40 which is the lowest threshold.

b. For the purposes of the interventional study (MII), the sensors should not auto start/stop recording.
    i. Click the three bars in the upper left corner of the application home screen, and select “Settings”.
    ii. Ensure that the toggle bar is off and greyed out for “Auto Start/Stop Recording”.

Table C7b. RunScribe™ Assessments Data Collection Step-by-Step Procedures

1.) Prior to use, ensure that the RunScribe sensors are charged.
2.) For the data collections in which the auto start/stop recording setting is in place (MI, MIII):
    a. Secure the LEFT and RIGHT footpods into the lace cradles (see **Setting up New RunScribe™ Sensors** 6a-c)
    b. Ensure that the footpods are charged and on (shake the footpods to see if they start blinking).
    c. Run with the sensors on, it is not necessary to run while connected to the phone application.
3.) For the data collections in which the auto start/stop recording setting is disabled (MIII):
    a. Secure the LEFT and RIGHT footpods into the lace cradles.
    b. Go into the RunScribe phone application, and turn Bluetooth on.
    c. Click on the three bars in the upper left corner of the home screen, and ensure the LEFT and RIGHT footpods are connected (Figure 14).
    d. Click on the Dashboard button next to get back to the home screen.
    e. Once ready to begin, click on the "Record" button and start running with smartphone on person (Figure 15). Once finished with the run, click the stop button on the dashboard.
4.) Download the runs stored on the footpods
    a. Following completion of each run, go back into the RunScribe application and ensure Bluetooth is on.
    b. Click on the three bars in the upper left corner of the home screen, and ensure the LEFT and RIGHT footpods are connected (Figure 14).
    c. Click on the Dashboard button next to get back to the home screen.
    d. In the upper right corner of the Dashboard, click on the sync button and the runs stored on the footpods will automatically start downloading (Figure 15).
    e. Once both sensors' data have downloaded and say "Sync Complete!", click "Done" in the upper left corner (Figure 15), and the run will then populate in the dashboard (Figure 16).

Figure 14.

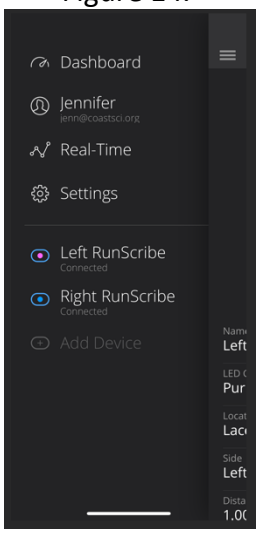


Figure 15.

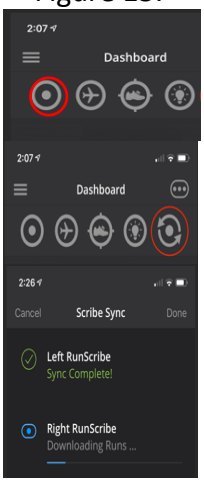


Figure 16.

Table C7c. RunScribeTM Assessments - Accessing Data from the Dashboard

1.) Go to https://dashboard.runscribe.com on a computer
    a. In the upper right screen, click "Login"
        i. Enter in the email and password for the specific account for the data that is being accessed
    b. On the left side of the screen, click "Runs" (Figure 17).
        i. Each of the runs that have previously been downloaded from the footpods will populate on the screen
    c. Click on the green date of the desired run on the left side of the screen (Figure 18).
    d. In the upper right corner of the selected run's screen, click on the download button and separately export the LEFT and RIGHT CSV files of the footpod data. Rename the files to adequately label the LEFT and RIGHT sensor datasheets (Figure 19).
    e. Repeat steps 12a-d for all data export.

Figure 17.

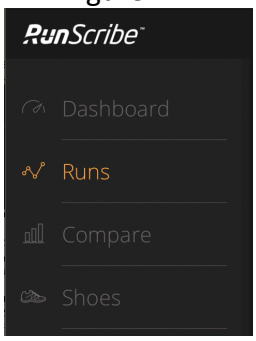


Figure 18.

Figure 19.

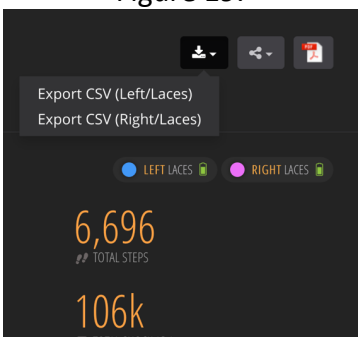
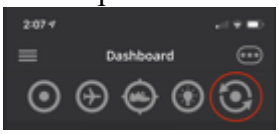


Table C7d. RunScribe™ Assessments – Instruction Sheet for Patients (M1&M3)

Instructions for Using the RunScribe™

1. The RunScribe™ devices are pre-registered. DO NOT MAKE YOUR OWN ACCOUNT.
2. Battery Instructions:
    a. The RunScribe™ uses watch batteries, which will be provided to you in the back of your sensor cases. To insert the batteries, rotate the black part on the back of the sensor so that the dot is aligned with the unlock symbol. You can then lift the black part off. Face the watch battery so that the "+" side is facing the "+" symbol inside the removed black part. Then, to put the back on after replacing the battery, align the dot on the black part with the unlocked symbol. Make sure the compartment is completely closed before rotating the black part back to the locked symbol.
    b. The batteries are estimated to last about 12-14 hours of recording data. If the light is blinking double red, you may need to change the battery or make sure that the battery is fitted properly into the sensor.
3. The lights on the front of the RunScribe™ pod will start to blink with movement, indicating that the device is on and working,
4. Shake the RunScribe™ pods and make sure that the lights are blinking before you start running.
5. The RunScribe™ sensors must be worn on the heel of the shoe. They also MUST be worn on the side indicated, or it will result inaccurate data. **RED/PINK=RIGHT, BLUE=LEFT.**
6. The RunScribe™ must be securely mounted within the cradle tab facing up. Upside down or loose footpods will result inaccurate data. **Please use a piece of tape** over the backs of your shoes to ensure that the sensors stay on.
7. The RunScribe™ will record data for as long as you are moving, and will time out after 250 second of inactivity.
8. High socks are recommended to prevent chafing or blisters from the clip.
9. When you are finished with you runs, please be sure to upload runs by pressing the "sync" button in the upper right-hand corner of the RunScribe application on your phone.



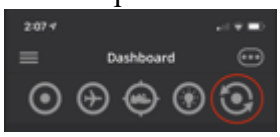
THANK YOU!

Please contact me at afd4au@virginia.edu if you have any questions!

RunScribe™ Assessments – Instruction Sheet for Patients (M2)

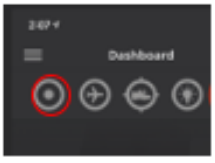
Instructions for Using the RunScribe™

1. The RunScribe™ devices are pre-registered. DO NOT MAKE YOUR OWN ACCOUNT.
2. Battery Instructions:
    a. The RunScribe™ uses watch batteries, which will be provided to you in the back of your sensor cases. To insert the batteries, rotate the black part on the back of the sensor so that the dot is aligned with the unlock symbol. You can then lift the black part off. Face the watch battery so that the "+" side is facing the "+" symbol inside the removed black part. Then, to put the back on after replacing the battery, align the dot on the black part with the unlocked symbol. Make sure the compartment is completely closed before rotating the black part back to the locked symbol.
    b. The batteries are estimated to last about 12-14 hours of recording data. If the light is blinking double red, you may need to change the battery or make sure that the battery is fitted properly into the sensor.
3. The lights on the front of the RunScribe™ pod will start to blink with movement, indicating that the device is on and working,
4. Shake the RunScribe™ pods and make sure that the lights are blinking before you start running.
5. The RunScribe™ sensors must be worn on the heel of the shoe. They also MUST be worn on the side indicated, or it will result inaccurate data. **RED/PINK=RIGHT, BLUE=LEFT.**
6. The RunScribe™ must be securely mounted within the cradle tab facing up. Upside down or loose footpods will result inaccurate data. **Please use a piece of tape** over the backs of your shoes to ensure that the sensors stay on.
7. The RunScribe™ will record data for as long as you are moving, and will time out after 250 second of inactivity.
8. High socks are recommended to prevent chafing or blisters from the clip.
9. When you are finished with you runs, please be sure to upload runs by pressing the "sync" button in the upper right-hand corner of the RunScribe application on your phone.



Recording Runs

1. When you are ready to go on a run, go into the RunScribe app on your phone
2. On the dashboard home screen, click on the three dots in the upper right-hand corner so that the option bubbles appear at the top of the screen. Click on the farthest left button to begin recording your run.
3. When you are finished, press the "stop" button, and then upload your run using step 9 above.



THANK YOU!

Please contact me at afd4au@virginia.edu if you have any questions!

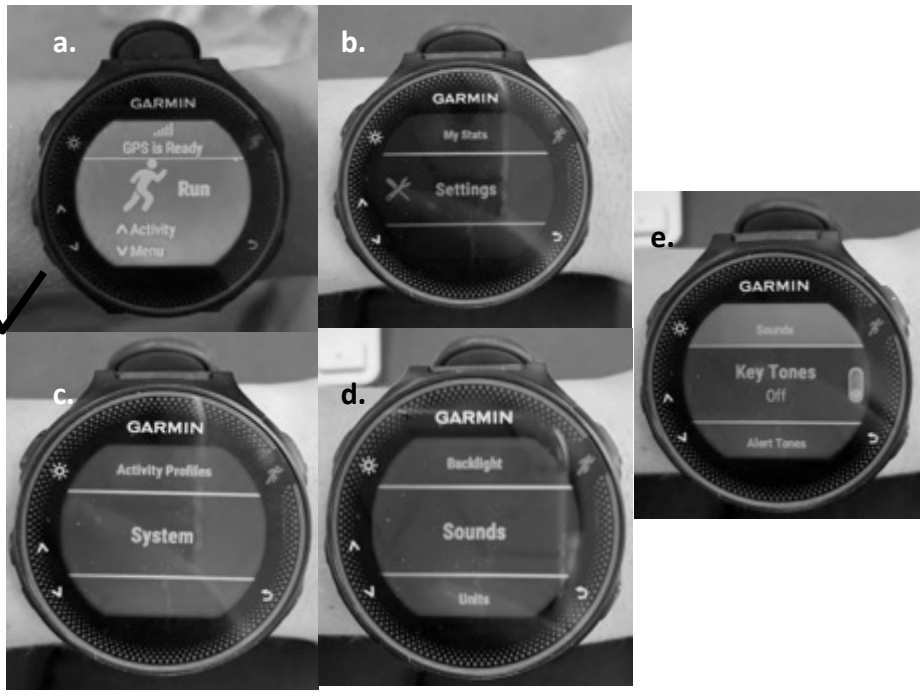
Table C8a. Garmin™ Feedback - Garmin Set-up (Instruction Manual)

1.) Initial set-up
   a. Select *(upper right corner button with the runner icon)* English language
   b. Select 12-hour time format
   c. Toggle *(toggle using the up and down buttons in the lower left corner)* to enter birth year
   d. Toggle to enter gender
   e. Toggle to enter weight

Figure 1.

2.) Turn off sound notifications
   a. Select *(upper right corner button with runner icon)*
   b. Press the down arrow to get to the menu (Figure 2a)
   c. Select "Settings" at the bottom of the menu (Figure 2b) → "System" at the bottom of the menu (Figure 2c) → "Sounds" (Figure 2d)
   d. Select on "Key Tones" to turn off, and toggle down to "Alert Tones" to turn off. (Figure 2e)

Figure 2.



3.) Turn off phone notifications

a. Download the Connect IQ application

b. Within the app, select the 3 dots in the lower right-hand corner.

i. Select settings (Figure 3a) → Messages (Figure 3b) → Toggle iOS Notifications to off (Figure 3c)

Figure 3.

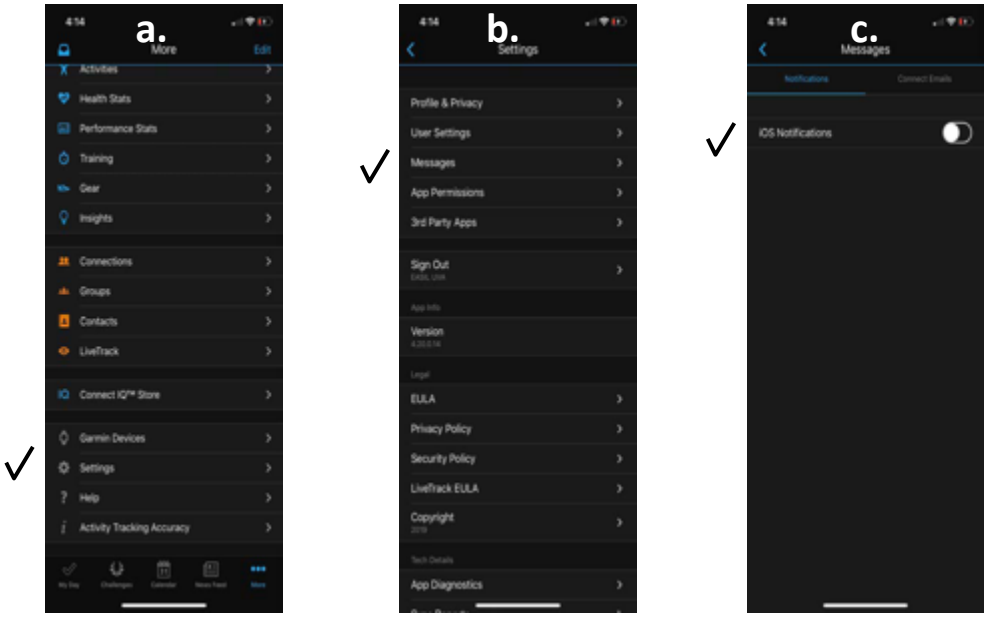
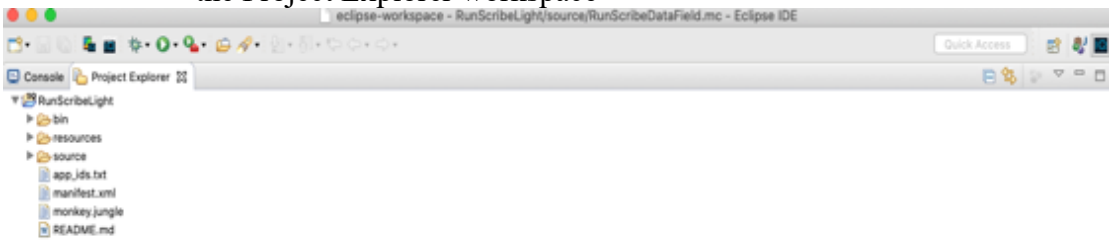


Table C8b. Garmin™ Feedback – Feedback Set-up

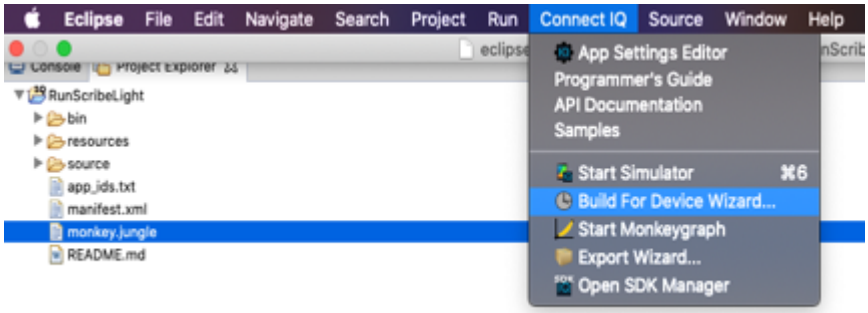
1.) Open the Eclipse workspace on a computer laptop/desktop
   a. Select the "File" drop-down menu, and select "Open Projects from File System
   b. Open the RunScribeLight custom edited script so the project appears in the Project Explorer workspace



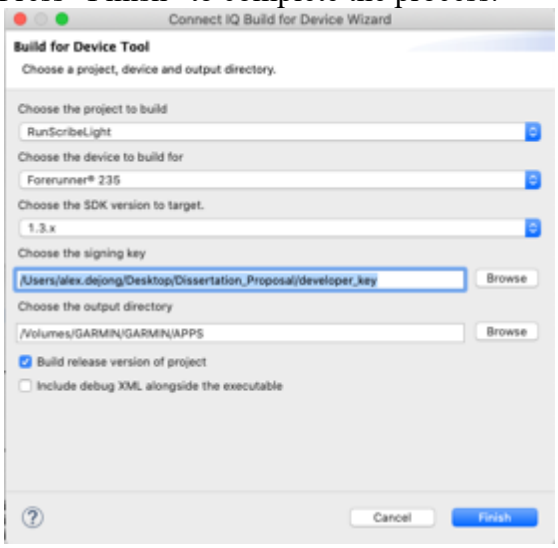
2.) The feedback script within the script is as follows:

```
313         // Update status
314         if ((mSensorLeft != null && mSensorRight != null) && (mSensorRight.searching == 0 || mSensorLeft.searching == 0)) {
315
316             // Check contact time
317             var gct_L = mSensorLeft.data[5];
318             var gct_R = mSensorRight.data[5];
319             if (gct_L >= 280.0 || gct_R >= 280.0) {
320                 // 3 quick vibrations
321                 var vibeData =
322                     [
323                         new Attention.VibeProfile(50, 75),
324                         new Attention.VibeProfile(50, 75),
325                         new Attention.VibeProfile(50, 75)
326                     ];
327                 Attention.vibrate(vibeData);
328             }
```

3.) Side-load the application onto the Garmin Wristwatch
   a. Plug in the Garmin directly into the computer
   b. In the Eclipse workspace in the "Connect IQ" drop-down menu, select "Build For Device Wizard"



c. In the pop-up menu, select build for the Forerunner 235 watch, version 1.3 x, use the personal developer key downloaded onto the desktop, and select the output directory to be to the Garmin App folder for the connected Garmin watch. Press "Finish" to complete the process.

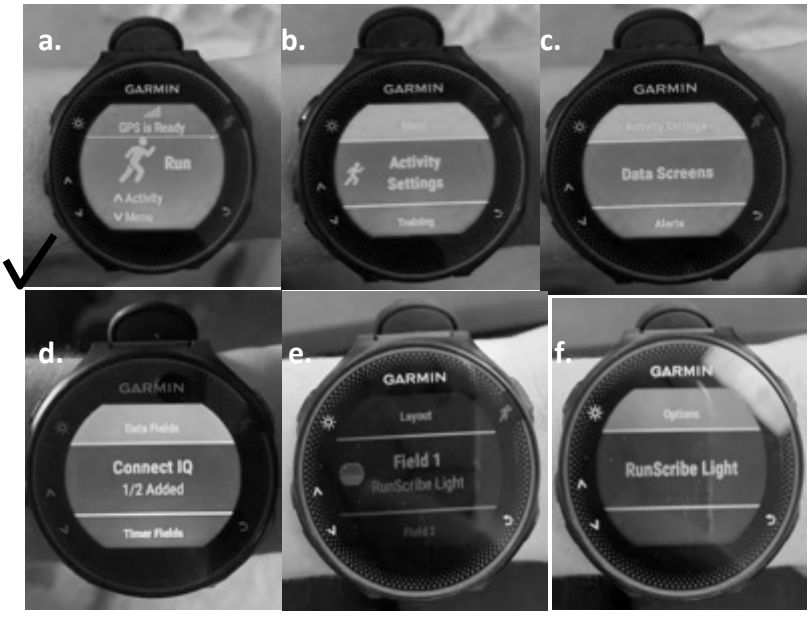


d. Once finished and the box says "Build Complete", eject the watch from the computer

4.) Select the feedback interface on the watch

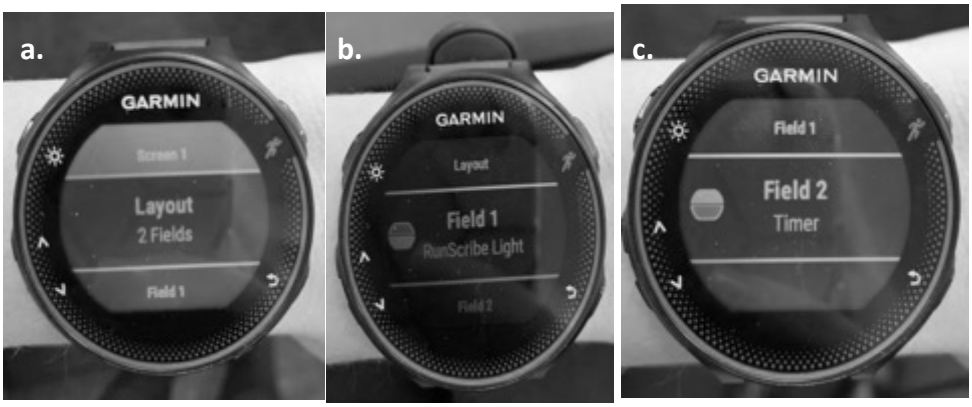
a. Select *(upper right corner button with runner icon)*
b. Press the down arrow to get to the menu (Figure 4a)
c. Select "Activity Settings" (Figure 4b)→ "Data Screens" (Figure 4c) → Connect IQ (Figure 4d) → Field 1 (Figure 4e) → RunScribe Light (Figure 4f; side-loaded project)

Figure 4.



5.) Adjust the View to be just RunScribe Light and Time
   a. Select "Activity Settings" → "Data Screens" → Screen 2 → Select to "Off"
   b. Go back *(bottom right bottom with the undo arrow)* to "Data Screens" → "Layout" (Figure 5a) → "Field 1" (Figure 5b) → Set to RunScribe Light
   c. Go back to "Layout" (Figure 5a) → "Field 2" (Figure 5c) → Set to Timer

Figure 5.



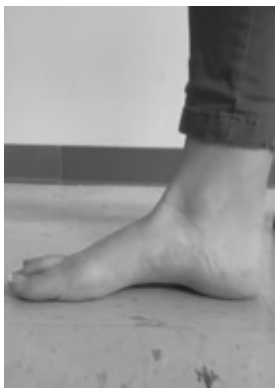
6.) Using the feedback
   a. Begin recording the run with the RunScribe **(see Table 7b)**
   b. On the Garmin, Select *(upper right corner button with runner icon)*
   c. Use the up "Activity" arrow
   d. Select "Run" → Then select *(upper right corner button with runner icon)*
   e. Begin running. The watch will vibrate when participants' contact time is above 280 ms, but will not vibrate if the contct time is below the threshold. Once the run is finished, press the back arrow, and stop recording on the RunScribes **(see Table 7b).**

Table C9a. Home-Exercise Programs - Links to Video Demonstrations

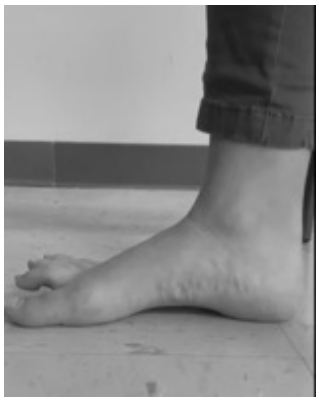
Anterior Reach Directions - Star Excursion Balance Test
https://drive.google.com/file/d/1hqdt7Rg5zfR6OCyHI-1acTWBklRNePkh/view?usp=sharing
Progression
https://drive.google.com/file/d/1RPGAh_fEhyfXom_569TMKE7Co9rG1rQX/view?usp=sharing

Posterior Reach Directions - Star Excursion Balance Test
https://drive.google.com/file/d/1kIB333uX1UbWf2UTSDCgG7MIUfmFb8Og/view?usp=sharing
Progression
https://drive.google.com/file/d/1QBbs4_J6Ll72Py7Txv-2tcXz5iJvLMTV/view?usp=sharing

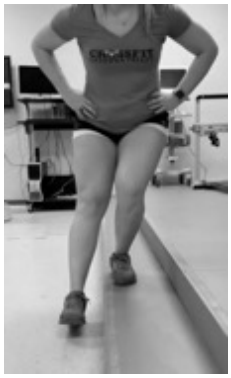
Short Foot Exercise and Great Toe Raises
https://drive.google.com/file/d/1vSQVXLC_FJli-iIltPWUcK641-YJEyzC/view?usp=sharing



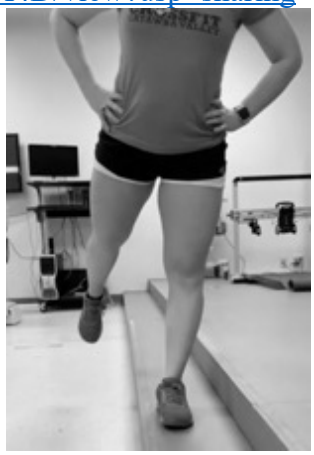
Short Foot Exercise and Lesser Toe Raises
https://drive.google.com/file/d/1ECyqt9wYgx5wz_l7p5D8vb8piXNvudUr/view?usp=sharing



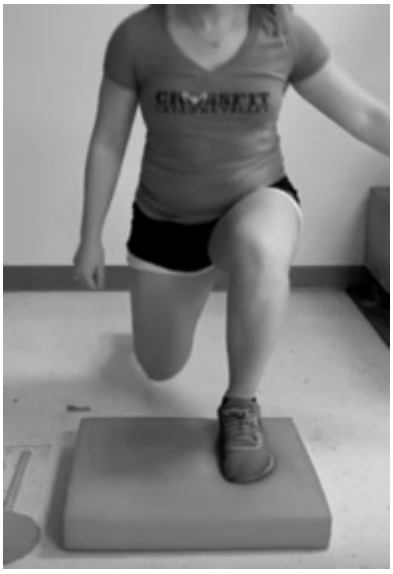
Lateral Step-Downs
https://drive.google.com/file/d/1WwnJZ9Y9xiYGcgfE0x4JYYKjJRggQB0r/view?usp=sharing
Progression
https://drive.google.com/file/d/1cIOJIeBSZd5_cpRXTJZ2jk6ZgJZzl68s/view?usp=sharing



Single-Leg Balance on Stair
https://drive.google.com/file/d/1K-_b8FWh7L8oaQGX4RiHbSw2Q_nSDuK0/view?usp=sharing
Progression: Add Leg Swings
https://drive.google.com/file/d/1M6m-uAp2IpEl02hXqywigCzbixWvtX4D/view?usp=sharing

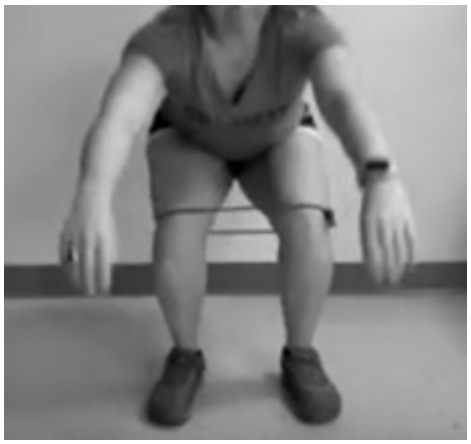


Lunges
https://drive.google.com/file/d/1YK9Sf0hFyz-UCL2K3BMaQ2tq7d-urW8V/view?usp=sharing

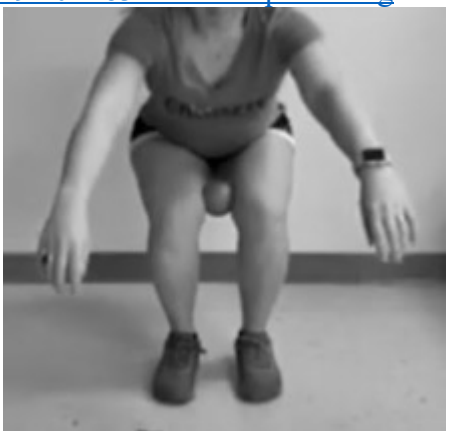


Monster Walks
https://drive.google.com/file/d/1gF8pio4S5m-O0KAu20DD4EAhkLYFlJ1C/view?usp=sharing
Progression
https://drive.google.com/file/d/1VMpSlV2zTKXQnQv8hazbE8dRcwE7M6AY/view?usp=sharing

Double Limb Squat: Valgus Alignment
https://drive.google.com/file/d/17nZNZkzPNz0fXCcpybcmtZ88PPa3V9nV/view?usp=sharing



Double Limb Squat: Varus Alignment
https://drive.google.com/file/d/1WLK-LR9HnmaH0NnGTfvCTo7I9N0aL83k/view?usp=sharing



Single Leg Squat: Valgus Alignment
https://drive.google.com/file/d/1efgBa-bUYu64L9jvOIRG12nlV6hi3_Xu/view?usp=sharing

Single Leg Squat: Varus Alignment

Table C9b. Home Exercise Program - Criteria-Based Exercise Prescriptions

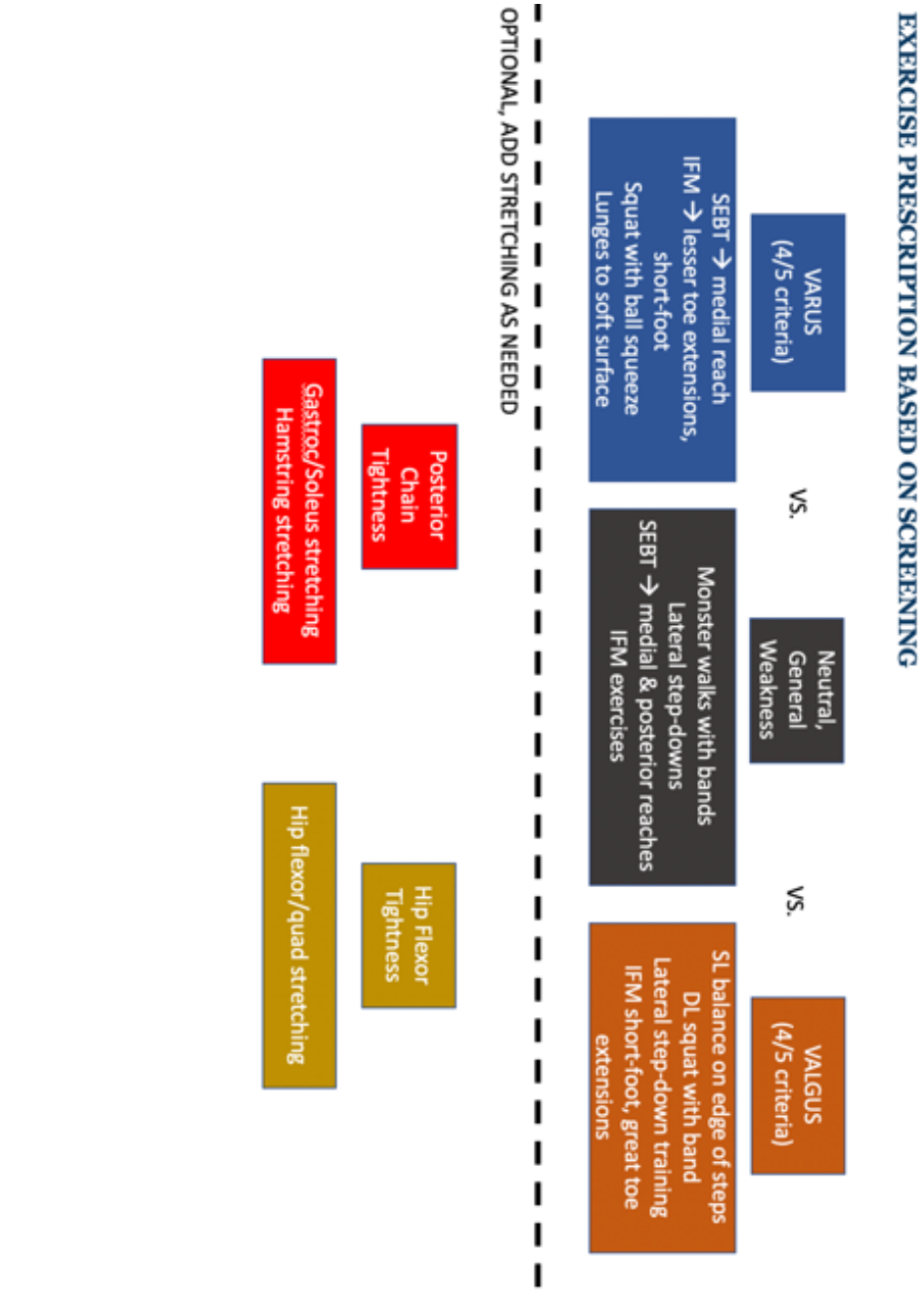


Table C9c. Home-Exercise Program - Progression Table

	GOAL PERFORMANCE	PROGRESSION 1	PROGRESSION 2
SEBT	stable pelvis, center of patella maintains over first ray → 15 consecutive reaches in prescribed directions	stable pelvis, center of patella maintains over first ray → 2 x 15 consecutive reaches in prescribed directions	stable pelvis, center of patella maintains over first ray → 12 consecutive reaches in prescribed directions on unstable surface
IFM	No use of extrinsic muscles during exercises, 50x seated	No use of extrinsic muscles during exercises, 50x standing	No use of extrinsic muscles during exercises, 50x single leg
SQUAT W/ BALL SQUEEZE	3x10 without dropping ball	SL squat with band to medialize knee, stable pelvis, center of patella over first ray 2x10	SL squat with band to medialize knee, stable pelvis, center of patella over first ray 3x10
LUNGES TO SOFT SURFACE	Center of patella tracking over the first ray, no contralateral pelvic drop, 2 x 15	Center of patella tracking over the first ray, no contralateral pelvic drop, 2 x 15 with resistance band	Center of patella tracking over the first ray, no contralateral pelvic drop, 2 x 15 with increased resistance
MONSTER WALKS	3 x forward and back length of living room, maintaining tension on band	3 x forward and back length of living room, maintaining tension on band (increased resistance)	5 x forward and back length of living room, maintaining tension on band (increased resistance)
LATERAL STEP-DOWNS	2 x 30 seconds of lateral step-downs, slow lower down (3-sec), stable pelvis, center of patella over first ray	2 x 30 seconds of lateral step-downs, faster lower down (2-sec), stable pelvis, center of patella over first ray	3 x 30 seconds of lateral step-downs, faster lower down (2-sec), stable pelvis, center of patella over first ray
SINGLE LIMB BALANCE ON STAIR	3 x 30 seconds, hands on hips without stepping down, stable pelvis	3 x 30 seconds, hands on hips with contralateral slow leg swing without stepping down, stable pelvis	3 x 30 seconds, hands on hips with contralateral fast leg swing without stepping down, stable pelvis
DOUBLE LIMB SQUAT W/ BAND	3x10 maintaining tension on band, center of patella over first ray	SL squat with band to lateralize knee, stable pelvis, center of patella over first ray 2x10	SL squat with band to lateralize knee, stable pelvis, center of patella over first ray 3x10

APPENDIX D
ADDITIONAL RESULTS

Additional Results Table D1.1. Operational definitions of sensor-derived measures.

Sensor-Derived Measure	Definition
Stride Length	Distance between two successive placements of the same foot (m)
Contact Time	Time the foot is in contact with the ground from initial contact to toe-off (ms)
Cadence	Number of steps taken per minute (steps/min)
Flight Ratio	Percentage of the running stride spent off the ground (%)
Shock	Composite score of impact and braking to represent total forces incurred per foot strike (g)
Impact	Vertical component of change in acceleration of the foot at initial contact (g)
Braking	Horizontal component of change in acceleration of the foot at initial contact (g)
Pronation Excursion	Pronation range of motion from initial contact to maximum pronation (°)
Maximum Pronation Velocity	Rate of pronation over time from initial contact to maximum pronation (°/second)

Additional Results Table D1.2. Example output from TSFresh feature extraction assessment.

```
['contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_10__attr_"slope"'
 'contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_10__attr_"stderr"'
 'contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_50__attr_"slope"'
 'contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_50__attr_"stderr"'
 'contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_5__attr_"slope"'
 'contact_time__agg_linear_trend__f_agg_"mean"__chunk_len_5__attr_"stderr"'
 'contact_time__agg_linear_trend__f_agg_"min"__chunk_len_10__attr_"stderr"'
 'contact_time__agg_linear_trend__f_agg_"min"__chunk_len_50__attr_"stderr"'
 'contact_time__agg_linear_trend__f_agg_"min"__chunk_len_5__attr_"slope"'
 'contact_time__agg_linear_trend__f_agg_"min"__chunk_len_5__attr_"stderr"'
 'contact_time__augmented_dickey_fuller__attr_"usedlag"'
 'contact_time__large_standard_deviation__r_0.2'
 'contact_time__linear_trend__attr_"slope"'
 'contact_time__symmetry_looking__r_0.05'
 'pace__agg_linear_trend__f_agg_"mean"__chunk_len_50__attr_"stderr"'
 'step_rate__agg_linear_trend__f_agg_"max"__chunk_len_10__attr_"stderr"'
 'step_rate__agg_linear_trend__f_agg_"max"__chunk_len_50__attr_"stderr"'
 'step_rate__agg_linear_trend__f_agg_"max"__chunk_len_5__attr_"stderr"'
 'step_rate__agg_linear_trend__f_agg_"mean"__chunk_len_50__attr_"stderr"'
 'step_rate__c3__lag_1' 'step_rate__c3__lag_2' 'step_rate__c3__lag_3'
 'step_rate__mean' 'step_rate__quantile__q_0.2'
 'step_rate__quantile__q_0.3' 'step_rate__quantile__q_0.4'
 'step_rate__quantile__q_0.6' 'step_rate__quantile__q_0.7'
 'step_rate__symmetry_looking__r_0.05'
 'stride_length__agg_linear_trend__f_agg_"mean"__chunk_len_50__attr_"stderr"']
```

Caption: Sample output from the TSFresh feature extraction assessment, with the first 25 feature outputs listed in the order of which they best differentiated between healthy and exercise-related lower leg pain groups.

Additional Results Table D1.3. Descriptive sensor-derived biomechanical measures for ERLLP and healthy groups.

Sensor-Derived Measure	**ERLLP Mean ± SD**	**Healthy Mean ± SD**
Stride Pace	3.47±0.15	3.78±0.08
Stride Length (m)	2.42 ± 0.38	2.42 ± 0.38
Contact Time (ms)	293 ± 9	285 ± 9
Cadence (steps/min)	167 ± 9	174 ± 9
Flight Ratio (%)	19.4 ± 6.31	20.3 ± 7.35
Shock (g)	15.8 ± 3.2	14.8 ± 3.3
Impact (g)	10.9 ± 3.3	10.5 ± 3.5
Braking (g)	11.0 ± 2.8	10.0 ± 2.9
Pronation Excursion (°)	-11.0 ± 8.9	-9.8 ± 11.2
Maximum Pronation Velocity (°/s)	520 ± 257	486 ± 229

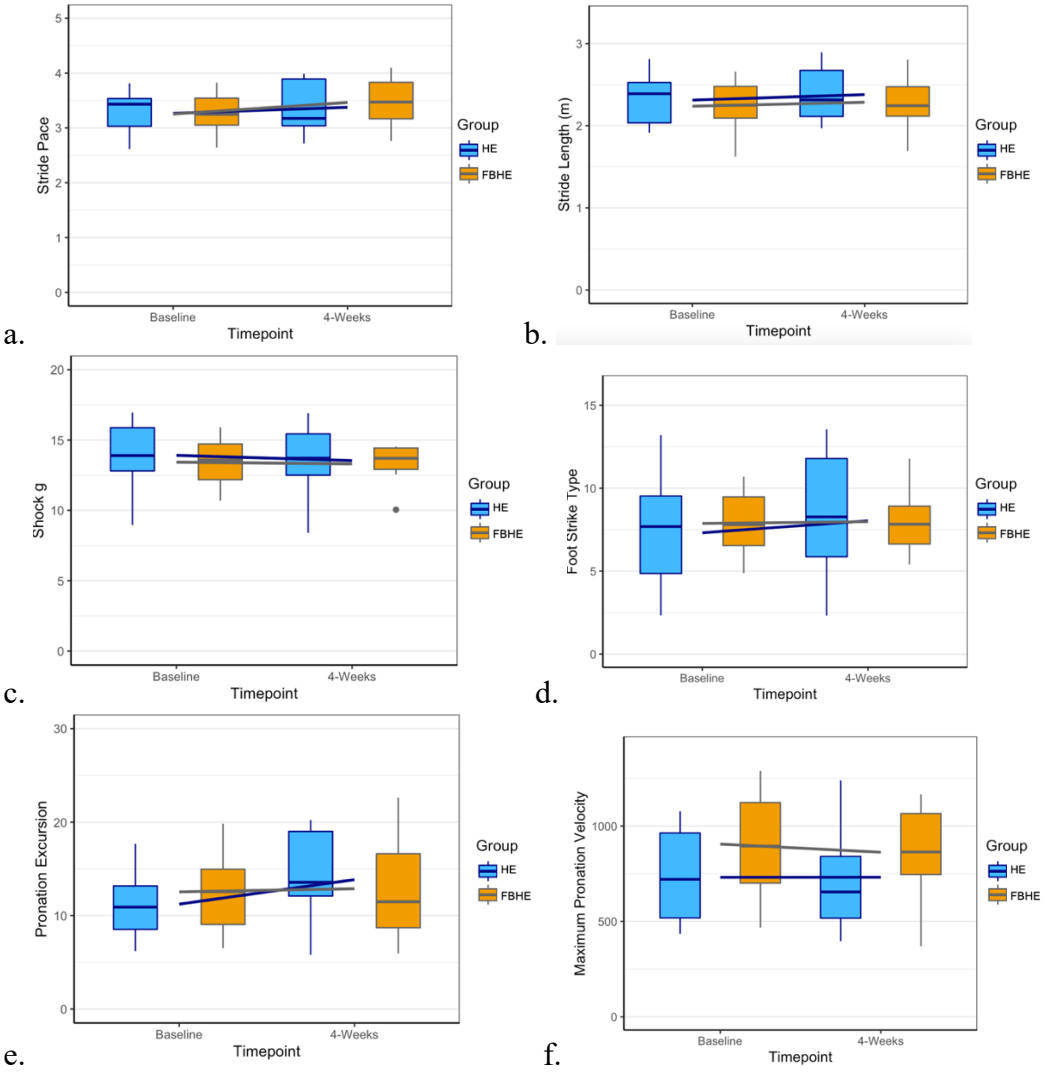
Caption: Average and standard deviation of group measures for all sensor-derived measures.
Abbreviations: ERLLP, exercise-related lower leg pain; SD, standard deviation.

Additional Results Table D2.1. Clinical alignment, ROM, and strength measures

	Baseline			4-Weeks		
	FBHE	HE	p	FBHE	HE	p
Foot Posture Index	5±2	5±3	.55	5±1	5±2	.59
Unloaded AHI	.358±.019	.361±.033	.79	.360±.032	.352±.037	.67
Loaded AHI	.332±.021	.326±.041	.73	.334±.021	.314±.031	.19
ARI	.920±.014	.881±.024	.002*	.924±.028	.896±.014	.02*
Arch Drop (mm)	0.5±0.2	0.6±0.2	.22	0.4±0.2	0.5±0.1	.06
WB Dorsiflexion (cm)	7±4	11±5	.12	7±4	13±3	.01*
SLR (°)	161±16	162±18	.92	162±15	169±13	.38
Thomas Test (cm)	4±2	5±3	.57	5±5	4±2	.42
Plantarflexion (°)	61.9±7.6	60.6±11.4	.81	56.7±9.7	60.5±13.1	.54
Dorsiflexion (°)	3.21±10.3	4.6±6.1	.09	4.71±7.9	8.1±4.8	.33
MTP Flexion (°)	36.6±14.7	46.6±9.0	.13	34.4±8.5	44.0±11.7	.10
MTP Extension (°)	41.9±7.4	44.2±21.6	.79	36.7±12.1	46.0±17.4	.26
Inversion (°)	24.4±5.9	21.6±4.2	.31	22.1±4.6	23.8±5.9	.54
Eversion (°)	6.4±2.1	9.1±3.4	.10	8.2±2.5	11.0±4.3	.16
MTP Strength (Nm/kg)	2.37±0.53	2.58±0.62	.04*	3.18±0.61[a]	3.16±0.95[a]	.02*
Inversion Strength (Nm/kg)	2.37±0.67	2.85±0.55	.15	2.73±0.63[a]	3.16±0.54[a]	.18
Eversion Strength (Nm/kg)	2.58±0.80	3.01±0.42	.21	2.92±0.87[a]	3.31±0.62[a]	.33
Dorsiflexion Strength (Nm/kg)	3.06±0.53	3.94±0.88	.04*	3.86±0.62[a]	4.34±0.96[a]	.02*
Plantarflexion Strength (Nm/kg)	4.96±1.34	7.42±1.78	.01*	6.34±2.55	8.77±2.11	.06
Knee Flexion Strength (Nm/kg)	2.65±0.47	3.49±1.10	.09	2.74±0.50	3.55±1.00	.08
Knee Extension Strength (Nm/kg)	4.15±0.96	5.71±1.33	.02*	4.77±0.89[a]	5.78±0.97[a]	.06
Hip Flexion Strength (Nm/kg)	4.82±1.18	5.03±0.54	.66	4.55±1.12	5.05±0.93	.36
Hip Extension Strength (Nm/kg)	4.61±1.43	5.01±0.79	.50	4.66±1.38	5.62±0.90	.13
Hip Abduction Strength (Nm/kg)	4.59±1.91	5.61±0.87	.20	4.46±1.91	5.98±1.04	.07

[a]Statistically significant compared to baseline at p≤.05
*Statistically significant differences between groups at p≤0.05
Caption: Mean and standard deviation of range of motion, alignment, and strength measures comparing groups and timepoints.
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise, ROM, range of motion; AHI, arch height index; ARI, arch rigidity index; SLR, straight leg raise; MTP, metatarsophalangeal

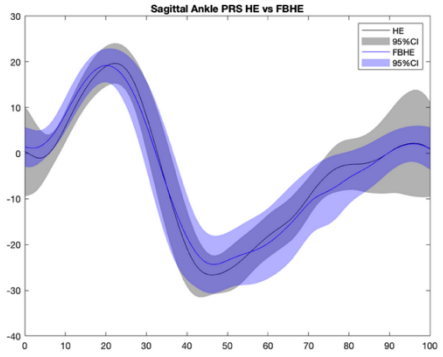
Additional Results Figures D2.1. Additional sensor-derived biomechanics outcomes



Caption: Sensor-derived biomechanical box plots comparing groups across primary study timepoints.
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise

Additional Results Figures D2.2. Indoor gait analysis results (a-j) comparing groups, (k-t) comparing timepoints, and (u) comparing group by time.

a.



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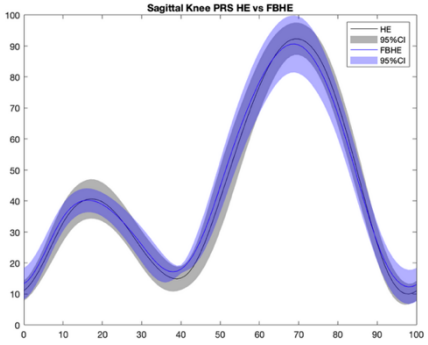

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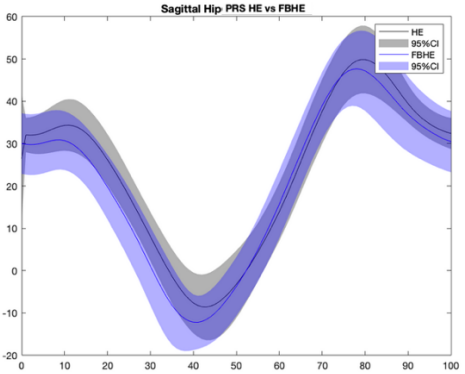

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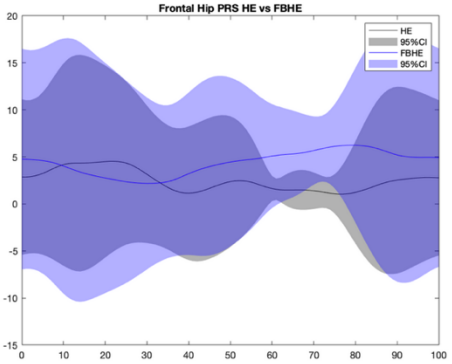

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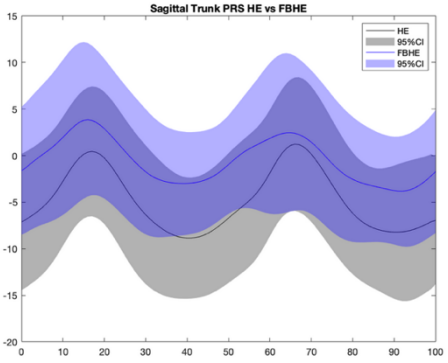

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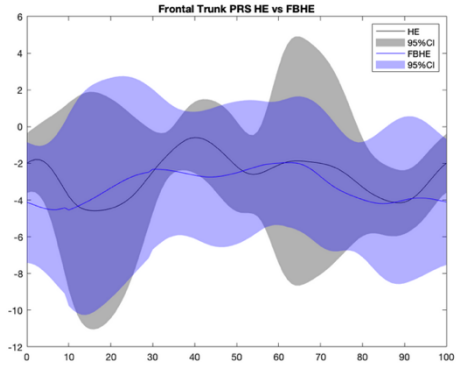

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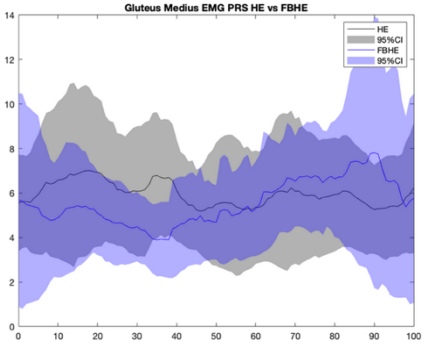
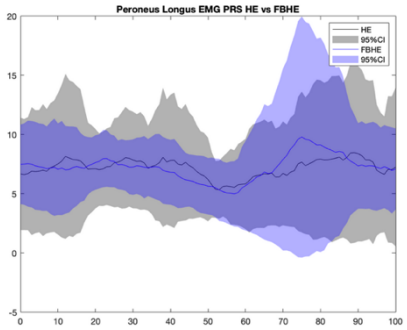
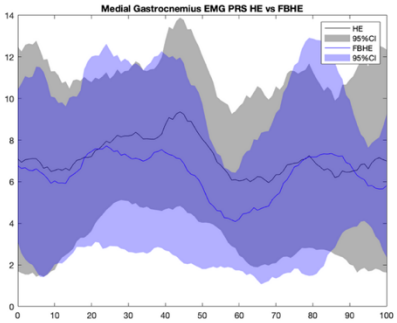

Gluteus Medius EMG PRS HE vs FBHE
HE
95%CI
FBHE
95%CI

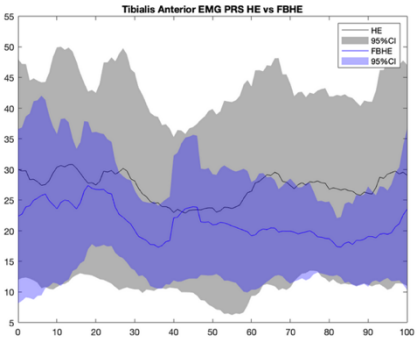
h.


Peroneus Longus EMG PRS HE vs FBHE
HE
95%CI
FBHE
95%CI

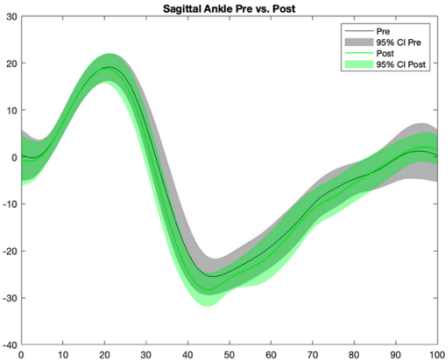
i.


Medial Gastrocnemius EMG PRS HE vs FBHE
HE
95%CI
FBHE
95%CI

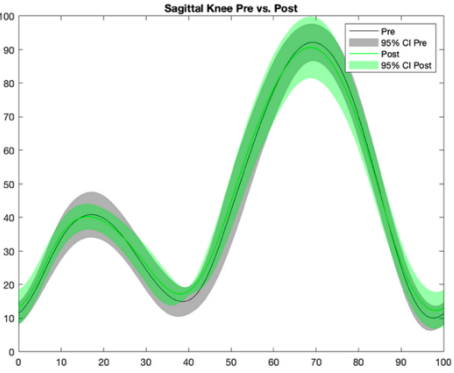
j.


Tibialis Anterior EMG PRS HE vs FBHE
HE
95%CI
FBHE
95%CI

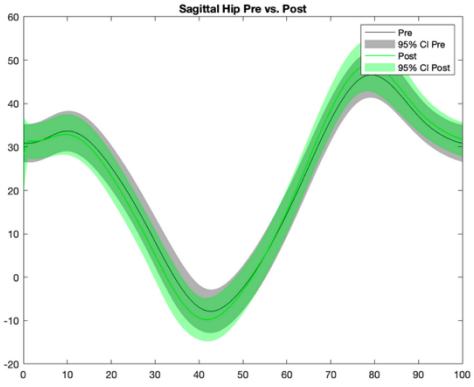
k.


Sagittal Ankle Pre vs. Post
Pre
95% CI Pre
Post
95% CI Post

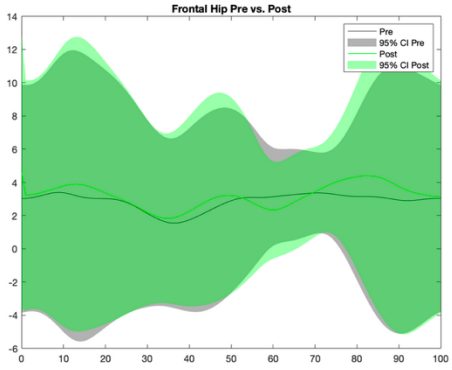
l.


Sagittal Knee Pre vs. Post
Pre
95% CI Pre
Post
95% CI Post

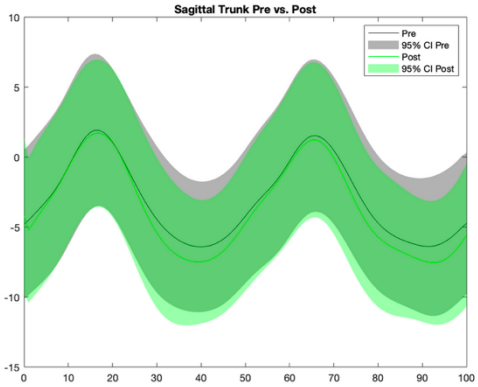
m.


Sagittal Hip Pre vs. Post
Pre
95% CI Pre
Post
95% CI Post

n.


Frontal Hip Pre vs. Post
Pre
95% CI Pre
Post
95% CI Post

o.



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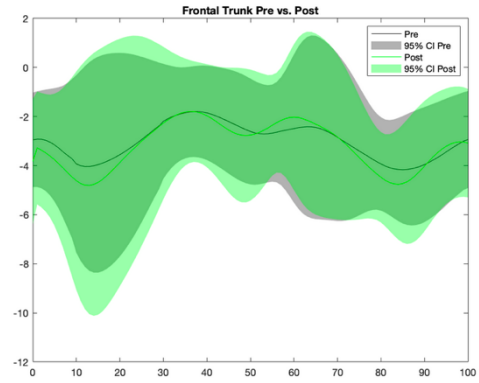

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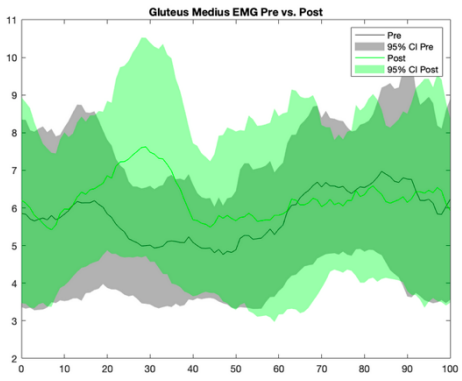

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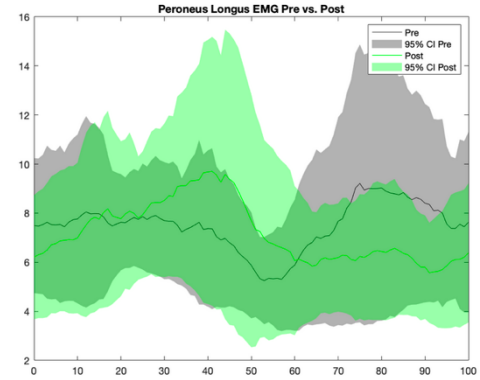

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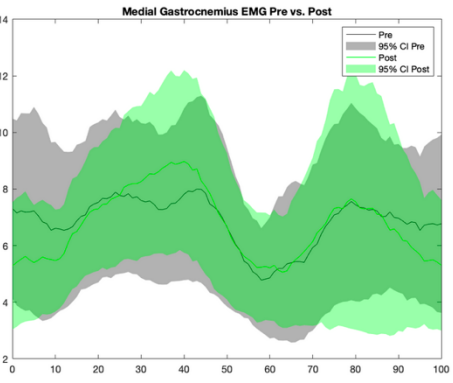

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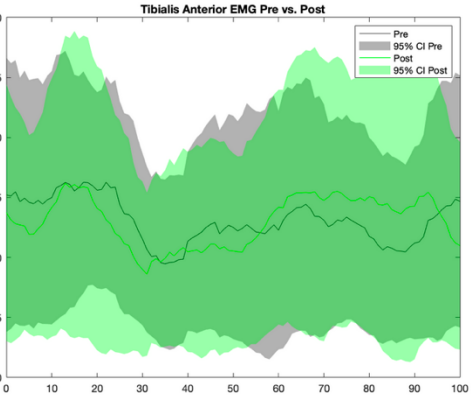
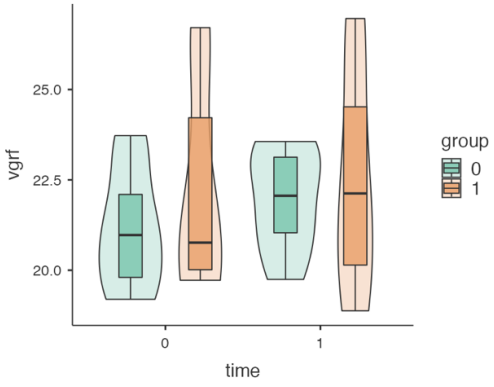


u.



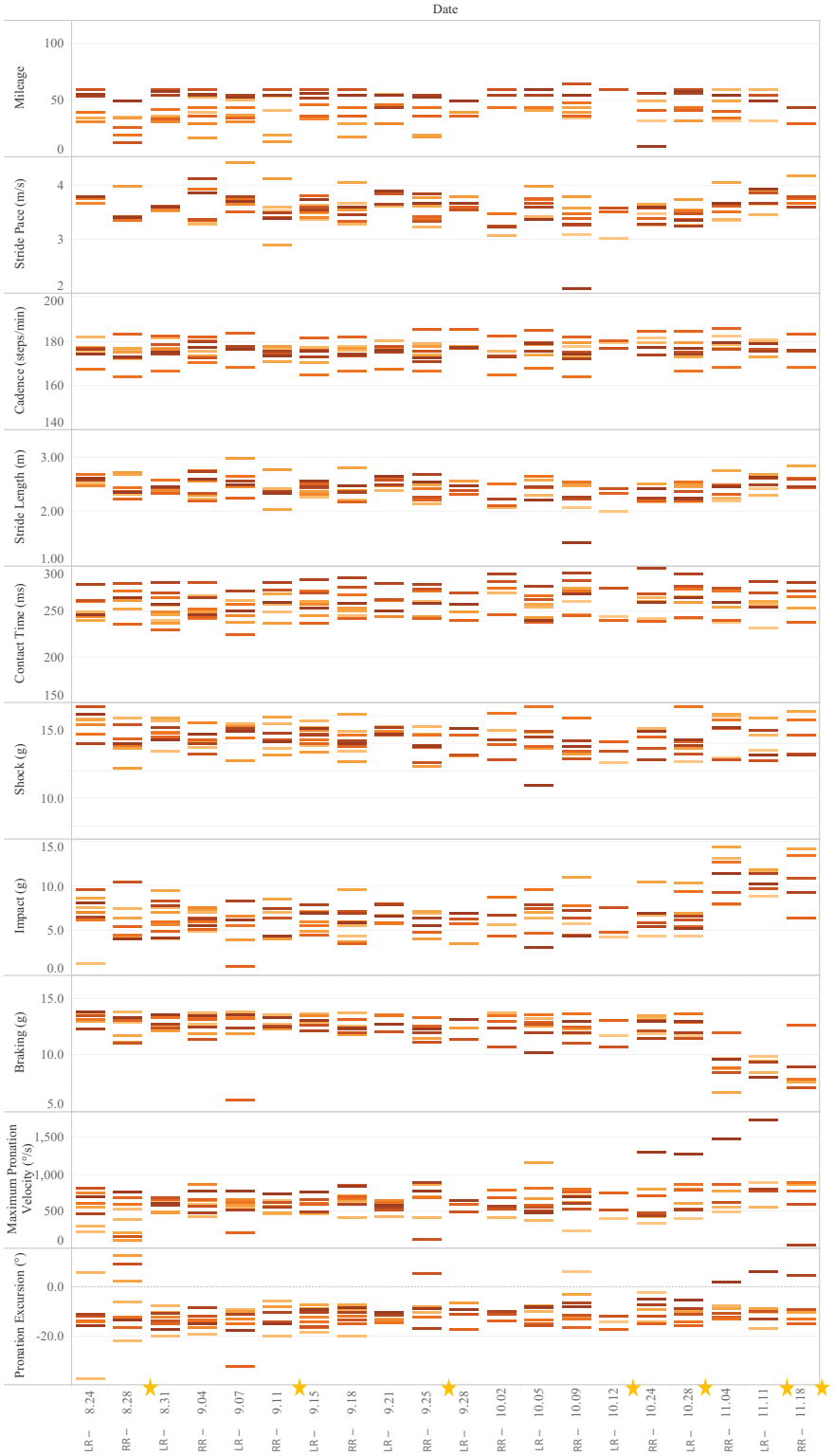
Caption: Statistical parametric mapping across groups and timepoints for indoor gait biomechanics.
Abbreviations: FBHE, contact time gait-training feedback with home exercise; HE, home exercise; PRS, preferred running speed; vgrf, vertical ground reaction force.
Figure u: group 0 = HE, group 1 = FBHE, time 0 = baseline, time 1 = 4-

Additional Results Table D3.1. Average gait biomechanics comparing long runs and recovery runs for male and female cross-country teams.

	Males			Females		
	Long Runs	Recovery Runs	p-value	Long Runs	Recovery Runs	p-value
Pace (m/s)	4.02 ± 0.25	3.78 ± 0.29	<.001*	3.61 ± 0.24	3.51 ± 0.32	.03*
Cadence (steps/min)	175 ± 5	173 ± 4	<.001*	177 ± 4	176 ± 5	.16
Stride Length (m)	2.75 ± 0.20	2.63 ± 0.21	<.001*	2.45 ± 0.18	2.40 ± 0.22	.09
Contact Time (ms)	250 ± 15	261 ± 15	<.001*	260 ± 15	264 ± 15	.10
Shock (g)	14.4 ± 1.8	14.1 ± 1.6	.30	14.4 ± 1.8	14.3 ± 1.1	.73
Impact (g)	7.0 ± 2.5	6.4 ± 2.3	.15	7.1 ± 2.5	6.7 ± 2.1	.29
Braking (g)	12.1 ± 2.0	12.2 ± 2.3	.87	12.1 ± 1.9	12.3 ± 1.3	.41
Maximum Pronation Velocity (°/s)	861 ± 374	829 ± 326	.34	641 ± 228	647 ± 245	.09
Pronation Excursion (°)	14.4 ± 5.8	13.5 ± 6.5	.58	11.4 ± 5.8	9.6 ± 6.8	.89

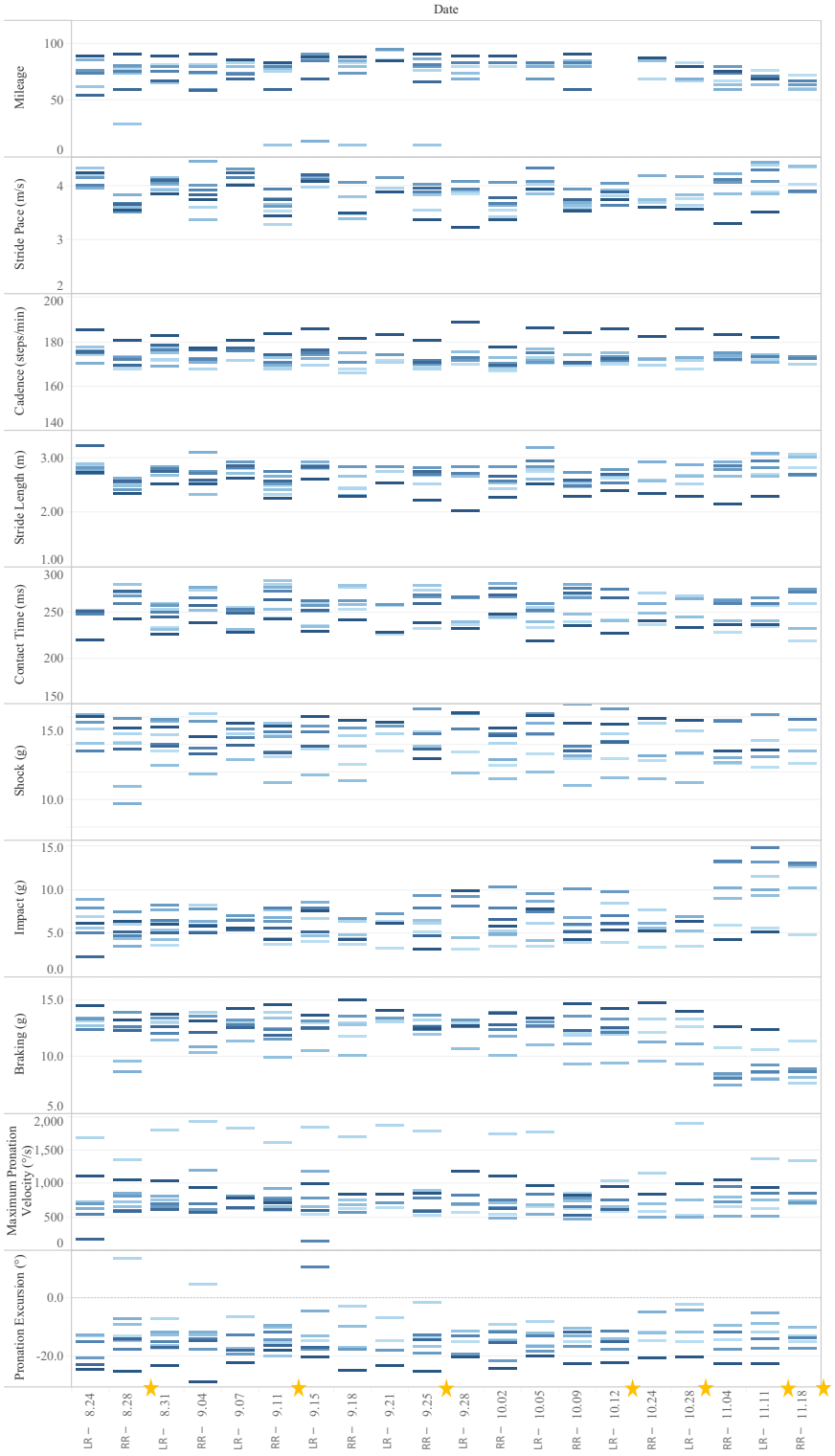
Caption: Sensor-derived biomechanical measures compared for long runs and recovery runs between male and female team averages across the season. Asterisks denote significant differences between run types within the teams.

Additional Results Figure D3.1a. Sensor-derived measures for individual female cross-country runners across the competitive season.



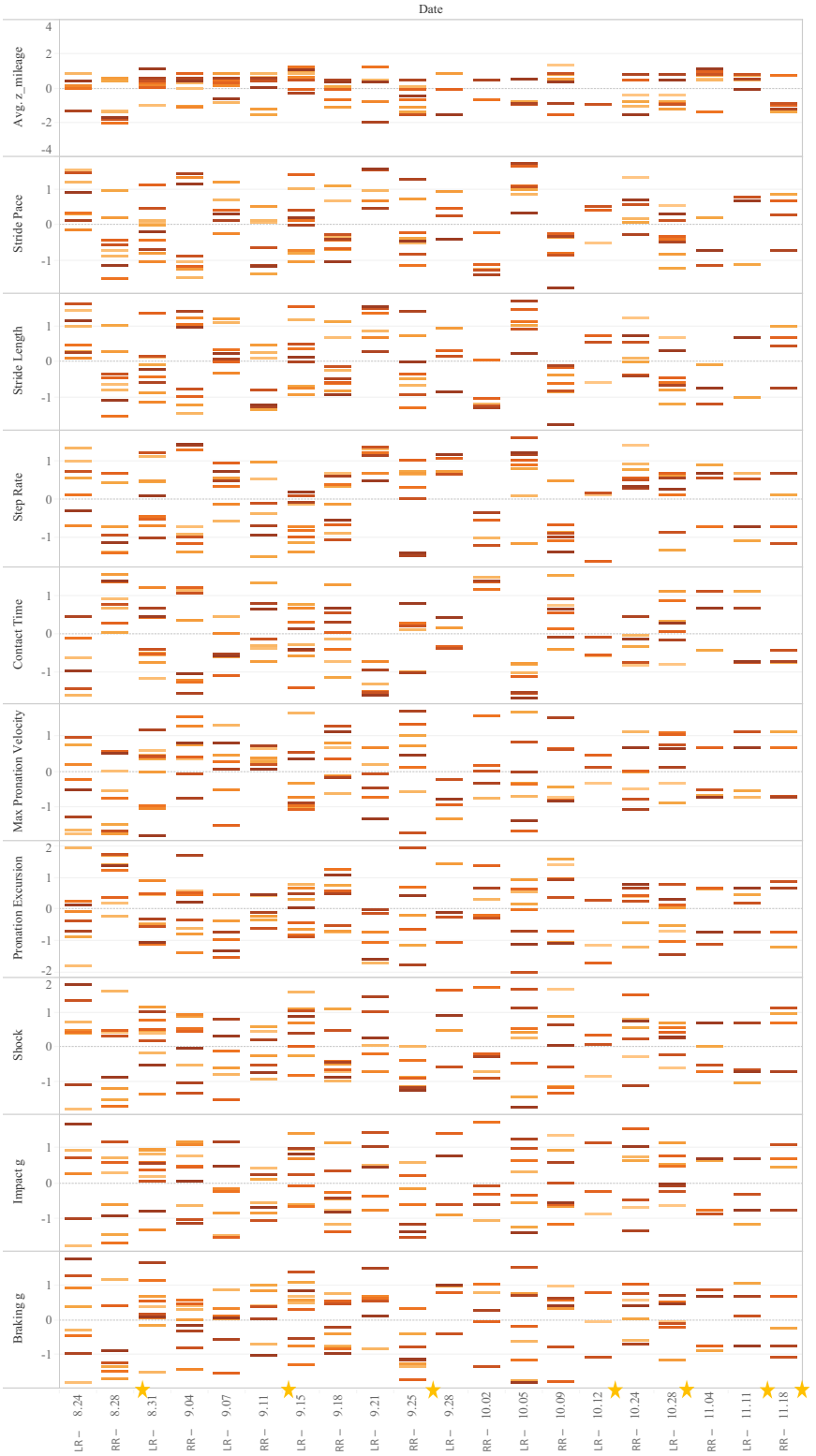
Caption: Each individual female runner's average sensor-derived metrics and mileage are plotted as a different shade of orange per recorded date across the season to visualize the spread of team data. Mileage is representative of the 7-day cumulative distance prior to the recorded run date. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis. Stars along the x-axis represent competition dates. *Abbreviations: LR, long runs; RR, recovery runs.*

Figure 3.1b. Sensor-derived measures for individual male cross-country runners across the competitive season.



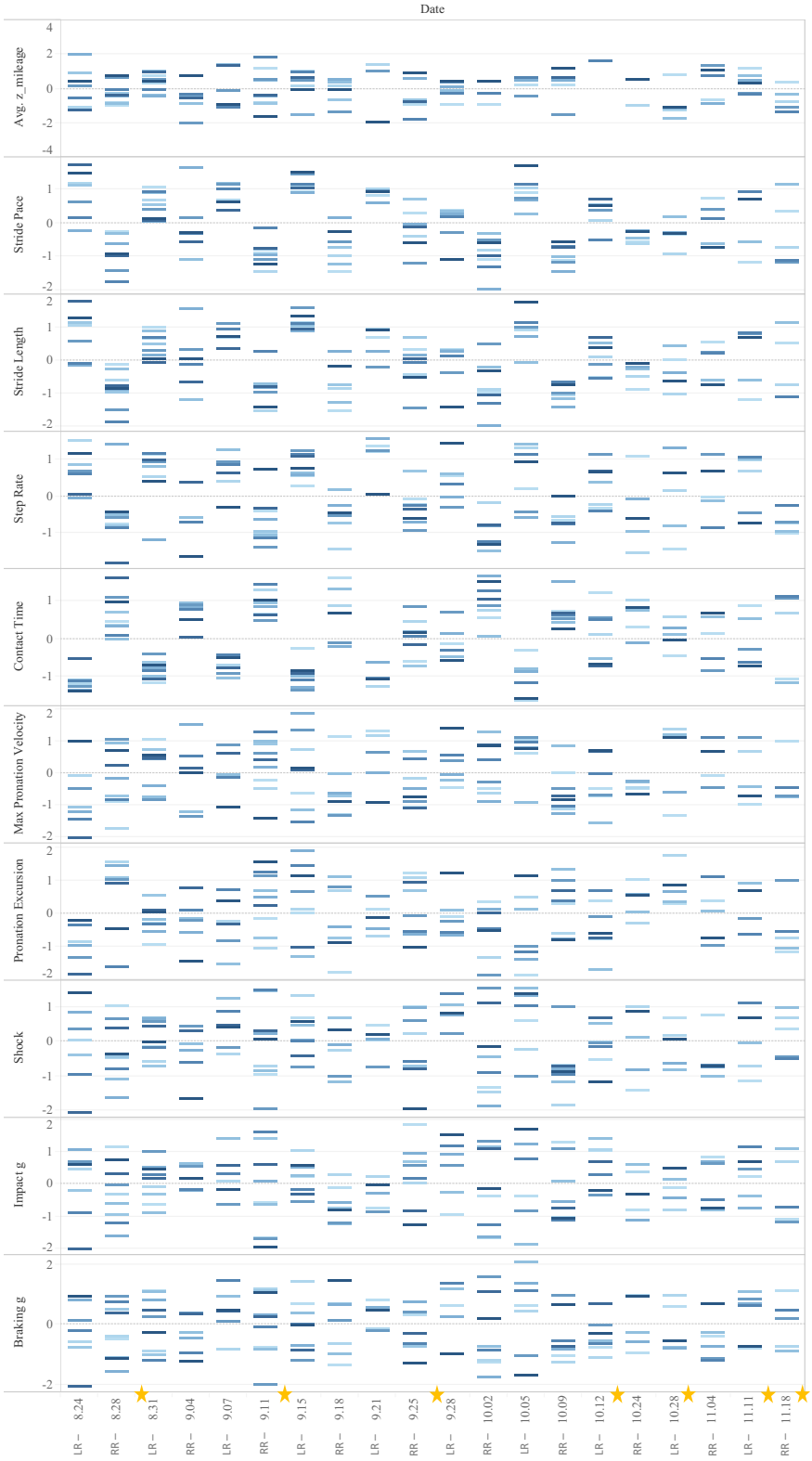
Caption: Each individual male runner's average sensor-derived metrics and weekly mileage are plotted as a different shade of blue per recorded date across the season to visualize the spread of team data. Mileage is representative of the 7-day cumulative distance prior to the recorded run date. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis. Stars along the x-axis represent competition dates.
Abbreviations: LR, long runs; RR, recovery runs.

Additional Results Figures D3.2a. Z-scores of mileage and sensor-derived measures for individual female cross-country runners across the competitive season.



Caption: Each individual female runner's z-score of sensor-derived metrics and weekly mileage are plotted as a different shade of orange per recorded date across the season to visualize the spread of team data. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis. Stars along the x-axis represent competition dates.
Abbreviations: LR, long runs; RR, recovery runs.

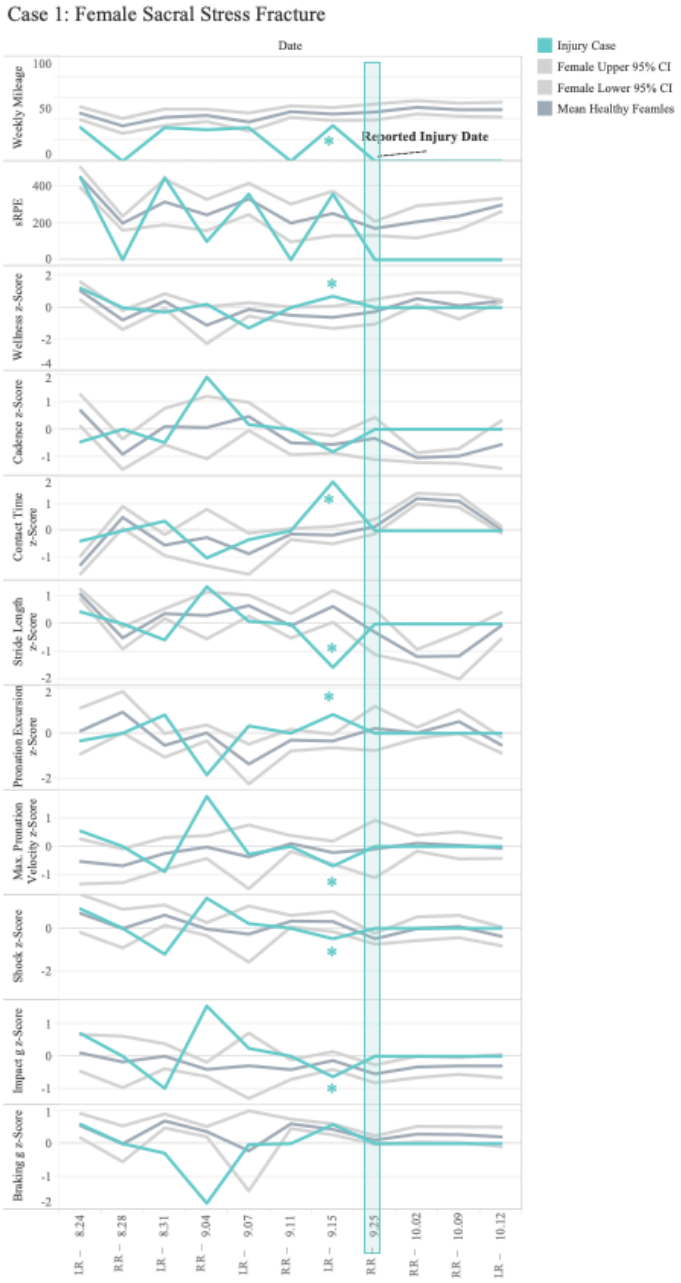
Additional Results Figures 3.2b. Z-scores of mileage and sensor-derived measures for individual male cross-country runners across the competitive season.



Caption: Each individual male runner's z-score of sensor-derived metrics and weekly mileage are plotted as a different shade of blue per recorded date across the season to visualize the spread of team data. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis. Stars along the x-axis represent competition dates.
Abbreviations: LR, long runs; RR, recovery runs.

Additional Results Figure 3.3a-h. Injury cases compared to healthy cross-country runners of the same sex across the competitive season.

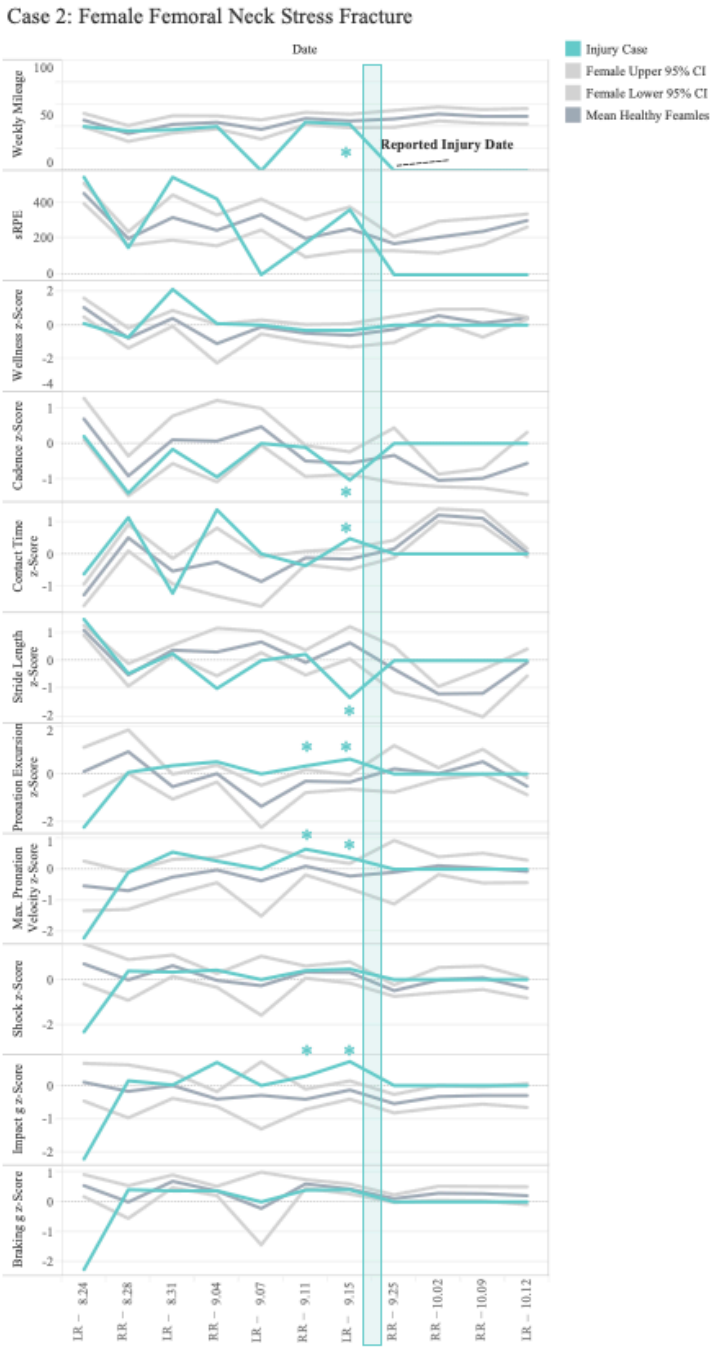
a.



Caption: Female sacral stress fracture case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy female teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was season-ending, and thus metrics fall to zero after the point of injury. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.

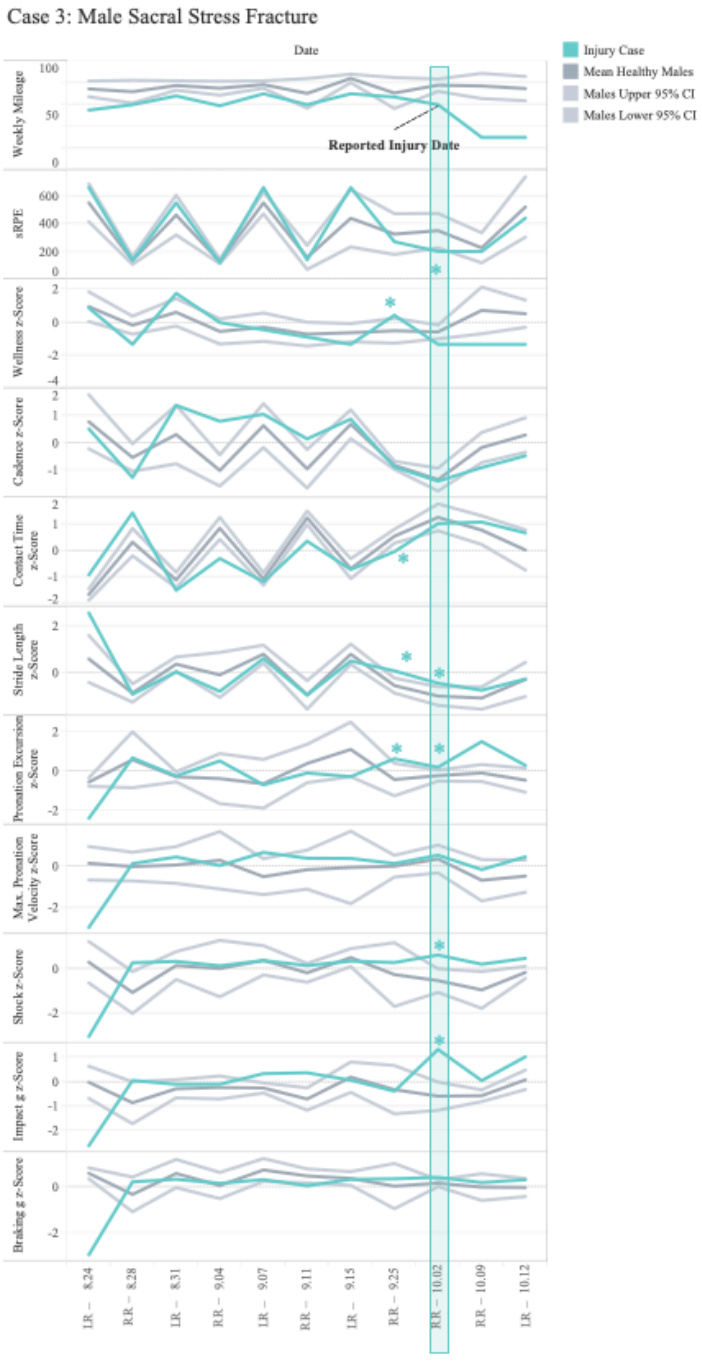
Abbreviations: LR, long runs; RR, recovery runs.

b.



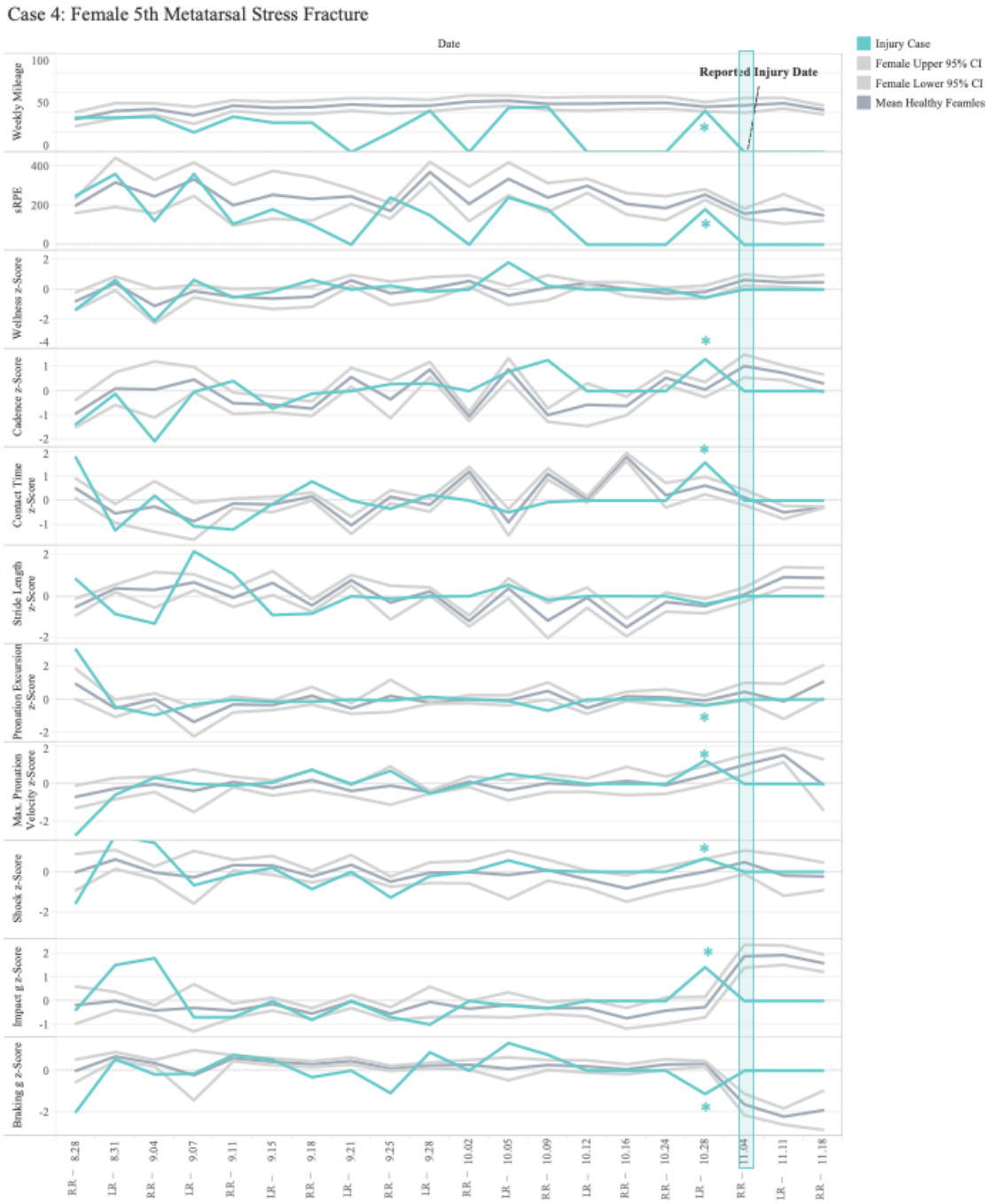
Caption: Female femoral neck stress fracture case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy female teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was season-ending, and thus metrics fall to zero after the point of injury. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

c.



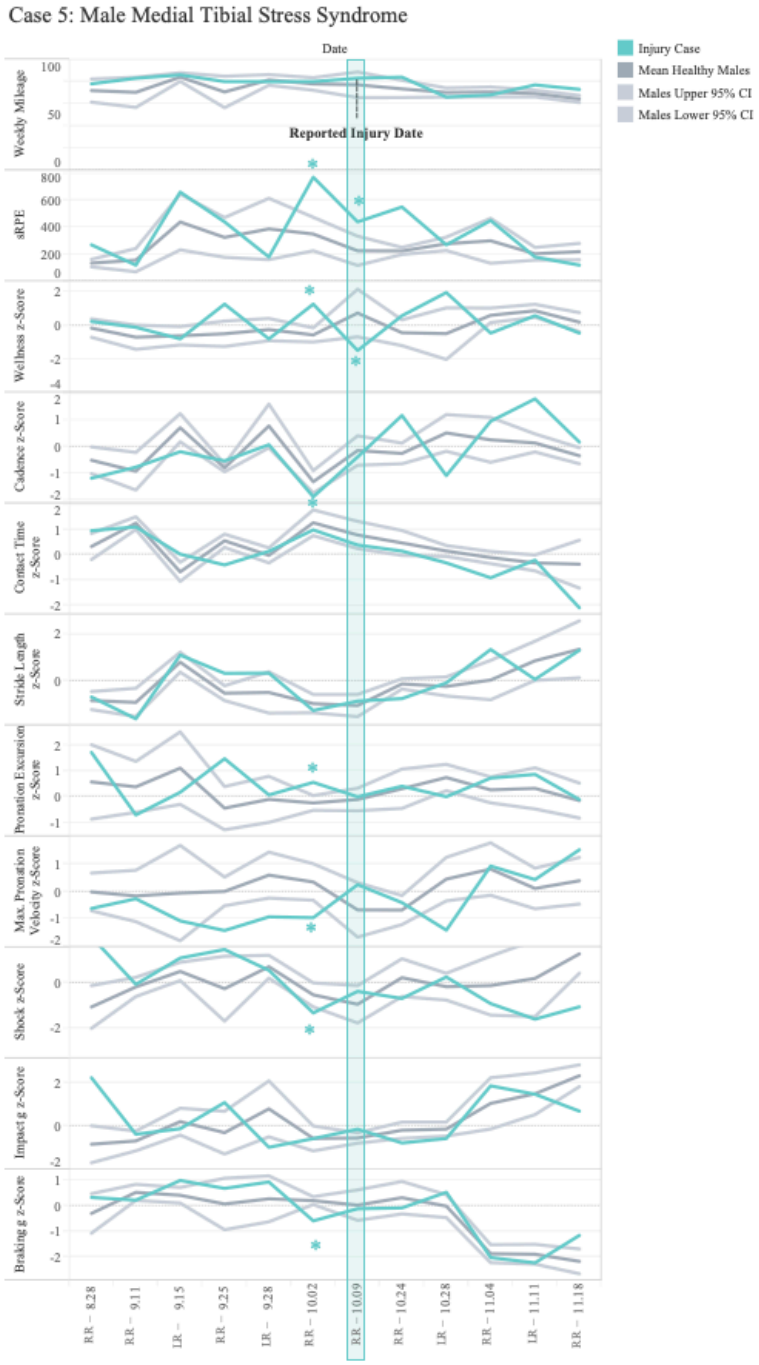
Caption: Male sacral stress fracture case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy male teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was season-ending, however radiographs confirming diagnosis were received on 10.15, and thus several additional runs were recorded post-injury. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis. *Abbreviations: LR, long runs; RR, recovery runs.*

d.



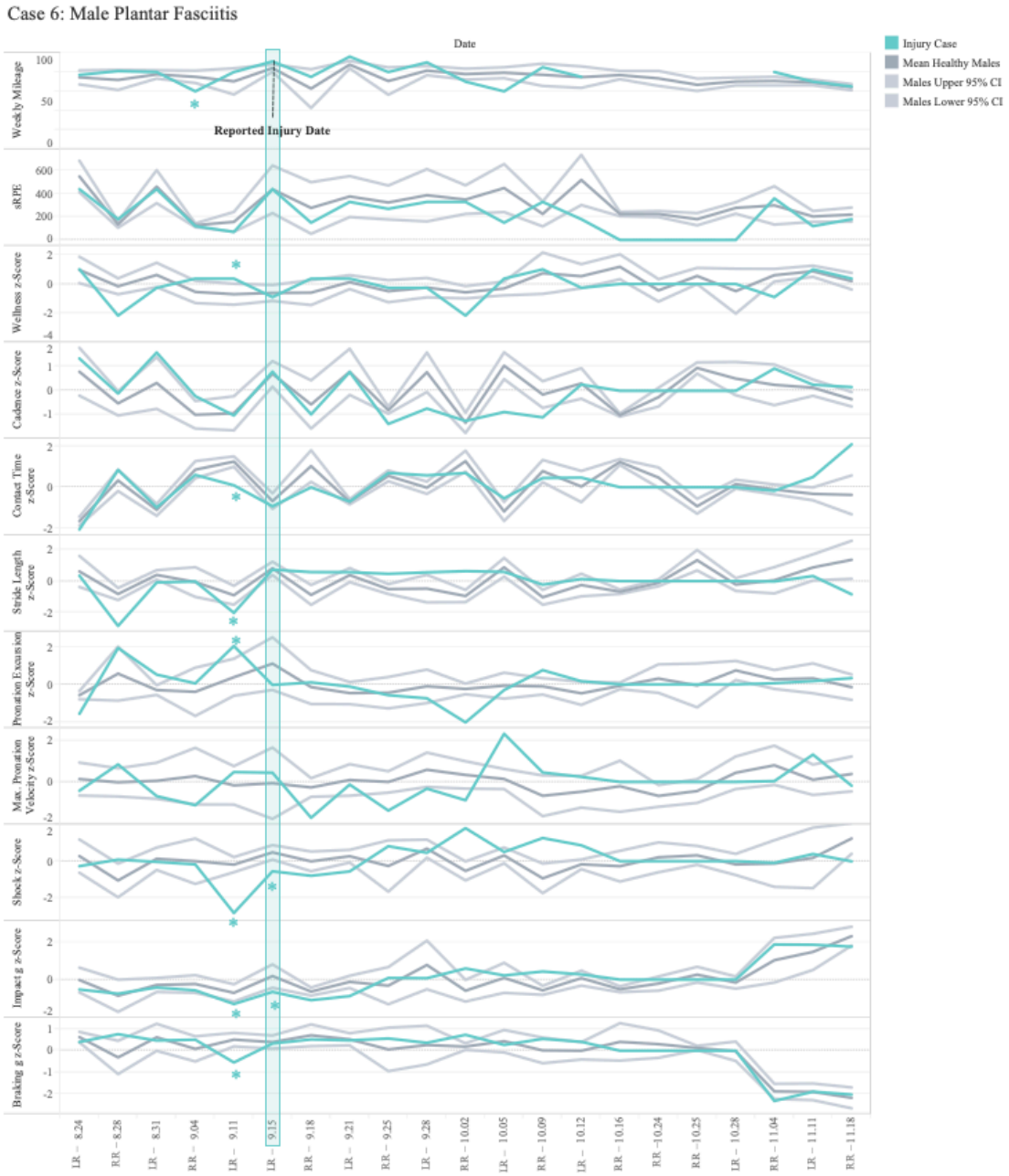
Caption: Female 5th metatarsal stress fracture case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy female teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was season-ending, and thus metrics fall to zero after the point of injury. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

e.



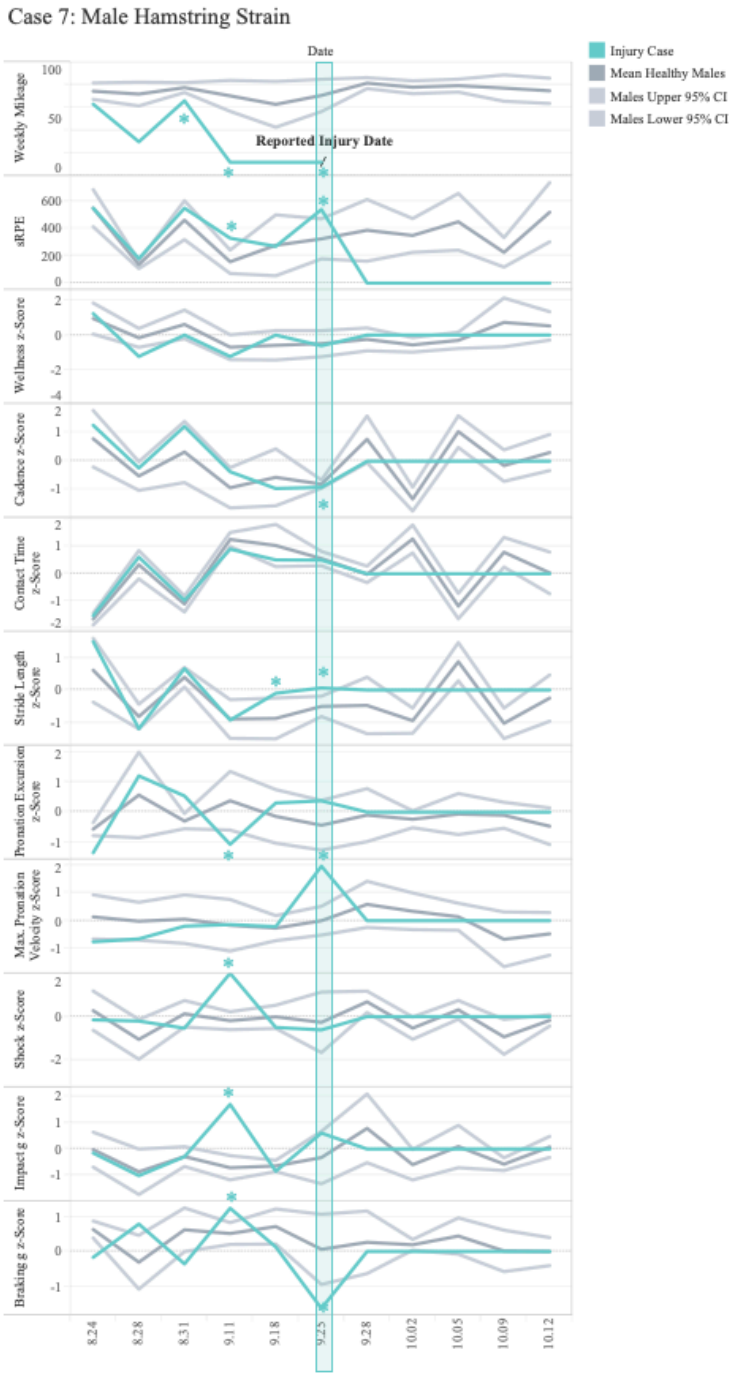
Caption: Male medial tibial stress syndrome case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy male teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was not season-ending; however, the athlete did miss several training dates due to injury, limiting the number of included runs. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

f.



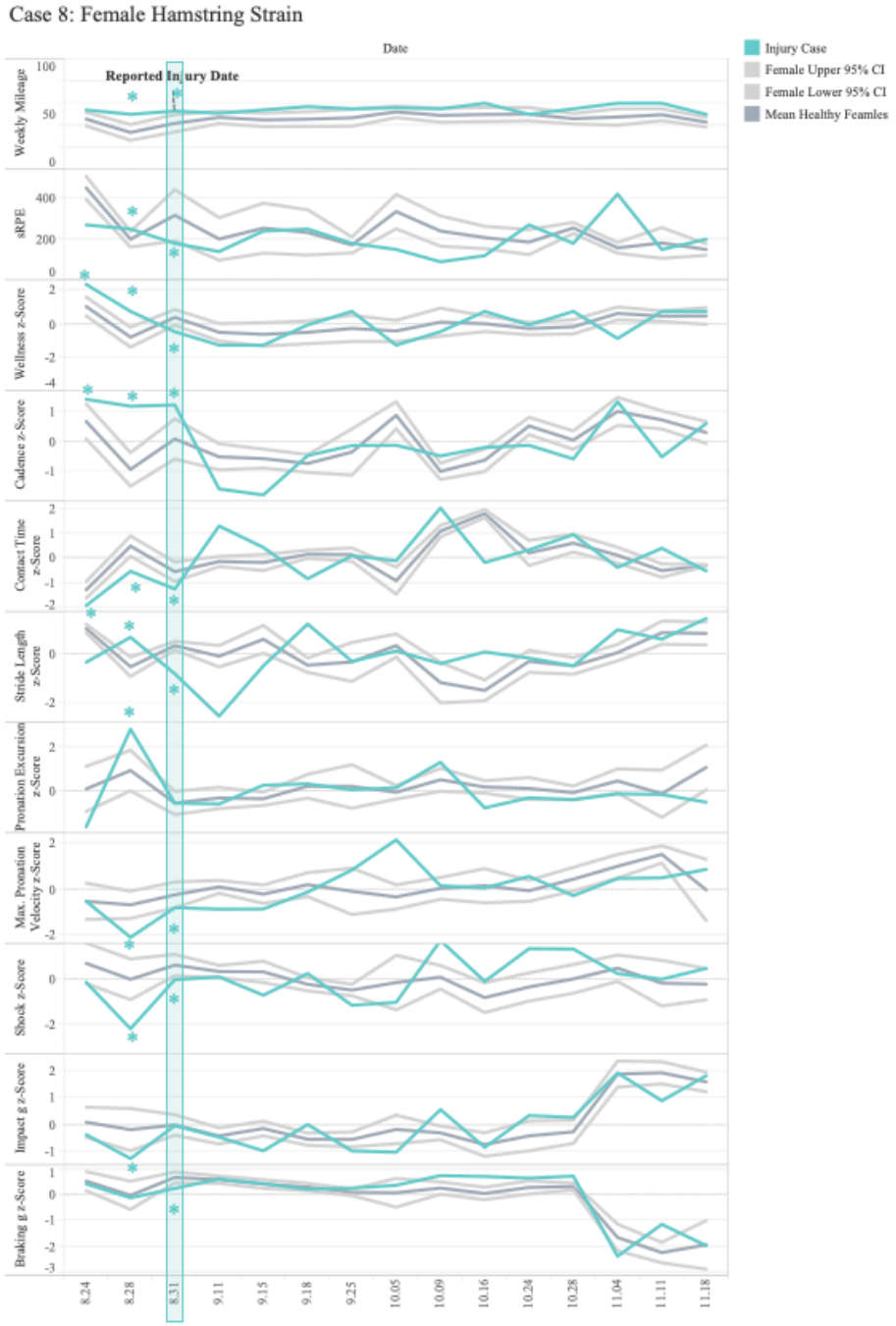
Caption: Male plantar fasciitis case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy male teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was not season-ending, and the athlete participated throughout the season. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

g.



Caption: Male hamstring strain case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy male teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was season-ending, and thus metrics fall to zero after the point of injury. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

h.



Caption: Female hamstring strain case gait biomechanics z-scores, wellness, and weekly mileage plotted against healthy female teammates across the season, up until the point of injury which is highlighted in a teal box. This injury was not season-ending; however, the athlete did miss several training dates due to injury, limiting the number of included runs. Metrics that extended beyond the team's 95% confidence intervals within 2 recorded dates preceding injury are denotated with asterisks. Long runs (LR) and recovery runs (RR) are denotated next to the respective dates on the x-axis.
Abbreviations: LR, long runs; RR, recovery runs.

APPENDIX E
Recommendations for Future Research

- Prospective assessments should be conducted among a larger, representative cohort of runners during outdoor training to elucidate biomechanical factors contributing to chronic lower extremity injuries
- Studies exploring the effects of outdoor gait training on an ERLLP population in regards to not only movement patterns, but also on patient-reported pain and disability, are necessary next steps.
- Prospective studies assessing runners in the field are necessary to determine the relationship between contact time and ERLLP development
- Future work is needed to determine if there are favorable treatment effects of outdoor gait-training on pain, function, and biomechanical outcomes in a larger, representative sample.
- Future studies assessing other prevalent chronic lower extremity injuries are needed to develop tailored intervention programs in the field, beyond exercise-related lower leg pain
- Future hypothesis-driven practical prospective monitoring studies with cross-country athletes are needed to determine if similar biomechanical changes are noted among injury cases
- Multi-site studies are needed across cross-country programs to reduce the influence of individual coaching style on participant outcomes
- Physiological assessments are necessary to determine other underlying contributing factors to injury risk and development among runners

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