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Medical disability discharge rates have increased over 600% in the last 25 years. The majority of these disabilities are due to musculoskeletal problems, with knee injuries representing a large fraction of this group. Running is a mode of exercise that is highly incorporated into military and civilian fitness programs to improve and maintain aerobic fitness. Unfortunately, up to 65% of runners sustain an overuse injury each year, with 25% of those injuries due to anterior knee pain (AKP).

The proposed prospective observational study will attempt to determine the factors that differentiate civilian recreational runners who remain injury-free from those diagnosed with AKP, the most common running injury, or any of the five most common overuse injuries. Runners who sustain a common overuse running injury will be compared to a non-injured cohort according to biomechanical, behavioral, and physiological risk factors. It is hypothesized that biomechanical, physiological, and behavioral risk factors will differentiate runners who do and do not get injured, and that certain factors will further differentiate those that sustain an AKP injury from those the sustain any of the most common lower extremity overuse injuries.

The study population will consist of 180 adult community distance runners who have been running a minimum of 5 miles/wk for at least 6 months without sustaining an overuse injury. Baseline testing will consist of lower extremity biomechanics testing, gathering training history information via questionnaires, and recording physiologic information (anthropometric and strength data). All baseline and follow-up data will be collected at the J.B. Snow Biomechanics Laboratory at Wake Forest University. Following baseline testing, injury status will be monitored via e-mail questionnaire every two weeks for the duration of the study. Six and 12-month follow-up data will be collected for all runners. Runners who sustain an overuse injury will schedule an appointment with a single study physician for evaluation within one week of sustaining the injury. Risks to the participants will be no greater than those associated with exercising on a daily basis.

We exceeded our recruitment goal by enrolling 184 runners in the study; compliance with biweekly reporting is 94% to date (7,340 responses to 7,832 emails sent). There were 100 injuries (54%) in the study group in the first year (we predicted 86 injuries or 45%). Of the 184 participants, 183 completed 6-month testing (99%) and 180 participants completed 12-month follow-up testing (98%). Results from this study will provide multi-disciplinary insight as to how a combination of gait mechanics, training behaviors, and physiological variables may combine to predict whether a runner will sustain a common overuse injury or not sustain an injury. These results will also augment clinical trials on the treatment, prevention, and mechanisms of injury. This study was funded through a USAMRMC Broad Agency Announcement (Opportunity Number: W81XWH-3 BAA08-1).

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## Table of Contents

	<u>Page</u>
Introduction.....	5
Body.....	6
Key Research Accomplishments.....	8
Reportable Outcomes.....	9
Conclusion.....	11
References.....	12
Appendices.....	13
Appendix A: “Differences in Running Mechanics and Flexibility Between Runners in Minimalist and Traditional Footwear”.....	14
Bibliography.....	15

## Introduction

The purpose of this prospective observational study was to determine the factors that differentiate civilian recreational runners who remain injury-free from those diagnosed with anterior knee pain (AKP), the most common running injury, or any of the five most common overuse injuries. Runners who sustained a common overuse running injury were compared to a non-injured cohort according to biomechanical, behavioral, and physiological risk factors. It was hypothesized that biomechanical, physiological, and behavioral risk factors will differentiate runners who do and do not get injured, and that certain factors will further differentiate those that sustain an AKP injury from those the sustain any of the most common lower extremity overuse injuries. The study population consisted of 184 adult community distance runners who had been running a minimum of 5 miles/wk for at least 6 months without sustaining an overuse injury. Baseline testing consisted of lower extremity biomechanics testing, gathering training history information via questionnaires, and recording physiologic information (anthropometric and strength data). All baseline and follow-up data were collected at the J.B. Snow Biomechanics Laboratory at Wake Forest University. Following baseline testing, injury status was monitored via e-mail questionnaire every two weeks for the duration of the study. Six and 12-month follow-up data were collected for all runners. Runners who sustain an overuse injury scheduled an appointment with a study physician for evaluation within as close to two weeks of sustaining an overuse injury. Risks to the participants were no greater than those associated with exercising on a daily basis.

Most recently, the Injury Recovery study was funded. Currently, we are in the process of recruiting 100 additional runners (65 are enrolled and participating to date) to add to the existing cohort of 184. We have also designed a randomized clinical trial on strength training to prevent musculoskeletal injury in female runners.

## Body

For the 184 runners enrolled and participating in the study, compliance with biweekly reporting was 94% (7,340 responses to 7,832 emails sent). There were 100 injuries in the study group in the first year of participation (116% of predicted). Results from this study will provide multi-disciplinary insight as to how a combination of gait mechanics, training behaviors, and physiological variables may combine to predict whether a runner will sustain a common overuse injury or not sustain an injury. These results will also augment clinical trials on the treatment, prevention, and mechanisms of injury.

Recruitment, testing, and study compliance have been excellent. We had an overwhelming response and interest to advertising, helping us to exceed our recruitment goal of 180 participants. All baseline testing and enrollment were completed by January 2012, and the use of the internet to update us on their injury and bi-weekly training status has been a complete success. Compliance is 94% to-date in responding to the bi-weekly emails. The injured participants were examined by our study physician in a timely manner, within two weeks of reporting the injury. We surpassed our predicted injury rate of 45%, with a total of 100 runners sustaining an injury in the first year (54%). Fifty-one runners sustained a Grade 1 injury (injury did not impact training/running, maintained full activity), 36 sustained a Grade 2 injury (injury reduced their weekly mileage), and 13 sustained a Grade 3 injury (injury interrupted their running for at least 2 weeks). Fifty-nine percent of the runners injured were male. Of the 108 males in the study, 59 were injured in the first year (55%), and of the 76 females in the study, 41 were injured in the first year (55%).

Monthly investigator meetings were scheduled to discuss study progress and possible ideas for abstracts, manuscripts, and presentations. We have had an abstract accepted for the American College of Sports Medicine (ACSM) annual meeting entitled "Differences in Running Mechanics and Flexibility between Runners in Minimalist and

Traditional Footwear". Additional abstracts and manuscripts using baseline data are in progress. Topics include: male/female differences in running mechanics, strength, and flexibility, differences between runners in minimalist footwear and regular footwear, and biomechanical differences between never injured versus previously injured runners. Outcome manuscripts will be written as we finish our final processing, cleaning, and analyses.

The following are completed deliverables of the TRAILS study:

- **Study planning : Completed**
- **Study recruitment: Recruitment exceeded**
- **Baseline testing: Completed**
- **Follow-up visits: FU6 conducted**
- **Follow-up visits: FU12 completed**
- **Baseline descriptive data analysis: completed**
- **Preliminary injury rates: completed**
- **Data analysis: ongoing. Baseline papers in progress**
- **Final injury rates: completed January 2013**
- **Report differences between injured and non-injured: began in January 2013 when all participants completed at least 12 months observation period.**
- **We also designed, wrote, and submitted a 3 year supplemental grant that will build on the parent grant**

The deliverables still in progress are the following:

- **Recruitment: additional 100 are ongoing. 65 out of 100 have been enrolled**
- **Injury Rates: new 100 are ongoing. 10 out of 65 have been injured to date**
- **Follow-up visits: FU6 being currently being conducted**

## Key Research Accomplishments

- Exceeded our recruitment goal(180)by enrolling 184 participants as of January 2012
- Nearly all baseline descriptive statistics on the study population have been completed (including variables on strength, flexibility, arch height, Q-angle, anthropometrics, injury and training history, and health status questionnaires)
- 99% retention for 6-month follow-up, and 98% retention for 12-month follow-up
- 100 injuries in the study group in the first year of participation in the study (116% of predicted), of which 27% are injuries to the knee
- 94% participant compliance to bi-weekly study emails
- Maximizing funding by having volunteers from Wake Forest and other universities aid our paid staff with various study roles. For example: - assist with participant testing, assist with data entry and phone calls.
- Monthly investigator meetings to discuss potential baseline papers, abstracts, presentations
- An abstract accepted and 6 baseline manuscripts and abstracts in progress

## Reportable Outcomes

We have succeeded in recruiting and enrolling 184 participants into the study. All baseline data have been double-data entered to insure accuracy, and checked thoroughly for quality control. Six-month and 12-month follow up data have been collected and double-data entered on all participants. We are currently in the process of analyzing the primary/secondary aims of the study. A poster abstract has been completed and accepted at a national conference, and we have begun the analyses on 6 other baseline abstracts and manuscripts. The working titles and primary authors for these abstracts/manuscripts are listed below:

1. DeVita. "Biomechanical Factors Associated with Knee Joint Forces in Running"
2. Messier. "Association between Overuse Injury and Biomechanics in Distance Runners"
3. Messier. "Differences between Male/Female Running Mechanics, Flexibility, and Strength"
4. Mihalko. "Quality of Life in Runners: Does Adherence Self-Efficacy Matter?"
5. Seay. "Differences in Lower Extremity Strength, Coordination and Coordination Variability between Runners in Minimalist Shoes Compared to Traditional Running Shoes"
6. Seay. "Differences in Lower Extremity Coordination between Runners with and without a History of Lower Extremity Overuse Injury"

The working titles for the preliminary outcome manuscript proposals are:

1. Factors that distinguish non-injured runners from injured runners with anterior knee pain: A prospective observational study. Messier et al.
2. Factors that distinguish non-injured runners from runners with common overuse injuries: A prospective observational study. Messier et al.

3. Does self-efficacy and pain mediate return to pre-injury running status in injured runners? Mihalko
4. Are the risk factors for injury different between male and females runners? Messier et al.

## Future Considerations

Related to the success we have had with recruitment, injury rate, compliance and retention, we have received funding in the past year for a 3-year study to examine injury recovery in runners. This will include adding 100 additional runners to the TRAILS parent grant. The injury recovery study will test runners enrolled in TRAILS that have recovered from grade 2 or grade 3 injuries (i.e., returned to pre-injury weekly mileage) to determine if biomechanical, physiological and psychological variables are also similar to pre-injury values. We hypothesize that runners who incur frequent injuries do not recover biomechanically, physiologically, and psychosocially from previous injuries.

## References

None to date

## Appendices



## Bibliography

### List of Personnel Receiving Pay from the Research Effort:

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