INJURY PREVENTION IN THE ATHLETE:

INVESTIGATION OF THE EFFICACY AND THE BIOMECHANICS OF A NEUROMUSCULAR TRAINING PROGRAM IN COLLEGIATE SOCCER PLAYERS

by

Holly Silvers-Granelli

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biomechanics and Movement Science

Summer 2017

INJURY PREVENTION IN THE ATHLETE:

INVESTIGATION OF THE EFFICACY AND THE BIOMECHANICS OF A NEUROMUSCULAR TRAINING PROGRAM IN COLLEGIATE SOCCER PLAYERS

by

Holly Silvers-Granelli

Approved: ____
Samuel C.K. Lee, Ph.D.
Director of the Biomechanics and Movement Science Program

Approved: ____
Kathleen S. Matt, Ph.D.
Dean of the College of Health Sciences

Approved: ____
Ann L. Ardis, Ph.D.
Senior Vice Provost for Graduate and Professional Education

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Lynn Snyder-Mackler, Sc.D.
Professor in charge of dissertation

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Mario Bizzini, Ph.D.
Member of dissertation committee

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

Karin Grävare Silbernagel, Ph.D.
Member of dissertation committee

I certify that I have read this dissertation and that in my opinion it meets the academic and professional standard required by the University as a dissertation for the degree of Doctor of Philosophy.

Signed: ____

William Rose, Ph.D.
Member of dissertation committee

ACKNOWLEDGMENTS

I would like to express my most sincere gratitude to my advisor, Dr. Lynn Snyder-Mackler, for her mentorship and for this incredible opportunity to enhance my career and further my knowledge base at an amazing institution. I will forever be indebted to you. I would like to thank my stellar dissertation committee, Dr. Karin Grävare Silbernagel, Dr. William Rose and Dr. Mario Bizzini for their thoughtful and poignant contributions to my overall theoretical learning and to the content of my dissertation. I would like to deeply thank my extraordinary laboratory friends and colleagues, Amy Arundale, Ryan Zarzycki, and Adam Marmon for their unrivaled dedication and energy they each devoted to this project. I walk away from this experience knowing that I have forged remarkable lifelong friendships with each of them. Thank you to the extended University of Delaware community. I have had an incredible experience during my four-year tenure at the university. I am so deeply grateful to have had the opportunity to earn a degree from this exceptional institution and to learn from some of the nations finest educators.

Without the incredible level of support, encouragement, love and cooperation of my husband, Dennis Granelli, this body of work would cease to exist. Your patience, compassion and cooperation during the last four years have been incredible, and so deeply appreciated. The way you honored me during this process make me so proud to be your partner in life. I would also like to dearly thank the entire Silvers' and Meola families; who provided me with wise and warm words of encouragement, love and support. I am exceedingly grateful and lucky to have a family as wonderful

and supportive as you all. Thank you to my dearly departed father, Joseph Edward Silvers, who always urged his girls to reach for the stars and tackle your most lofty goal. The world is truly our oyster, Dad! And, finally, thank you to my cherished son, Luke Joseph Granelli, who makes everyday inordinately more blessed and a treasure worth living. I hope that your Mommy makes you proud. I love you so dearly.

"The purity of heart is to will one thing."

Søren Kierkegaard

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Background

Soccer related injuries are a relatively common occurrence across gender, age and level of competition. The impact of sports related injury is complex and far-reaching; inflicting potential long-term physical, emotional and financial consequences for the athlete to contend with long after their athletic career has finished.

Purpose

The purpose of this body of work was to 1) evaluate the efficacy of the FIFA 11+ program in a randomized controlled trial, 2) identify how the FIFA 11+ program may impact the rate of anterior cruciate ligament injury, 3) identify how program compliance affects injury rate and overall soccer team performance, 4) and to analyze the kinetic and kinematic biomechanical changes associated with the utilization of the FIFA 11+ over a competitive season.

Methods

A prospective randomized controlled trial was performed in NCAA male collegiate soccer players to analyze the efficacy of the FIFA 11+ program over the course a soccer season. Injury rate and time loss due to injury were analyzed and compared to a skill and age matched control group. Anterior cruciate ligament injury

rates were specifically analyzed to determine if the FIFA 11+ program could effectively decrease the rate of ACL injury in soccer players.

A secondary analysis of the data was performed to analyze the role of team compliance on the overall effectiveness of the FIFA 11+ program. Compliance data from the intervention group was stratified into three tertiles (high, moderate and low) to analyze how the variability in compliance may impact overall injury rate. Overall team performance was also assessed. A record of each team's wins, losses and ties was recorded and analyzed based on the level of compliance.

A biomechanical analysis of kinetic and kinematic variables was conducted to analyze the biomechanical changes in female soccer players using the FIFA 11+ compared to a control group. Two functional tests were analyzed: a single leg squat and a single leg trip hop test. The subjects were analyzed at two time points; a pre-test analysis prior to the season and a post-test analysis at the culmination of the season.

Clinical Significance

The information obtained in this dissertation supports the importance of the consistent implementation of injury prevention protocols in sport. The FIFA 11+ program has demonstrated its' ability to decrease injury rate, including ACL injury rate, and improve overall team performance. Compliance is a critical component to the overall impact of the program; teams utilizing the program more consistently demonstrated lower injury rates and more success with respect to team performance.

By prospectively analyzing changes in soccer specific movement patterns across the course of a competitive season in females, we are now able to more fully understand how the program is beneficial to the athlete with respect to injury reduction and how the program imparts' a protective benefit. The pre/post season analysis revealed favorable biomechanical changes in the hip, including increases in hip flexion angle, increase in hip extensor moment increases in hip abduction moment and decreases in hip internal rotation angle. This information will guide future researcher on how to optimize injury prevention efforts, improve the content and efficiency of therapeutic prevention interventions, and to potentially identify high-risk athletes prospectively prior to a deleterious injury occurring. If these methods are implemented with optimal compliance and consistency early in an athlete's career, the overall risk of injury may be significantly reduced and the long-term health and athletic career longevity may be extended through the later decades of life. Furthermore, the physical and financial longitudinal impact(s) of many sports related injuries may be significantly mitigated, thus improving overall quality of life of the athlete, extending well past the tenure of a collegiate athletic career.

Chapter 1

BACKGROUND AND SIGNIFICANCE

Soccer Epidemiology

Soccer is the most widely played sport among both men and women, with approximately 300 million registered players globally.[1-3]It is currently the third most popularly played sport, with over 13 million Americans participating at the youth and adult levels. [4, 5] Major League Soccer (MLS) is currently in its 22nd season and has grown to 20 professional teams within the United States and in Canada. [6] In the high school setting, there are approximately 412,000 high school male and 372,000 high school female soccer players.[7] In the collegiate setting, there are approximately 27,000 collegiate male and 33,000 female collegiate soccer players participating in NCAA soccer in the United States.[8, 9] The number of athletic participants is increasing annually and this increase imparts a multitude of positive effects with respect to physical health, psychological health, overall wellness and is influential in decreasing the onset of illness and systemic disease. The inherent risks associated with soccer participation are well documented.[10-20] In the last two decades, numerous attempts have been made to gain a fuller understanding about the mechanism of soccer related injury and how researchers can reduce the incidence of such injuries.[13, 18, 21-35]

Sports related injuries are common. There are approximately 4.5 million sports related injuries in the United States annually occurring between the ages of 5-

24, with two-thirds of the injuries originating in the lower extremity.[36] There have been numerous research studies published elucidating the incidence and prevalence of soccer related injury in both males and females; recreational, amateur and professional players; and youth, high school, collegiate and adult players. [17, 21, 31, 37-39] A 2006 report generated by the US Consumer Product Safety Commission's injury surveillance database estimated that there were 186,544 soccer-related injuries. Approximately 80% of these injuries occurred in soccer players under the age of 24. [40, 41] In the National Collegiate Athletic Association (NCAA), soccer injuries have been shown to be interdependent on the level of play, player position, field type, timing of injury and gender. The injury rate (IR) in the NCAA is 18.8/1,000 athletic exposures (AE) in men's soccer games and 16.4 in women's soccer games.[10, 42] Women's soccer has highest IR for any sport in the NCAA and men's soccer is ranked as the third highest IR, ranking closely behind football and wrestling.[43] In the high school setting, the injury risk in this younger cohort is identical to what is reported in the collegiate setting: the IR for girl's soccer ranks first and boy's soccer ranks third. [44]. Injury prevention programs, however, have the inherent ability to statistically decrease the incidence of soccer related injury, the severity of injury, and the time loss associated with such injury.[32, 34, 45-47]

In the past two decades, many injury prevention efforts were focused solely on female athletes; particularly focused on anterior cruciate ligament (ACL) injury prevention.[24, 28, 34, 47-49]Those efforts were well targeted, since the incidence of ACL injury in female athletes exceeds that of male counterpart.[24, 50-52] Recent work has expanded their focus to include all injuries that occur during soccer participation, the injury mechanisms related to the male soccer player, and how injury prevention programs have effectively reduced the rate of all soccer related injury in the male cohort. [17, 27, 32, 45, 53-56]

Injury Prevention in Soccer

Soccer related injuries are a relatively common occurrence across gender, age and level of competition. The high prevalence of soccer related injury has been well documented in the literature. [57-66] The impact of sports related injury is complex and far-reaching; inflicting potential long-term physical, emotional and financial consequences for the athlete to contend with long after their athletic career has finished. The rate of injury in soccer depends on several factors: age, level of competition, position on the field, field type, timing of injury and gender.[55] Injuries incurred during soccer most commonly involve the lower extremity and most commonly occur in a game situation.[16, 67-69] In studies analyzing the injury rates of professional male soccer athletes, overall injury rate (IR) ranged from 6.2-13.2 injuries per 1000 Athletic Exposures (AE). The National Collegiate Athletic Association (NCAA) has long recognized the high rate of injury in men's and women's soccer. Men's game IR ranked third (18.8) and women's game IR ranked fourth overall (16.4), respectively, for all NCAA sports per 1000 athletic exposures (AE). When the data was stratified by gender, women's soccer had the highest game IR overall. The IR for practices was equally high, with women ranking fourth (5.2/1000 AE) and men ranking fifth (4.3/1000 AE) compared to 13 other NCAA collegiate sports.[43] Furthermore, the male IR is 4 times higher in games compared with practices [20] and women's collegiate IR is 3 times higher in games than in practices. Approximately 70% of game and practice injuries affected the lower extremities. [70] The shear magnitude of these injury rates, coupled with the increasing number of athletes participating in collegiate soccer, served as a meaningful impetus to actively intervene and attempt to reduce the current rate of injury, the severity of injury, and time loss associated with injury.

The earlier injury prevention programs primarily focused specifically on anterior cruciate ligament (ACL) injury reduction and prevention, namely in the female athlete, due to the high rate of injury in this specific cohort. [17, 29, 34, 49, 71] Most of these neuromuscular training programs included a variety of strengthening, plyometric and agility based drills that addressed the major deficits most commonly associated with the female athlete that had sustained an ACL injury. [48, 52, 72] Several programs have been designed as dynamic warm-up programs in order to increase implementation fidelity and compliance, as well as to capitalize on the advantages associated with improved joint-position sense found as a component in well-designed neuromuscular training warm-up programs. [34, 71, 73] Despite the development and the evolution of the aforementioned programs, there is a continued and implicit need to address soccer related injury in totality and for an enhanced understanding of the most common mechanisms of injury in soccer. Recent studies have analyzed injury mechanisms in male and female soccer players to further delineate the specific kinetics and kinematics directly involved in the mechanism of injury.[68, 74] After analyzing videos of male and female athletes incurring a soccer related injury, the authors have begun to establish the high risk positioning most commonly associated with the sport, namely defensive play with the involved player at or near full hip and knee extension.[68, 74] The continued delineation of the risk factors associated with sports related injury will further the clinicians' ability to elucidate and refine a comprehensive intervention program to effectively decrease the injury rate in sport. Furthermore, the cohesive and consistent implementation of injury prevention and reduction protocols may be considered a very viable and cost-effective option to reducing the rate of soccer injury. [75] This knowledge can provide critical insight to help improve existing injury prevention protocols and secondary prevention strategies. Understanding the epidemiology and the mechanism of injury will allow researchers to refine and expound upon the current gold standard for injury prevention; thus decreasing the long-term deleterious sequelae commonly endured after incurring an injury. [76]

The Role of Compliance

The role of compliance in injury prevention protocols has been well documented in the literature. [77-79] Current research has demonstrated an inverse correlation of injury rate and time loss due to injury with the compliance of effective injury prevention protocols.[34, 79] The scientific medical community continues to struggle with consistency in implementation, program fidelity, and therapeutic compliance across all levels of competitive soccer play. The manner in which the program is delivered may impact the rate or program adoption. Studies have analyzed how different program delivery systems impact compliance, and furthermore, the rate of injury.[46] Nations such as the United States, Canada, and many regions of Asia and Africa, are confronted by a large geographic expanse when it comes to efficient and feasible medical delivery and public health messaging. The concept of using instructional DVD's, online streaming resources and smart phone applications may offer a cost-effective alternate delivery system for injury prevention protocols in the event that a skilled medical professional is unable to be present. [46]

It is critical to understand the rationale of why coaches, teams, players, and parents choose to implement a scientifically vetted injury prevention program, or not too. Even though intervention programs have been shown to successfully reduce the rate of injury in competitive sport, the potential public health benefit and impact will not be realized if such interventions are not utilized consistently. Therefore, encouraging coaching and player motivation toward implementing injury prevention methodology into their training repertoire could have important public health ramifications and positive socio-economic impacts on the aforementioned cohorts.

Team Performance and Compliance

Team performance has been closely linked to player health and availability. [80-84] Careful attention is paid to match scheduling, training loads, minutes played and overall exposure in order to mitigate risk to the individual athlete. Researchers in a variety of sports have demonstrated a significant association between injury rates and playing performance.[85-87] Including the analysis of team performance is an integral component in the effort to increase compliance rates. [88-90] Coaches, managers and athletes are often more concerned about individual or team performance outcomes as opposed to actual injury reduction. If researchers can draw a correlation between compliance to an injury prevention program and improved team performance measured in a higher number of wins and fewer losses, this concept may resonate with coaching staffs and ultimately increase overall compliance rates.

Conclusions

In conclusion, this proposed body of work will enhance the existing literature in the field of injury prevention. Analyzing the efficacy of the FIFA 11+ program in the male collegiate athlete will allow a broader extrapolation to a wider cohort of athletes. We will demonstrate that the fact that the FIFA 11+ program is a feasible neuromuscular training protocol that can effectively reduce the rate of non-contact ACL injury. We will provide evidence to support the notion that higher compliance to the training program will decrease injury rates more effectively and improve overall team performance. Furthermore, we will provide biomechanical evidence that details the favorable kinematic and kinetic changes that are initiated by virtue of implementing the program consistently. These changes will support the documented injury reduction rates. This information will be exceedingly useful to researchers and clinicians as we continue to improve and refine injury prevention and reduction efforts.

Specific Aims

The overall purpose of this body of work is to expound upon the existing literature and evaluate the efficacy of an injury prevention program (FIFA 11+) in a large scale randomized controlled trial involving sixty-one NCAA male collegiate soccer teams, identify how the FIFA 11+ program may effectively reduce the rate of ACL injury, identify how program compliance affects injury rate and overall soccer team performance, and to analyze the kinetic and kinematic biomechanical changes associated with the utilization of the FIFA 11+ over a competitive season in collegiate soccer players across Division I and II.

The specific aims of this project are to:

1. Determine the efficacy of the FIFA 11+ injury prevention program in Division I and Division II male collegiate soccer players.

    - Hypothesis 1.1: Athletes utilizing the FIFA 11+ program as their dynamic warm-up will demonstrate lower game and practice injury rates compared to their age and skill matched control counterparts.

    - Hypothesis 1.2: Athletes utilizing the FIFA 11+ program as their dynamic warm-up will demonstrate decreased severity of injury, translating to a decrease in time loss secondary to injury, compared to the control group.

    - Hypothesis 1.3: Athletes in the intervention group utilizing the FIFA 11+ program will demonstrate a decrease in injury rate (IR) on the day of actual utilization compared to days that the program is not utilized.

    - Hypothesis 1.4: Athletes utilizing the FIFA 11+ program will demonstrate a lower rate of ACL injuries compared to their age and skill matched control counterparts.

2. Determine how variation in compliance impacts the ability of an injury prevention program to impart its' benefit onto the athletes and the overall success of a soccer campaign.

    - Hypothesis 2.1: Teams with higher compliance to the FIFA 11+ program will demonstrate lower injury rates throughout the course of a competitive season.

    - Hypothesis 2.2: Teams with higher compliance to the FIFA 11+ program will experience decreased time loss due to injury than teams with moderate or lower compliance to the protocol.

    - Hypothesis 2.3: Teams with higher compliance to the FIFA 11+ program will demonstrate an improvement in their overall win-loss record compared to the control team and to the teams with low(er) compliance to the prevention program.

3. Quantify biomechanical differences between a baseline pre and post-season single leg squat and triple hop test assessment in collegiate soccer players

    - Hypothesis 3.1: Players participating in the FIFA 11+ dynamic warm-up will demonstrate favorable biomechanical changes in sagittal plane kinetics and kinematics during the single leg squat and triple hop test compared to the control group.

    - Hypotheses 3.2: Players participating in the FIFA 11+ dynamic warm-up will demonstrate favorable biomechanical changes in frontal plane kinetics and kinematics of hip and knee during the single leg squat and triple hop test compared to the control group.

Chapter 2

THE EFFICACY OF THE FIFA 11+ INJURY PREVENTION PROGRAM IN THE COLLEGIATE MALE SOCCER PLAYER

Introduction

Soccer is the most widely played sport among both men and women, with approximately 300 million registered players globally. [1, 2, 91] The growth of the sport in the United States has been unprecedented. It is currently the third most popularly played sport, with over 13 million Americans participating at the youth and adult levels. Major League Soccer (MLS) is currently embarking upon its' 20th season and has grown to 20 professional teams within the United States and in Canada since its' inception, with further expansion on the horizon.[19] In addition, there are approximately 412,000 high school male and 23,000 collegiate male soccer players participating in NCAA soccer in the United States.[8] This number of participants is increasing annually and imparts a multitude of positive effects with respect to emotional and physical wellness and health, and in influential in decreasing the onset of illness and systemic disease. However, the risks associated with soccer participation have been well documented.[11, 14, 15, 17, 18, 50, 92-96] In the last two decades, numerous attempts have been made to gain a fuller understanding about the mechanism of these injuries and how researchers can reduce the incidence of such injuries[16, 24, 25, 28, 97-100]

Soccer related injuries are not uncommon. There have been numerous research studies published elucidating the incidence and prevalence of soccer related injury in both males and females; recreational, amateur and professional players; and youth and adult players.[13, 39, 60, 101] Researchers have also focused on variations in injury rate occurring on artificial turf versus grass and during tournament play versus regular season play.[96, 102, 103] However, there is a growing body of evidence validating the notion that injury prevention programs have the inherent ability to decrease the incidence of soccer related injury and the time loss associated with such injury.[32, 34, 45-47, 79] In the past two decades, many injury prevention efforts were focused solely on female athletes; namely on ACL injury prevention.[24, 28, 49, 104, 105] Recent publications have focused on the injury mechanisms related to the male soccer player, but most of the injury prevention interventions have focused on women and girls.[27, 54, 55, 103, 106]

The rate of injury in soccer depends on several factors; age, level of competition, position on the field, environmental setting, location of injury, time of injury and gender. These injuries most commonly involve the lower extremities and typically consist of mild to moderate sprains, strains or contusions.[106, 107] In studies analyzing the injury rates of professional male soccer athletes, researchers have found an overall injury rate ranging from 6.2-13.2 injuries per 1000 AE.[19, 96, 102] In a collegiate analysis of male soccer injury, the game injury rate was 21.92/1000 AE in Division I and 20.43 in Division II. The practice injury rate was 4.60/1000 AE in Division I and 4.40 in Division II.[42]

The Fédération Internationale de Football Association (FIFA) and its Medical Assessment and Research Centre (F-MARC) developed injury prevention programs, such as the "11" and the "FIFA 11+" in an effort to improve strength and reduce the incidence of all injuries incurred as a result of soccer participation.[34, 47, 108] These programs have been evaluated in both genders, in recreational, amateur and semi-professional soccer, and, additionally, in court based sports (basketball, Longo et. al) [32, 34, 45, 47, 109, 110] To address the compliance issue and perhaps, some of the inadequacies of the therapeutic exercises initially selected for the "11" protocol, an international group of researchers reconvened and restructured the "11" program and developed a dynamic warm-up program that addressed the major deficiencies that were deemed to be ubiquitous to the soccer athlete; renamed as the "FIFA 11+" program. The program effectively reduced soccer related injury in multiple studies and has been shown to optimally, from a physiological perspective, prepare the athlete for competition.[3, 31, 45, 49, 109] The program has also demonstrated the ability to improve muscular strength that may be deemed integral to injury prevention.[22, 111]

This aim of this research study was to describe the use of the FIFA 11+ program in competitive male soccer athletes in the collegiate setting. We hypothesized that the teams who participated in the FIFA 11+ intervention program would have a lower rate of injury and incur a reduction in time loss to injury in comparison to the control group.

Methods

A prospective cluster randomized controlled trial was conducted in Division I and Division II NCAA men's soccer teams. Every athletic director, head soccer coach and head athletic trainer from each institution with a men's college DI or DII soccer program (N=396) was contacted via a formal letter, an email that reiterated the written letter, and a direct phone call. The letter and email included a hyperlink for video clips that featured former and current prominent US Soccer players and a coach who discussed the nature and importance of prevention in the sport of soccer (http://vimeo.com/25708967 & http://vimeo.com/25708960). The inclusion criteria required that you are a current student athlete participating at a NCAA Division I or Division II member institution and that you have not participated in an injury prevention program in the past four competitive seasons. Sixty-five institutions consented to participate with the participants from each institution ranging in age from 18 to 25 years. Human ethics internal review board approval was obtained through Quorum IRB (Seattle, WA, USA). Prior to randomization, player consent was obtained and a documentation of coaching understanding was signed by each institution to ensure that there was a thorough understanding of the expectations of study participation. The randomization of each club was conducted utilizing a random number generator once every enrolled team had been identified. (Figure 1) Upon randomization of the enrolled institutions, the intervention group (IG) received an instructional FIFA 11+ DVD, prevention manual and explanatory placards describing the FIFA 11+ intervention at length (www.f-marc.com/11plus). (Appendix A)

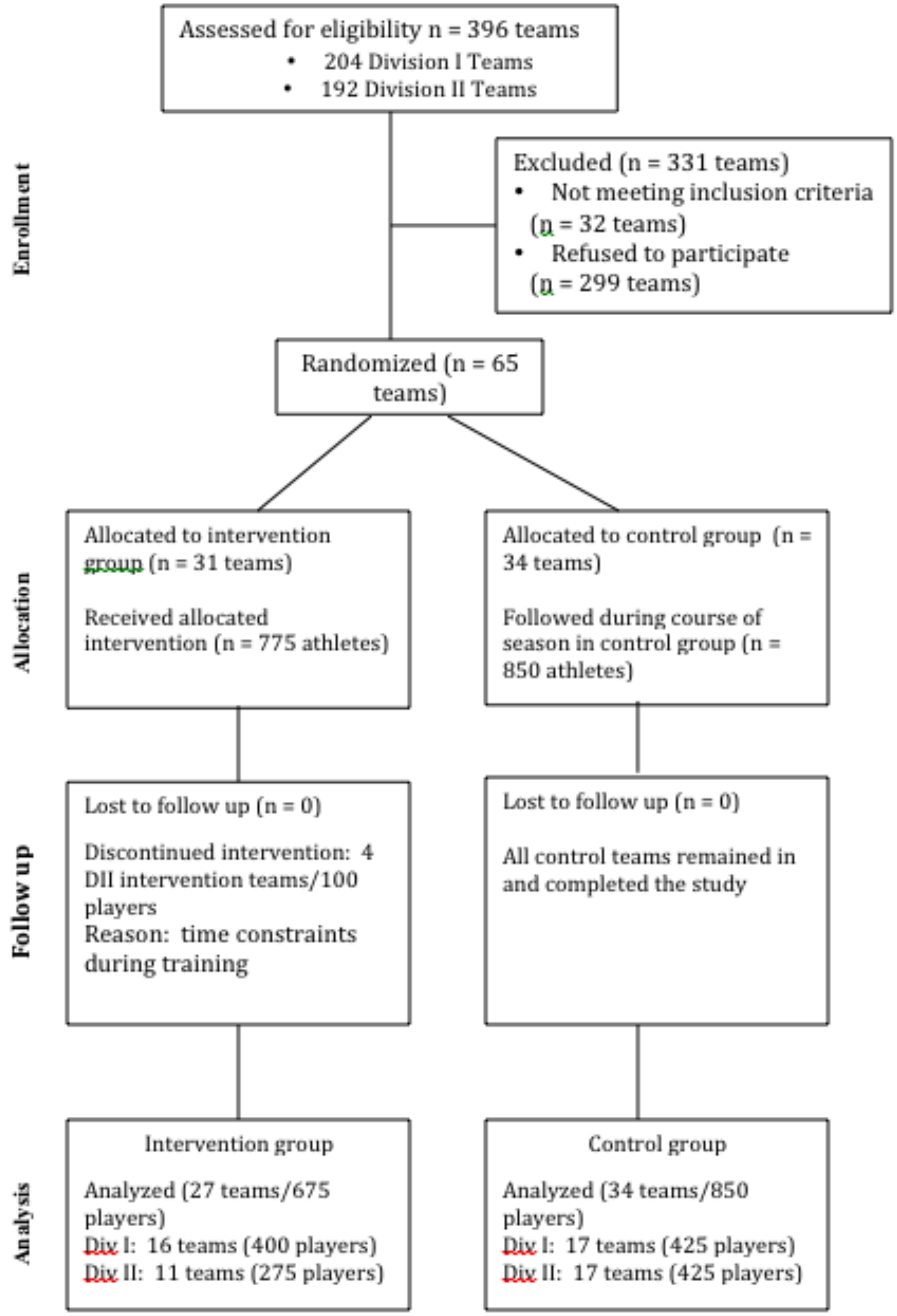

Figure 1 Description of NCAA Team Randomization and Study Flow

An internet-based injury surveillance system was utilized (HealtheAthleteTM, Overland Park, Kansas) by every enrolled institution. Every athletic exposure, injury incurred, utilization of the FIFA 11+ program and compliance data was entered weekly by the team's certified athletic trainer and verified by the research staff. Sixty-one institutions completed the study during the Fall, 2012 season (August – December): 34 control institutions (N=850 athletes) and 27 intervention (N=675 athletes) institutions. (Figure 1) Demographic information including age, position played, and leg dominance was also collected. Upon the completion of the season, the injury data entry was confirmed by each athletic trainer and batched with their individual institution's data collection system for accuracy and thoroughness. During the course of the season, the compliance of the program was monitored by the research team weekly.

Intervention Program

The FIFA 11+ is an injury prevention program designed as an alternative warm-up program to address lower extremity injury incurred in the sport of soccer for athletes over the age of 14.[10] It is a twenty-minute program that is utilized on the field without any addition or onerous equipment necessary. It consists of 15 exercises divided into three separate components: running exercises (8 minutes) that encompass cutting, change of direction, decelerating and proper landing techniques, strength, plyometric and balance exercises (10 minutes) that focus on core strength, eccentric control and proprioception, and lastly, running exercise (2 minutes) to conclude the warm-up and prepare the athlete for athletic participation. There are three levels for each specific exercise (level 1, level 2, level 3) that increase the difficult for each respective exercise. This allows for both individual and team progression throughout the course of the competitive season (http://f-marc.com/11plus/home/).[26] (Appendix A) In this specific study, the FIFA 11+ program served as the intervention program over the course of one competitive collegiate soccer season. The warm-up was suggested to be utilized three times per week for the duration of the season.

Exposure, injury data entry and compliance

Upon consenting to participate in the study, each team roster was entered into the HealtheAthlete™ Injury Surveillance System (Overland Park, Kansas). The surveillance system was a web-based system that was a data secured, HIPAA compliant site that utilized VeriSign secure second factor logon feature. The injury and exposure data for each player on the roster was entered by the team's certified athletic trainer (ATC). All injuries were entered weekly by the ATC and were verified and crosshatched with their institutional injury surveillance system at the end of the competitive season. The ATC indicated on which days from the FIFA 11+ program was completed and which athletes participated in the training, respectively. The NCAA calendar was entered for each respective club to delineate the soccer schedule, which commenced in August, 2012 and ended in December, 2012 (contingent upon the success of the institution in the NCAA playoff tournament). No unique identifiers that would reveal the identity of the team or the athlete were visible to any of the research staff.

The operational definition for athletic exposure (AE) was defined as participation in any team practice or game during preseason or in-season. The authors decided to use athletic exposure over hours of playing time secondary to the NCAA substitution rules.[46] An injury was defined as any physical complaint sustained by a player that results from a football match or football training, irrespective of the need for medical attention or time-loss from football. A time-loss injury was defined as a player receiving medical attention is referred to as a ‘‘medical-attention’’ injury and an injury that results in a player being unable to take a full part in future football training or match play as a ‘‘time-loss’’ injury.[38]

Statistical methods and Data Analysis

All statistical analyses were conducted utilizing SPSS for Windows version 22. Descriptive and inferential tests were used to compare the CG and IG, including t-tests, χ^2 tests, and Generalized Linear Regression Models (GLM), with Logit link function and Poisson distribution for count data. Two GLMs were used to test if there was a significant difference in the number of days missed due to injury between the IG and CG and secondly, to test if the number of days missed due to injury was different for athletes who had used the FIFA 11+ on day of injury. (Biostatistics Core Facility University of Delaware, Newark, DE) All injuries that occurred throughout the Fall, 2012 soccer season were analyzed by location, duration and turf type (grass versus artificial turf).

Results

The control group (CG) consisted of 850 athletes (56%) in 34 teams (56%) who had 44,212 (56%) athletic exposures (AE) (Games: 13,624 and Practices: 30,588). The intervention group (IG) consisted of 675 athletes (44%) in 27 teams (44%) who had 35,226 (44%) AE (Games: 10,935 and Practices: 24,391). The average utilization of the FIFA 11+ in the IG was 32.78±12.13 doses over the course of the season. There was no significant difference between the age of the injured athletes (20.38±1.64 IG and 20.68±1.47 CG), nor was there a difference in the number of injured athletes based on player position (Table 1).

There was a significantly higher proportion of athletes injured in the CG, 665 (70%, Incidence Rate (IR) = 15.04/1000 AEs), than in the IG, 285 (30%, IR= 8.09/1000 AEs), χ^2 (1)=207.74, p < .001, Φ=.369. The CG had a significantly higher average number of injuries per team (*M*=19.56, *SD*=11.01) than the IG (*M* =10.56, *SD* =3.64), t (59) = 4.07. p < .001, Cohen's d = 1.16 (see Table 1).

	Control	Intervention
Teams	34	27
Players (N)	850 Division I: 425 (17 teams) Division II: 425 (17 teams)	675 Division I: 400 (16 teams) Division II: 275 (11 teams)
Age (mean, SD, years)	20.68 y, SD ± 1.46	20.40 y, SD ± 1.66
# Athletic exposures (AE)	Total: 44, 212 AE's Game: 13,624 AE's Practice: 30,588 AE's	Total: 35,226 AE's Game: 10,935 AE's Practice: 24,291 AE's
Injuries incurred (#/%) by position	Defender: 204/30.67% Forward: 132/19.85% Midfielder: 256/38.50% Goalkeeper: 73/10.98%	Defender: 92/32.28% Forward: 67/23.51% Midfielder: 101/35.44% Goalkeeper: 25/8.77%
Total # of injuries/% of total injuries **Mean, Std. Deviation**	Total: 665 M = 19.56, SD ±11.11* Division I: 355/54.2% M=22.19, SD±12.0 Division II: 310/46.6% M=17.22, SD±10.03	Total: 285 M = 10.56, SD ± 3.64* Division I: 198/69.5% M=9.9, SD ± 3.11 Division II: 87/30.5% M=12.43, SD ± 4.61
Total # Injuries/% ***Game vs. Practice***	**Game:** 392/58.9%; M=11.53, SD±5.84* **Practice:** 273/41.1%; M=8.03±6.24*	**Game:** 185/64.9%; M=6.85,SD ±3.17* **Practice:** 100/35.1%; M=3.70±2.13*
Incidence Rate (IR)	Total: 15.04/1,000 AE*	Total: 8.09/1,000 AE*

per 1000 Athletic exposures (AE) ***IR Game vs. Practice***	Game: 28.77/1,000 AE* Practice: 8.93/1,000 AE*	Game: 16.92/1,000 AE* Practice: 4.01/1,000 AE*
Days lost to injury (days) **Mean, Std Deviation**	Total: 8790 days M =13.02*, SE = 1.09	Total: 2764 days M = 9.31*, SE = 0.96
Time loss (days / % of injuries)		
No time loss	201/30.2%	104/36.5%
1-3 days lost	126/18.9%	31/10.9%
4-7 days lost	94/14.1%	43/15.1%
8-29 days lost	164/24.7%	81/28.4
30 and more days lost	80/12.0%	26/9.1%

Table 1 Control versus intervention: injury rates, means, std. deviations and days lost to injury

When the data was stratified by division of play (I or II) and for game and practice, the DI CG had a significantly higher number of game injuries (N=200, 56.3%, M=12.5, SD±5.51, IR=29.36) compared to IG DI game injuries (N=122, 64.1%, M=6.13, SD±2.47, IR=18.83, $p = 0.000038$) (Table 2). There was a similar outcome for DI and DII practices. There was a significant difference between the DI CG practice injuries (N=155, 43.7%, M=9.69, SD±7.6, IR=10.13) compared DI IG practice sessions (N=76, 35.9%, M=3.44, SD±1.86, IR=5.146, $p = 0.0027$). There was also a significant difference between the DII CG practice injuries (N=118, 38%, M=6.56, SD±4.42, IR = 7.72) compared to the DII IG practice injuries (N=24, 27.9%, M=3.14, SD±1.57, IR=2.36, $p=0.0457$). There was no significant difference found between the CT and IG in DII game injuries. (see Table 2)

			Control	Intervention	p value
Division I	Games	Total Injuries	200	122	
		% DI Injuries	56.30%	64.10%	
		Mean/SD	12.5 ± 5.51	6.13±2.47	
		IR	29.36	18.83	0.000038
	Practices	Total Injuries	155	76	
		% DI Injuries	43.70%	35.90%	
		Mean/SD	9.69±7.60	3.44±1.86	
		IR	10.13	5.146	0.0027
Division II	Games	Total Injuries	192	63	
		% DII Injuries	62%	72.41%	
		Mean/SD	6.14±0.376	9.29±3.90	
		IR	28.19	14.14	0.3762
	Practices	Total Injuries	118	24	
		% DI Injuries	38%	27.59%	
		Mean/SD	6.56±4.42	3.14±1.57	
		IR	7.72	2.36	0.0457

Table 2 Table depicting all injuries collected during the season and stratified by division of play and game versus practice: number, % of total injury, mean, standard deviation, IR and p values are reported.

The injury rates were significantly lower in the IG when stratified for type of injury as well (Table 3). The highest number of reported injuries in both the CG (were ankle injuries. The CG reported 115 ankle injuries, accounting for 17.3% of total CG injuries (IR=2.601) compared to 59 ankle injuries in the IG (% of total=20.7%, IR =0.675, RR=0.646 (0.48 to 0.87)). Knee related injuries were the second highest reported injury for both groups. The CG reported 102 total knee injuries (15.3%, IR=2.307) compared to 34 in the IG (11.9% total injuries, IR=0.965, RR=0.4198 (0.29 to 0.61)).

Table 3 Table depicting all injuries collected during the season and stratified by body area: number, IR, % total injury, rate ratio (95% confidence interval and number needed to treat – NNT).

Table 3: Total Injury Counts

	Control Group (n=850)			Intervention group (n=675)				
Area	CON Injuries	IR CON /1000 AE's	% total injury CON	IG Injuries	IR IG /1000 AE's	% total injury IG	Rate ratio (95% CI)	NNT
Ankle	115	2.601	17.293	59	1.675	20.702	0.646 (0.48 to 0.87)	21
Knee	102	2.307	15.338	34	0.965	11.930	.4198 (0.29 to 0.61)	14
Head	61	1.380	9.173	31	0.880	10.877	0.64 (1.42 to 0.97)	39
Ham-string	55	1.244	8.271	16	0.454	5.614	0.366 (0.21 to 0.63)	24
Foot	49	1.108	7.368	22	0.625	7.719	0.565 (0.35 to .093)	40
Groin	48	1.086	7.218	23	0.653	8.070	0.603 (0.37 to 0.98)	45
Hip	45	1.018	6.767	16	0.454	5.614	0.448 (0.26 to 0.79)	34
Quad	44	0.995	6.617	25	0.710	8.772	0.716 (0.44 to 1.16	68
Leg	39	0.882	5.865	25	0.710	8.772	.087 (0.49 to 1.32)	113
Shoulder	30	0.679	4.511	6	0.170	2.105	0.251 (0.11 to 0.06)	38
Spine	30	0.679	4.511	9	0.255	3.158	0.378 (0.18 to 0.79)	46
Hand	10	0.226	1.504	6	0.170	2.105	0.756 (0.28 to 2.07)	348
Torso	10	0.226	1.504	9	0.255	3.158	1.13 (0.46 to 2.77)	638
Elbow	9	0.204	1.353	2	0.057	0.702	0.251 (0.05 to 1.15)	114
Wrist	7	0.158	1.053	0	0.000	0.000	0.008 (0.001 to 0.017)	121
Neck	6	0.136	0.902	1	0.028	0.351	0.209 (0.025 to 1.73)	179
Chest	3	0.068	0.451	0	0.000	0.000	0.004 (0.0026 to 0.01)	283
Arm	1	0.023	0.150	1	0.028	0.351	1.26 (1.179 to 20.1)	3279
Forearm	1	0.023	0.150	0	0.000	0.000	1.25 (0.078 to 20.1)	3279
Totals:	665		100.000	285		100.000		

A Poisson regression was used to compare the total number of days missed between groups, IG versus CG, and for field types, grass versus turf because number of days missed is a count variable and normality was violated for both groups. The overall model was significant, LR χ^2 (2) =263.06, $p < .001$. There was a significantly higher number of days missed in the CG (*M* =13.02, *SD* = 26.82) than in the IG (*M*=9.31, *SD* = 14.83), Wald χ^2 (2)= 7.35, *b* = .34, *SE* = .12 *p* = .007, for each day missed in the IG 1.4 days were missed in the CG, OR = 1.40. Total days missed secondary to injury was 8776 in the CG compared to 2824 in the IG. There was no difference in either group for days missed based on field type, Wald χ^2 (2)= .91, *b* = .13, *SE* = .14, *OR* = 1.15, *p* = .341.

A second Poisson regression was used for those who were in the IG to compare the number of days missed if the injury occurred on a day where the intervention was used. The model was significant, LR χ^2 (2) =6.02, $p < .049$. There was a significantly higher number of days missed when the intervention was not used on day of injury (*M* =10.65, *SD* = 15.35) than when it was used (*M*=6.56, *SD* = 10.44), Wald χ^2(1)= 4.26, *b* = 4.08, *SE* = 1.98, *p* = .039. There was no difference on the number of days missed in the intervention group based on field type, Wald χ^2 (1)= .90, *b* = 2.10, *SE* = 2.21, *p* = .343.

Discussion

The FIFA 11+ was designed as a concise and comprehensive warm-up program to address the lower extremity injuries associated with the sport of soccer. In this study, the principal finding in this RCT reflected that by virtue of utilizing the FIFA 11+, there was an overall reduction of injury in the IG by 46.1% and a relative risk reduction of 1.9; demonstrating the decreased likelihood of an athlete in the IG group being injured. This is consistent with other studies that have elucidated the efficacy of the 11+ in similar populations. [32, 34, 45, 47] There was a statistically significant reduction in injury with respect to individual injury (CG IR =15.04 vs. IG IR 8.09/1000 AE, p<0.001) and with relationship to injuries per team (M CG = 19.56 vs. M IG 10.56, p<0.001). This reinforces the findings of other authors elucidating the protective benefit of the FIFA 11+ program for both men and women.

When the data was analyzed for division of play (Division I or II), there were significant reductions in the IG for DI game (CG IR= 29.36, IG IR=18.83, p=0.000038) and practice injuries (CG IR = 10.13, IG 5.146, p=0.0027) and DII practice injuries. There was no statistical difference in DII game injuries, but a trend for injury reduction in this cohort was apparent (p=0..3762). (Table 2) This injury distribution with respect to level of play and game versus practice injury are consistent with the existing literature.

The FIFA 11+ program was first tested in female soccer players in Norway. Soligard et al. completed a cluster, randomized controlled trial in 125 female youth soccer clubs in Norway (aged 13-17): 65 teams in the intervention group (N = 1055) (IG) and 60 teams in the control group (N = 837) (CG) followed the protocol for one season (eight months). During the season, 264 players had relevant injuries: 121 players in the IG and 143 in the CG (rate ratio 0.71, 95% CI 0.49–1.03). In the IG there was a significantly lower risk of injuries overall (0.68, 0.48–0.98), overuse injuries (0.47, 0.26–0.85), and severe injuries (0.55, 0.36–0.83). This indicates that a structured warm-up program can prevent injuries in young female soccer players.[34]

In a small cohort study conducted in men's collegiate soccer in the United States, Grooms et. al. (2013) utilized the FIFA 11+ intervention for one Division III soccer team (N = 41, 18-25 years). The first season served as the referent season (REF) and the second season served at the intervention assessment (IG). The injury rate in the REF was 8.1 injuries/1000 athletic exposures (AE) with 291 days lost and 2.2 injuries/1000 AE and 52 days lost in the IG season. The IG demonstrated reductions in the relative risk (RR) of lower extremity injury of 72% (RR = 0.28, 95% CI=0.09, 0.85) and time lost to lower extremity injury ($P < .01$). Despite the small sample size, there was a statistically significant reduction in injury rate and time loss to injury. The researchers noted excellent compliance and adherence to the program and benefited from direct oversight from an ATC at every exposure.[45]

A recent study investigated the efficacy of the FIFA 11+ in the male soccer cohort in African Lagos Junior League. Owoeye et al. (2014) utilized the FIFA 11+ intervention in a cluster randomized trial in 20 teams (N=416 players: Intervention (IG) = 212 players, Control (CON) = 204 players) over the course of 6 months. In total, 130 injuries were recorded affecting 104 (25%) of the 416 players. The FIFA 11+ program significantly reduced the overall rate of injury in the IG group by 41% [RR = 0.59 (95% CI: 0.40 - 0.86; $p = 0.006$)] and all lower extremity injuries by 48% [RR = 0.52 (95% CI: 0.34 - 0.82; $p = 0.004$)]. However, the rate of injury reduction based on secondary outcomes mostly did not reach the level of statistical significance.[32]

The FIFA 11+ program has been shown to be an efficient means of achieving optimal physiological readiness for sport.[112, 113] The program has also been shown to increase muscle activation in the abdominal rectus, gluteus medius and minimus immediately after completing the program, corroborating its' effect on core activation.[45] Daneshjoo, et. al. analyzed the effect of the FIFA 11+ on knee strength in male competitive soccer players. Quadriceps and hamstring strength was assessed after 24 sessions of utilizing the FIFA 11+ program in U-21 male soccer players (N=36), concentric quadriceps peak torque (PT) increased 27.7% at $300°\cdot s^{-1}$ in the dominant leg ($p<0.05$) and the concentric hamstring PT increased by 22%, 21.4% and 22.1% at 60°·s-1, $180°\cdot s^{-1}$ and $300°\cdot s^{-1}$, respectively in the dominant leg, and by 22.3%, and 15.7% at $60°\cdot s^{-1}$ and $180°\cdot s^{-1}$, in the non-dominant leg compared to the control group.[22]

The results in the aforementioned manuscripts suggest that consistent utilization of a neuromuscular training program, such as the FIFA 11+, may impart a protective benefit to the soccer athlete by achieving an optimal state of physiological preparedness for soccer competition and sufficient biomechanical training to offset the risk of injury associated with soccer participation.

Evolution of the Program

Steffen et. al. attempted to reduce the incidence of ACL injury by using a set of exercises known as "The 11." It was a cluster-randomized controlled trial to test the efficacy of the "11" on injury risk in female soccer players (IA, 59 teams, n = 1,091) compared with a control group (CA, 54 teams, n = 1,001) [10]. A total of 396 players (20%) sustained 483 injuries. There was no difference in overall injury rate between the IA (3.6 injuries/1000 hr, (CI) 3.2–4.1) and CA (3.7, CI 3.2–4.1; RR = 1.0 (0.8–1.2); p = .94), nor was there a difference in the incidence rate for type of injury. The training program was utilized during 60% of the soccer training sessions in the first half of the season, but only 14 out of 58 intervention teams completed more than 20 prevention training sessions throughout the course of the season. The researchers noted no effect of the injury prevention program on the injury rate, perhaps, secondary to the exercises not being specific enough to address the biomechanical deficiencies present in this population. Furthermore, the low compliance rates amongst the intervention groups could negatively impact the prevention benefit.[53] However, a study analyzing the efficacy of the "11" in adult male amateur players (N = 23 teams, 11 Intervention, 223 players (IG) and 12 control teams, 233 players (CON) showed a significant difference in knee injury, but not in overall injury incidence (9.6 (8.4-11.0) per 1000 athletic hours for the IG and 9.7 (8.5-11.1) for the CON), despite having good compliance (73% team and 71% player).[47] "The 11" program was subsequently revamped into "The 11+" to address the inadequacies in the former programs' components.

Program Dissemination

The NCAA FIFA 11+ program was delivered without direct contact to the ATC at each respective institution due to the wide geographic expanse of the randomized groups. The researchers relied solely on video, DVD and printed materials to ensure proper implementation of the program with proper biomechanical technique. The fact that the ATC was the point person for FIFA 11+ delivery as well as injury collection is a strength of the study, as ATC's are highly qualified and well educated members of the multidisciplinary medical team. The subject of program delivery has been the source of debate in the literature.[24, 33, 34, 46, 47, 114] Steffen et. al. examined the impact of different delivery methods on compliance and injury rates in youth soccer. Teams that had supervision and had access to a coach focused workshop demonstrated greater adherence to the FIFA 11+ program compared to the control teams, who only had access to the educational website (85.6% and 81.3% respectively, control 73.5%). Players with high adherence to the FIFA 11+ program had a 57% lower injury risk, but this was not statistically significant. This research demonstrates that despite financial and geographic limitations associated with the multicultural and global appeal of the sport of soccer, the factor that remains critical to optimal injury prevention outcomes in imploring the coaching and training staff to regularly utilize such programs on a weekly basis.

Another factor to consider with implementation is the timing of the intervention during the course of training. The PEP program and the FIFA 11+, amongst others, have been designed as dynamic warm-up programs to be utilized prior to training.[28, 34, 49] The rationale behind this method of delivery is to increase compliance, as warm-ups are consistently utilized in the sport of soccer, and to neuromuscularly prepare the athlete for training in a non-fatigued state. When a neuromuscular training program is delivered, it should be completed with proper biomechanical technique. If the exercises are completed in a fatigued state, or with poor or inconsistent biomechanical technique, a pathokinematic motor pattern may be neuromuscularly reinforced. A study that utilized an injury prevention program post-training, albeit in a fatigued state, and devoid of a strength element, was largely unsuccessful in reducing the rate of ACL injury across three sports.[33]

Limitations

There are several factors to consider with respect to the methodological limitations of the study. The study was only completed over the course of one NCAA competitive season (August – December). The average Division I and II teams have 18/18 games and 51/52 practices respectively, throughout the course of the season.[115] Due to the truncated nature of the collegiate season, it is often challenging to impart the full neuromuscular benefit of such a program secondary to the short duration of the season compared to domestic professional and European leagues (9 – 10 month season). In addition, the training for the study was accomplished remotely via a website (f-marc.com/11plus), an educational video clip (Vimeo™), an instructional DVD, manual and pdf poster detailing the elements and the progression of the FIFA 11+. There was no direct contact or training with each individual institution or the team ATC due to the wide geographical expanse of the study population. However, the ATC was responsible for initiating each session at their respective institution and for entering the injury data in a medical database. The certified ATC served as a highly qualified medical professional that vastly improved the quality of the data entered into the HealtheAthlete™ secured system.[19] In a recent study, various FIFA 11+ implementation strategies were investigated in a cluster randomized controlled trial. The study compared (1) unsupervised website directed FIFA 11+ implementation to a comprehensive coach-focused workshop (2) with and (3) without regular supervision by a physical therapist. The researchers found that teams in the comprehensive and regular interventions demonstrated greater compliance, but was not statistically significant. Players with higher compliance to the program showed lower injury rates, statistically significant either. [79] However, this may speak to the overall effectiveness and generalizability of the program. In this current study, we found a statistically significant difference between compliance groups in relationship to injury rate. Even in the lowest compliance (LC) IG teams (n-4, range 10-19 doses), those athletes demonstrated an injury rate significantly lower than the control teams (IR 10.353±2.21 LC, 8.545±2.46 MC, 6.39±2.71 HC vs. 15.04±11.01 CON, $p=0.034$). In continents with extensive geographic expanse, such as those in North and South America, Africa and Australia, researchers may often depend on electronic dissemination of medical information and program implementation. Although the authors contend that direct contact with the coaches and players is optimal, electronic educational dissemination has been shown to be effective and cost-efficient. In spite of the anonymous delivery system utilized in this study, the program was initiated during the preseason portion of the season and continued throughout the duration of the season with significant reductions in injury and time loss due to injury. The authors contend, from a public health perspective, that the ease, the generalizability of the program and the ability to deliver and disseminate the injury prevention message meaningfully and effectively over a vast geographic area are strengths of the program.

Future Directions

There have been several research studies that have illuminated the protective benefit of utilizing the FIFA 11+ prevention program as a viable alternative to an existing warm-up protocol. There have been notable reductions in injury rates both in male and in female soccer players and the time loss due to injury had been significantly reduced by virtue of utilizing the FIFA 11+ program. In order to fully understand the biomechanical changes imparted by the FIFA 11+ through the kinematic chain, a thorough pre/post utilization biomechanical motion analysis amongst men and women in various age groups and levels of competition would be warranted, and is being conducted at the present time.

Conclusions

The FIFA 11+ was shown to reduce injury rates and time loss due to injury in the competitive male collegiate soccer player in a statistically significant manner. The more consistently the program was utilized, the greater the injury prevention benefit was imparted onto the athlete. The benefits of sport participation are numerous, and far outweigh the risks associated with such. However, the likelihood of incurring an injury by virtue of participating in soccer should not be underestimated. As clinicians, it is integral to our collective ethos to recognize the risks associated with sport and to profess the merits of the prevention protocols that have presented in the peer reviewed literature. This information may successfully reduce the incidence of sport related injuries in a meaningful way. As researchers, we will continue to set our sights higher in order to improve the quality and efficacy of the prevention programs available to the athletic community, respectively. We recognize and embrace the need for program compliance and further randomized controlled trials to elucidate the epidemiology, etiology, mechanism of injury(s) and the ultimate reduction and prevention of sports related injury.

Chapter 3

DOES THE FIFA 11+ INJURY PREVENTION PROGRAM REDUCE THE INCIDENCE OF ACL INJURY IN MALE SOCCER PLAYERS?

Introduction

Soccer-related injuries are a relatively common occurrence across sex, age, and level of competition. The high prevalence of soccer-related injury has been well documented [57-66]. Injuries incurred during soccer most commonly involve the lower extremity and most commonly occur in a game situation [16, 67-69]. The National Collegiate Athletic Association (NCAA) has reported that the game-related injury rate in men's and women's soccer games ranked third and fourth for all NCAA sports, respectively [42, 92]. Anterior cruciate ligament (ACL) injuries continue to consistently negatively impact recreational, competitive, and professional athletes globally. There are approximately 200,000 ACL injuries that occur in the United States annually making it the most commonly injured ligament in the knee [116, 117]. The NCAA's Injury Surveillance System (ISS and DATALYS) reported that the overall ACL injury rates were 1.45 per 10,000 athletic exposures for female athletes and 0.60 per 10,000 athletic exposures for male athletes [118]. Gilchrist et al. [24] noted that 31% of Division I soccer athletes polled had a history of knee injury and 14% had a history of ACL injury. The documented increase in incidence and the increased risk associated with prior knee injury initiate an obvious concern for the health and integrity of the articular cartilage of the knee in this young athletic cohort longitudinally [119-123].

For the last three decades, there has been a variety of effective ACL injury prevention programs developed, namely for high-risk sports [14, 22, 24, 29, 30, 34, 49, 71, 77]. Many of these programs have focused specifically on female athletes [24, 29, 34, 47, 71, 124] and have included a variety of strengthening, plyometric, and agility-based drills that addressed the major deficits most commonly associated with ACL injury [48, 52, 72]. Several programs have been designed as dynamic warm-up programs to increase program utilization and compliance and to capitalize on the biomechanical advantages associated with improved joint position sense [34, 71, 73]. Despite the development and the evolution of the aforementioned programs, there is a continued and implicit need to address soccer-related injury in totality. The FIFA 11+ injury prevention program was designed to address all soccer-related injuries not only specific to the knee or to the ACL [34]. It is a dynamic on-the-field warm-up that is time-efficient and requires no additional equipment. The efficacy of the program has been documented and decreases in overall injury rate have been shown in both male and female soccer players [32, 34, 45, 77]. However, prior studies did not specifically analyze the ability of the FIFA 11+ prevention program to reduce the number of ACL injuries in male soccer players.

The purpose of this study was to examine if the FIFA 11+ injury prevention program can (1) reduce the overall number of ACL injuries in men who play competitive college soccer and whether any potential reduction in rate of ACL injuries differed based on (2) game versus practice setting; (3) player position; (4) level of play (Division I or II); or (5) field type.

Methods

As previously reported in an earlier publication, a prospective cluster randomized controlled trial was conducted in Division I and Division II NCAA men's soccer teams in the Fall 2012 season [77]. Every NCAA member institution with a men's Division I or Division II soccer program (N = 396) was contacted through a formal letter, email, and a direct phone call. The correspondence included a hyperlink for a video that featured former and current prominent US soccer players and a coach who discussed the nature and importance of prevention in the sport of soccer (http://vimeo.com/25708967 and http://vimeo.com/25708960). Of the 396 eligible teams, 299 met the inclusion criteria. Sixty-five institutions consented to participate with the male participants from each institution ranging in age from 18 to 25 years. The additional institutions opted out of the study noting time restrictions, no current issues with injuries in their team, not enough coaching staff to implement the program, not wanting to implement the program in the competitive fall season, or lack of interest. Human ethics internal review board approval was obtained through the Quorum institutional review board (Seattle, WA, USA).

The inclusion criteria stipulated that each subject was a male college soccer player between the ages of 18 and 25 years in good academic standing and was medically cleared to participate in the 2012 season. The teams confirmed that they had not participated in an injury prevention program in the past 4 academic years to avoid subject contamination. Before simple computer-generated team randomization, individual player informed consent was obtained and a documentation of coaching understanding was signed by each institution to ensure robust comprehension of the expectations of study participation.

On computer-generated randomization of the enrolled institutions, the intervention group received an instructional FIFA 11+ DVD, prevention manual, and explanatory placards describing the FIFA 11+ intervention (www.f-marc.com/11plus). The FIFA 11+ is a 15- to 20-minute on-the-field dynamic warm-up program used before games and training performed two to three times a week throughout the entire season. It includes strength, agility, proprioceptive, and plyometric exercises and was designed to reduce injuries most commonly identified in soccer players.

A secure Internet-based injury surveillance system was utilized (HealtheAthlete; Cerner Corporation, Overland Park, KS, USA) by every enrolled institution (control group and intervention group). Every athletic exposure, injury incurred (including ACL injury), mechanism of injury, and date of return to play were entered weekly by the team's certified athletic trainer The environmental conditions of the ACL injury were also considered with respect to field type: grass versus artificial turf. Sixty-five institutions were randomized using a simple computer-generated randomization and 61 completed the study during the Fall 2012 season (August to December): 34 control institutions (N = 850 athletes; 17 Division I teams [425 players] and 17 Division II teams [425 players]) and 27 intervention institutions (N = 675 athletes; 16 Division I teams [400 players] and 11 Division II teams [275 players]) (Fig. 1). Demographic information including age, position played, and leg dominance was also collected. During the course of the season, the research staff monitored the data entry for each institution. In the event that no logon to the injury surveillance system was detected and no data were uploaded into the system for 14 days, a computer-generated email was dispersed and a research staff member followed up immediately. On the completion of the season, the data entry was confirmed by each certified athletic trainer and the accuracy and completeness with their individual institution's internal data collection system were established. As a result of the loss of four intervention teams to followup, a per-protocol analysis of the data was completed.

Statistical Analysis

All statistical analyses were conducted utilizing IBM SPSS Statistics Editor for MAC Version 24 (IBM Corporation, Armonk, NY, USA). Descriptive and inferential tests were used to compare the control group and intervention group, including frequency counts, t-tests, chi square tests, factorial analysis of variance, and logistic regression tests (Biostatistics Core Facility University of Delaware, Newark, DE, USA). Injury rates were calculated based on athletic exposures and are expressed as a rate per 1000 athletic exposures.

Results

There were 1305 overall team exposures to the FIFA 11+ in the intervention group (405 games and 900 training sessions) over the course of the season with an average of 2.19 FIFA 11+ utilizations over the course of the season per week. The control group consisted of 850 athletes (34 teams [56%]) who had 44,212 adverse events (games: 13,624 and practices: 30,588). The intervention group consisted of 675 athletes (27 teams; 44%) who had 35,226 adverse events (games: 10,935 and practices: 24,291) [77]. There was no difference between the ages of the athletes at the time of ACL injury (control group: 20.68 ± 1.46 years versus intervention group: 20.40 ± 1.66 years, range, 20.24-21.81, $p = 0.914$) (Table 4). The risk of ACL injury was lower in the teams that used FIFA 11+ than in those that did not (1.1% [three of 19] versus 2.4% [16 of 19]; relative risk [RR], 0.24; 95% confidence interval [CI], 0.07-0.81; p = 0.021). When identifying the mechanism of ACL injury, there was a higher injury rate in the control group compared with the intervention group for both contact and noncontact mechanisms. For contact ACL injuries, there were fewer injuries in the athletes who used the FIFA 11+ compared with those who did not (0.35% [one of seven] versus 0.90% [six of seven]; RR, 0.21; 95% CI, 0.03-1.74; p = 0.148). For noncontact mechanisms, there were fewer ACL injuries in the athletes who utilized the FIFA 11+ compared with those who did not (0.70% [two of 12] versus 1.5% [10 of 12]; RR, 0.25; 95% CI, 0.06-1.15; p = 0.049), representing a 75% decrease in noncontact ACL injury (Table 5).

<table>
<tr><th></th><th>Control</th><th>Intervention</th><th>Range</th><th>P value</th></tr>
<tr><td>Players (N) /Teams</td><td>850 / 34 teams
Division I: 425 (17 teams)
Division II: 425 (17 teams)</td><td>675 / 27 teams
Division I: 400 (16 teams)
Division II: 275 (11 teams)</td><td>-</td><td>-</td></tr>
<tr><td>Age (mean, SD, years)</td><td>20.68 y, SD ± 1.46</td><td>20.40 y, SD ± 1.66</td><td>20.24-21.81 y</td><td>0.914</td></tr>
<tr><td rowspan="3"># Athletic exposures (AE)</td><td>Total: 44, 212 AE’s</td><td>Total: 35,226 AE’s</td><td rowspan="3">-</td><td rowspan="3">-</td></tr>
<tr><td>Game: 13,624 AE’s</td><td>Game: 10,935 AE’s</td></tr>
<tr><td>Practice: 30,588 AE’s</td><td>Practice: 24,291 AE’s</td></tr>
</table>

Table 4 Control versus Intervention Group Demographic values

With the numbers available, there was no difference between the ACL injury rate within the FIFA 11+ and the control groups with respect to game and practice sessions (games--intervention: 1.055% [three of 15] versus control: 1.80% [12 of 15]; RR, 0.31; 95% CI, 0.09-1.11; p = 0.073 and practices—intervention: 0% [zero of four] versus control: 0.60% [four of four]; RR, 0.14; 95% CI, 0.01-2.59; p = 0.186) (Table 5).

	Control			**Intervention**			**RR (95% CI)**	**P value**
Total Injuries		**N / %**	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
	Total	665/ 100%	15.04	Total	285/ 100%	8.09	0.54 (0.49-0.59)	<0.001 *
	Game	392/ 58.9%	28.77	Game	185/ 64.9%	16.92	0.59 (0.52-0.68)	<0.001 *
	Practice	273/ 41.1%	8.93	Practice	100/ 35.1%	4.01	0.46 (0.38-0.57)	<0.001 *
Knee Injuries		**N / %**	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
	Total	102/ 15.3%	2.307	Total	34/ 11.9%	0.965	0.42 (0.29-0.61)	<0.001 *
Mechanism of ACL		**N / %**	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
	Total	16 / 2.41%	0.362	Total	3/ 1.05%	0.085	0.24 (0.07-0.81)	0.021*
	Contact	6/ 0.90%	0.135	Contact	1/ 0.35%	0.028	0.21 (0.03-1.74)	0.148
	Non-contact	10/ 1.50%	0.226	Non-contact	2/ 0.70%	0.057	0.25 (0.06-1.15)	0.049*
ACL's Game vs. Practice		**N / %**	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
	Game	12/ 1.80%	0.881	Game	3/ 1.05%	0.283	0.31 (0.09-1.11)	0.073
	Practice	4/ 0.60%	0.131	Practice	0	0.0	0.14 (0.01-2.59)	0.186
ACL's incurred (#/%) by position		**N / %**	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
	Defender	5/ 0.75%	0.339	Defender	1/ 0.35%	0.085	0.25 (0.03-2.15)	0.207
	Forward	5/ 0.75%	0.339	Forward	0	0	0.11 (0.01-2.07)	0.142
	Midfield	6/ 0.90%	0.54	Midfield	2/ 0.70%	0.227	0.42 (0.06-2.07)	0.142
	Goalie	0	0	Goalie	0	0	1.26 (0.03-63.36)	0.908

ACL's by Division		N / %	IR		N / %	IR	RR (95% CI)	P value
	Division I	7/ 1.05%	0.317	Division I	2/ 0.70%	0.114	0.30 (0.06-1.45)	0.136
	Division II	9/ 1.35%	0.407	Division II	1/ 0.35%	0.057	0.12 (0.02–0.93)	0.042*

Table 5 Control versus Intervention Group Comparison Chart, injury frequency, % of total injury, Injury rates, RR's with 95% confidence intervals and p-values. * denotes statistical significance with $p<0.05$.

With the numbers available, there were no differences associated with player position in either group; the incidence rates for midfielders, defenders, forwards, and goalkeepers in the intervention group were 0.227, 0.085, 0, and 0, whereas in the control group they were 0.54, 0.339, 0.339, and 0, respectively ($p = 0.207$) (Table 5).

We observed no differences with the numbers available between the ACL injury rates for Division I between groups (intervention: 0.70% [two of nine] versus control: 1.05% [seven of nine]; RR, 0.30; 95% CI, 0.06-1.45; $p = 0.136$). However, the risk of injury was lower in the intervention group than the control group in Division II athletes (intervention: 0.35% [one of 10] versus control: 1.35% [nine of 10]; RR, 0.12; 95% CI, 0.02-0.93; $p = 0.042$) (Table 5).

A two-way analysis of variance was conducted to compare the main effects of field type between the intervention group and control group on contact versus noncontact ACL injury. A logistic linear regression (Poisson) analysis was used to compare the number of ACL injuries between groups, intervention versus control, and for field types, grass versus turf, because number of ACL injuries is a count variable and normality was violated for both groups. There was no difference between the number of ACL injuries in the control versus the intervention group that occurred on grass versus turf (Wald chi square [1] = 0.473, b = 0.147, SE = 0.21, p = 0.492). There were no differences in the number of ACL injuries that occurred on grass between the teams that used the FIFA 11+ versus those that did not (control group: 1.05% [seven of nine] versus intervention group: 0.7% [two of nine]; RR, 0.36; 95% CI, 0.08-1.73; p = 0.201). However, there were more ACL injuries that occurred on artificial turf identified in the control group (1.35% [nine of 10]) versus the intervention group (0.35% [one of 10]; RR, 0.14; 95% CI, 0.02-1.10; p = 0.049; Table 6).

	Control			**Intervention**				
		N / %	**IR**		**N / %**	**IR**	**RR (95% CI)**	**P value**
Grass	Total	7/ 1.05%	0.158	Total	2/ 0.70%	0.057	0.36 (0.08-1.73)	0.201
	Non-contact	4/ 0.60%	0.090	Non-contact	2/ 0.70%	0.057	0.63 (0.12-3.48)	0.535
	Contact	3/ 0.45%	0.067	Contact	0	0.0	0.18 (0.01-3.58)	0.256
Turf	Turf Total	9/ 1.35%	0.204	Total	1/ 0.35%	0.035	0.14 (0.02-1.10)	0.049*
	Non-contact	6/ 0.90%	0.135	Non-contact	0	0.0	0.10 (0.01-1.72)	0.111
	Contact	3/ 0.45%	0.678	Contact	1/ 0.35%	0.35	0.18(0.01-3.48)	0.256
	Grass vs. Turf within CG: p = 0.719			Grass vs. Turf within IG: p=0.645				

Table 6 ACL injuries within the CG and IG by field type. The main effect for field type= F(1,18)=1.885, p=0.190 and the main effect for group = F(1,18)=0.131, p=0.723. The interaction effect was not significant F(1,18)=2.762, p=0.117. There was a significant difference between the CG (N=9, 1.35%, IR=0.407) and the IG (N=1, 0.35%, IR=0.057) for all ACL injuries that occurred on artificial turf (RR=0.14, 95% CI: 0.02 to 1.10, p=0.049).

Discussion

The FIFA 11+ was designed as an injury prevention program to address the most common soccer-related injuries. Unlike other injury prevention programs, the FIFA 11+ was not solely designed to decrease ACL injury [29, 30, 49, 71]. To our knowledge, the degree to which the program may effectively reduce the rate of ACL injury has not been examined [32, 34, 45, 47, 110]. This current study demonstrated that the FIFA 11+ program decreased the overall incidence rate of ACL injury by 77% in competitive collegiate male soccer players. There was no difference in ACL injury rates based on grass, games versus practices, in Division I athletes, or between player positions. However, there were fewer ACL injuries incurred in the Division II teams that utilized the FIFA 11+ compared with the control group (p = 0.042). In addition, there were more ACL injuries that occurred on artificial turf identified in the control group compared with the intervention group (p = 0.049).

The study's limitations include that four intervention teams were lost to followup and, therefore, an intent-to-treat analysis was not feasible. A per-protocol analysis was completed, which might inflate the reported benefit to the intervention group. This study only involved male soccer players. The rate of ACL injury in the male collegiate cohort is typically lower than the female injury rate [42, 92, 94]. However, the initial study of the FIFA 11+ was conducted using female soccer players, hence the decision to study the male population in this specific study [34]. In addition, the study has been lacking the statistical power to sufficiently compare ACL injury rates in the various subgroups despite the fact that the study encompassed 1525 athletes participating on 61 collegiate soccer teams. The occurrence of an ACL injury is a relatively rare event, and as a result of the prospective nature of the study design, we were limited in our analysis attributable to the low incidence rate of ACL injury during the data collection period. The analysis comparing ACL injury rates in games and practices, for Division I athletes and for grass injuries, showed no difference compared with the overall ACL injury rate and the overall injury rate reported and analyzed in an earlier publication [77]. Although steps were taken to mitigate team and player contamination to injury prevention program exposure, we were unable to fully account for program exposure that may have occurred in the high school and club soccer setting or in the event that the athlete transferred from another institution. This study demonstrated a decreased overall risk of ACL injury and noncontact ACL injury in men in the intervention group. The study did not reflect a decrease in contact ACL injury despite the fact that there was only one contact ACL injury reported in the intervention group compared with six in the control group. This may be explained by the fact that ACL injuries, despite their deleterious nature, are a relatively rare event in the sport of soccer, which is evident when analyzing the injury rate.

There was no difference in male ACL injury rate between groups with respect to player position. This is inconsistent with prior research that has demonstrated that defenders are at a higher risk for ACL injury than other player positions [68, 74]. A recent study highlighted the fact that, on video analysis of ACL injuries occurring in the sport of soccer, 73% of the injuries occurred while defending [68]. An additional study corroborated these findings suggesting that the most common playing situations preceding an ACL injury were defensive in nature 77% of the time: pressing followed by kicking and heading [74]. Ascertaining meaningful knowledge about the incidence of ACL injury based on the specific demands of player positioning may allow researchers to improve existing injury prevention and reduction methods [68, 74, 125].

We did not observe a difference in ACL injury rates between the FIFA 11+ and control teams in Division I soccer, but we did observe fewer ACL injuries among Division II teams that trained using FIFA 11+. Historically, game and practice injury rates have been shown to be lower in Division II and III compared with Division I [43]. This might be attributed to differences in the intensity of play and overall skill level across divisions. This may also represent an important finding on program delivery and overall program efficacy. The FIFA 11+ program was designed to be administered by coaches, parents, or athletes who may or may not have any medical expertise, clinical background, or a biomechanical knowledge base. Division II athletes traditionally are not privy to as many resources as Division I athletes and may not have direct oversight during program delivery by a certified athletic trainer or strength and conditioning coach for every game and training session. Therefore, the data suggest that this program can be effectively implemented without demanding the presence of a licensed medical professional. This has important implications from a public health perspective with respect to cost-effectiveness and the ease of program implementation [46, 108].

Although the overall risk of injury was not greater on turf than on grass, the risk of injury on turf was lower in the group that used FIFA 11+ than the group that did not. Field type has been discussed in prior work and has often been found to be associated with an increased risk of ACL injury in other NCAA sports [126, 127]. Researchers and clinicians should consider the role that field surface may play in addition to friction coefficient from the shoe-surface interface and peak torque measures between the shoe and playing surface [128-130]. Further clinical investigation is warranted to enhance the understanding of how these variables may affect the rate of ACL injury.

Conclusions

The results of this study demonstrated the ability of the FIFA 11+ to decrease the incidence of ACL injuries in competitive collegiate male soccer players by 77%. This information may have an important impact on the development and advancement of injury prevention protocols and may mitigate risk to soccer athletes who utilize the program. This knowledge can provide critical insight to help reduce the rate of ACL injury in male soccer players, improve the efficacy of existing ACL injury prevention protocols, and improve secondary prevention strategies. Future studies should investigate the efficacy of the FIFA 11+ program with respect to ACL injury prevention in female collegiate players. In addition, the cost-effectiveness of utilizing this prevention program in the collegiate cohort should be analyzed to determine if the cost associated with program implementation is justified.

Chapter 4

IMPLEMENTATION OF THE FIFA 11+ WITH HIGH COMPLIANCE LEADS TO POSITIVE TEAM PERFORMANCE OUTCOMES

Introduction

Compliance and adherence to injury prevention programs have been a significant obstacle, from a public health perspective.[131, 132] Universally, implementation rates for scientifically vetted injury prevention program have been low, and even if a successful implementation occurs, the compliance to the programs tends to decrease over time. [46, 78, 79] Compliance to training programs has been low and inconsistent. [133] Low compliance to an injury prevention program has been linked to increased injury rates over the course of a competitive season. [47] Establishing a dose-response relationship between neuromuscular training programs and injury incidence rates would, ostensibly, serve as a positive incentive for coaches and athletes to regularly utilize these prevention programs during training. [131] Despite efforts to increase coaching awareness and exposure to existing neuromuscular training program efficacy, high levels of program implementation are not achieved, despite effectively impacting coaching attitudes and intent to implement.[82]

Injury to a player has obvious negative consequences to both the individual athlete and the team.[86] Coaches are often pressured to make strategic decisions when their preferred starting athlete is unavailable for selection due to injury. Efforts to educate coaches to injury risk and restrictions for athletes returning to play after sustaining an injury are successful.[134] The percentages of coaches who adopt these procedural methodologies consistently are limited, even at the professional levels of competition.[135] Coaches' perceptions of injury prevention protocols are often are subject to negative associations; such as using valuable practice time, lack of sport specificity, and lack of player commitment.[136] There is overwhelming evidence that the benefits of implementing injury prevention methodology may far outweigh any cost, real or perceived, associated with the internal and external factors that may disrupt compliance.[137, 138]

The purpose of this study was to determine: 1) if implementation of the FIFA 11+ would impact team performance outcomes and 2) if high adherence and compliance to the FIFA 11+ injury prevention program would improve overall team performance for male collegiate Division I and II soccer players. The aim of this study was analyze the tertiles of compliance (high, medium and low) with respect to overall team performance (wins, losses and ties).

We hypothesized:

- Hypothesis 4.1: Teams that utilized the FIFA 11+ program would have more wins, fewer losses and fewer ties compared to the control group (CG).
- Hypotheses 4.2: Teams that had high compliance to the FIFA 11+ program, would demonstrate improved team performance demonstrated by more wins and fewer losses over the competitive season compared to moderately compliance teams.

- Hypothesis 4.3: Teams that had high compliance to the FIFA 11+ program, would demonstrate improved team performance demonstrated by more wins and fewer losses over the competitive season compared to low compliance teams.

.

Methods

This is a secondary analysis of a prospective cluster randomized controlled trial, which was conducted in Men's Division I and II soccer teams competing in the National Collegiate Athletic Association (NCAA). Sixty-five institutions were randomly assigned utilizing a computerized random number generator and completed the intervention study during the Fall, 2012 competitive soccer season (August – December): 34 control institutions (N=850 athletes) and 31 intervention institutions (N=775 athletes) with athletes between the ages of 18-25. Four Division II intervention teams discontinued the intervention (N=100) secondary to time and personnel constraints. Therefore, a per-protocol analysis for the remaining teams was utilized. For the compliance aspect of the study (current study), only the intervention teams that completed the study were utilized (27 teams, N=675). The competitive season lasted from August through early December. (Figure 1)

All sixty-one teams were monitored with respect to team performance. Twenty-seven of sixty-one Division I and Division II NCAA men's soccer (football) teams were also monitored for FIFA 11+ program compliance. Human ethics internal review board approval and informed consent was obtained through Quorum IRB (Seattle, Washington, USA). Individual player consent was obtained and a documentation of coaching understanding was signed by each institution to ensure that there was a thorough understanding of the expectations of study participation.

An internet-based injury surveillance data collection system was utilized (HealtheAthlete™, Overland Park, Kansas, USA) by every enrolled institution in the study. Implementation of the FIFA 11+ program and compliance data was entered weekly by the team's certified athletic trainer and verified by the research staff. Upon the completion of the competitive soccer season, compliance data entry was confirmed by each certified athletic trainer (ATC) and verified with their individual institution's data collection system for accuracy and thoroughness. The performance record for each individual IG and CG team was ascertained by the head researcher (HSG), using an online query at the culmination of the NCAA competitive season.

Statistical Analysis

The outcome variables examined were levels of compliance and team performance record: wins, losses and ties. Compliance was defined as follows: low (LC) ranged between 1-19 doses/season (less than one dose per week), moderate compliance (MC) ranged between 20-39 doses/season (one to less than two doses per week), and high (HC) was defined as implementation >40 doses per season (more than two doses per week). All statistical analyses were conducted utilizing SPSS for Macintosh, Version 24, Armonk, NY: IBM Corp. Descriptive and inferential tests were used to compare the CG and IG, the tertiles of compliance (high, medium, low), to team performance. A paired t-test was used to analyze outcome (wins, losses and ties) to group (IG versus CG). A one way-MANOVA test was utilized to analyze tertiles of compliance to win/loss/tie record. This was followed up by one-way ANOVA tests to analyze how compliance impacted wins, losses and ties, independently. A Tukey post-hoc analysis was used to analyze specific differences between levels of compliance and specific outcome measures.

Results

Wins, losses and ties were analyzed for both the CG and the IG. In the IG, compliance was stratified into tertiles and wins, losses and ties were analyzed comparatively. For the IG, there were significantly more wins (IG: 10.67±2.63 versus CG: 8.15±3.83, CI, 7.95 – 9.69, p = 0.005) and fewer losses (IG: 5.56±1.97 versus CG: 8.12±3.59, CI, 5.66 to 7.43, p = 0.002) recorded over the course of the competitive season. There was no significant difference in ties (IG: 2.37±1.64 versus CG: 2.29±1.61, CI, 1.46 to 2.31, p=0.856)

	Control	Intervention	Standard Error	95% Confidence Interval	p value
	Mean ± SD	Mean ± SD			
Wins	8.15 ± 3.83	10.67 ± 2.63	0.44	7.95 to 9.69	p = 0.005
Losses	8.12 ± 3.59	5.56 ± 1.97	0.44	5.66 to 7.43	p = 0.002
Ties	2.29 ± 1.61	2.37 ± 1.64	0.21	1.46 to 2.31	p = 0.856

Table 7 Comparison of Wins, Losses and Ties in the CG versus IG with Standard Error, 95% Confidence Intervals (CI) and p values

The next set of analyses was solely based on the intervention group's outcome measures. When the IG was stratified into tertiles of compliance, a one-way multivariate analysis of variance was conducted to determine if the effect of compliance on the number of wins, losses and ties. The tertiles of compliance were defined as high, moderate and low. (Table 2)

	Compliance	Team N	Wins Mean ± SD	Std. Error	95% Confidence Interval Lower	Upper
Wins	Low	4	8.0 ± 1.63	0.96	6.02	9.98
	Moderate	14	9.86 ± 1.46	0.51	8.80	10.92
	High	9	13.11 ±2.57	0.64	11.79	14.43
	Total	27	10.67 ± 2.63	-	-	-
Losses	Low	4	6.25±1.89	0.87	4.46	8.04
	Moderate	14	6.29 ± 1.9	0.47	5.33	7.24
	High	9	4.11± 1.36	0.58	2.92	5.31
	Total	27	5.56 ± 1.97	-	-	-
Ties	Low	4	3.5 ± 2.38	0.80	1.84	5.16
	Moderate	14	2.43 ± 1.79	0.43	1.54	3.32
	High	9	1.78 ± 0.67	0.54	0.67	2.88
	Total	27	2.37 ± 1.64	-	-	-

Table 8 Level of compliance, N = number of teams (N), number of wins represented as Mean ± Standard Deviation (SD), Standard Error, and 95% Confidence Interval limits for tertiles of compliance and team performance.

There was a statistically significant difference between the levels of compliance on the combined dependent variables (performance outcome: wins, losses and ties), $F(3, 22) = 3.780$, $p = 0.004$; Wilks' $\Lambda = .435$; partial $\eta 2 = .340$. When the data was analyzed independently with follow-up ANOVAs, there was a statistically significant difference in compliance for wins ($F(2, 24) = 12.38$, $p < .001$; partial $\eta 2 = .508$) and losses ($F(2, 24) = 4.663$, $p=0.019$; partial $\eta 2$ = ..280), using a Bonferroni adjusted α level of 0.025. However, there was no significant difference found between compliance and ties ($F(2, 24) = 1.609$, $p=0.221$; partial $\eta 2 = .118$. Tukey post-hoc tests showed that for wins, highly compliant teams had more wins than moderate ($p=0.002$) or low compliance teams ($p=0.001$). For losses, highly compliant teams had significantly fewer losses than moderately compliant teams (p=0.019), but not for low compliance teams (p=0.122). No significance was found between groups for ties. (Table 3)

	Compliance	Compliance compared	Mean Difference	Std. Error	p value	95% Confidence Interval	
						Lower	Upper
Wins	Low	Moderate	-1.86	1.09	0.224	-4.58	0.86
		High	-5.1111*	1.15	0.001	-7.99	-2.23
	Moderate	Low	1.86	1.09	0.224	-0.86	4.58
		High	-3.2540*	0.82	0.002	-5.30	-1.20
	High	Low	5.1111*	1.15	0.001	2.23	7.99
		Moderate	3.2540*	0.82	0.002	1.20	5.30
Loss	Low	Moderate	-0.04	0.99	0.999	-2.50	2.43
		High	2.14	1.04	0.122	-0.47	4.75
	Moderate	Low	0.04	0.99	0.999	-2.43	2.50
		High	2.1746*	0.74	0.019	0.32	4.03
	High	Low	-2.14	1.04	0.122	-4.75	0.47
		Moderate	-2.1746*	0.74	0.019	-4.03	-0.32
Tie	Low	Moderate	1.07	0.91	0.479	-1.20	3.35
		High	1.72	0.97	0.196	-0.69	4.13
	Moderate	Low	-1.07	0.91	0.479	-3.35	1.20
		High	0.65	0.69	0.616	-1.06	2.37
	High	Low	-1.72	0.97	0.196	-4.13	0.69
		Moderate	-0.65	0.69	0.616	-2.37	1.06

Table 9 Tukey post-hoc analysis comparing level of compliance (low, moderate and high) to wins, losses and ties, respectively. The highlighted yellow cells reflect statistical significance with p<0.05).

Overall, level of compliance was statistically different than the control group. Each compliance group (low, moderate and high) had more wins (p=0.005) and fewer losses (p=0.002). There was no statistical difference for ties (p=0.856). (Figure 1)

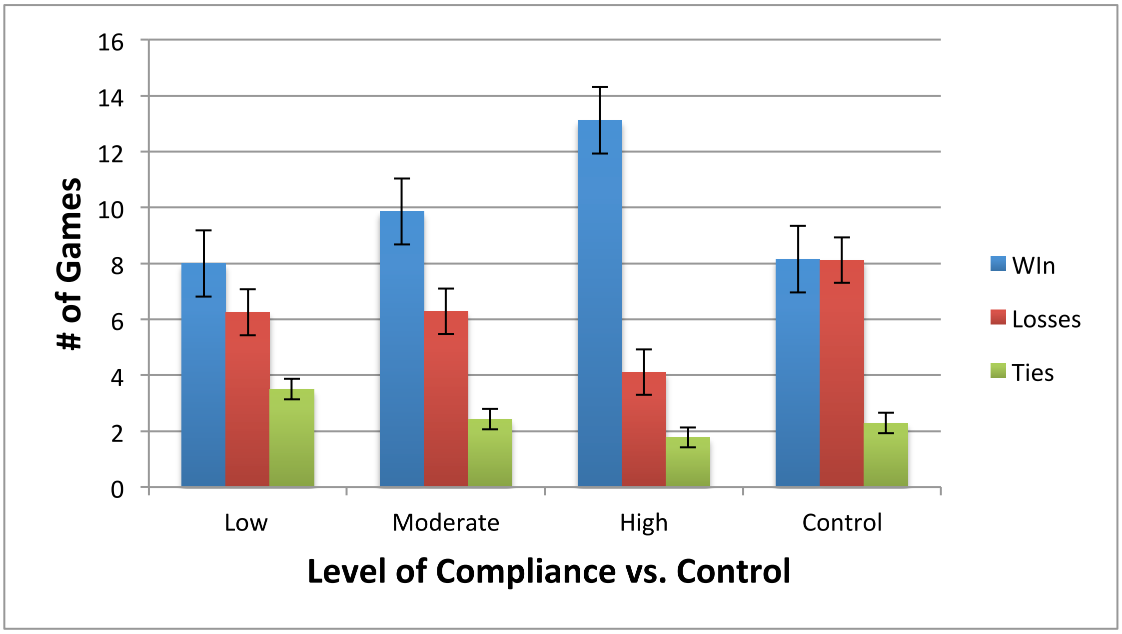

Figure 2 Number of wins, losses and ties based on level of compliance (low, moderate and high) compared to the control group. Bars represent standard error.

Discussion

This study analyzed how the implementation of the FIFA 11+ program impacted overall team performance during a competitive season in male collegiate soccer players. In addition, this study analyzed how differences in compliance within the intervention group impacted the win/loss record of the IG teams. The results support each of the hypotheses. The implementation of the FIFA 11+ has a positive impact on overall team performance. The teams that implemented the program recorded more wins and fewer losses throughout the competitive season compared to the CG teams that were utilizing their own warm-up protocol. There was no significant difference between the IG and the CG for number of ties recorded during the season. Furthermore, the teams that were highly compliant implementers of the FIFA 11+ recorded more wins and fewer losses compared to the teams with moderate and low compliance. There was no statistical difference recorded between levels of compliance and ties recorded.

This study is the first of its' kind to analyze how team performance may be positively impacted by virtue of using the FIFA 11+ warm-up program. Prior studies have analyzed how the individual user might be impacted by virtue of using the program.[84, 139]. Use of the FIFA 11+ program has led to significant changes in vertical jump height, lower extremity strength, improvement in sprint speed and improvement in proprioceptive balance testing. [22, 112, 113] Positron emission tomography (PET) musculature activation analysis of athletes using the program demonstrated increased uptake in the cells of the gluteus minimus, gluteus medius, and rectus abdominus muscles compared to controls ($p<0.05$).[111] These specific muscles have been hypothesized to have a protective benefit with respect to knee and hip injuries incurred in the sport of soccer.[140, 141] In addition, the FIFA 11+ has been shown to be as effective as other traditional warm-up programs in increasing individual oxygen uptake, core temperature and systemic lactate levels. [112] This is an important aspect of the program when medical personnel delineate the value of using the FIFA 11+ to directly replace a team's traditional warm-up program.

There have been numerous studies that have extolled the merits of the program with respect to lower injury rates and decreases in the severity of injury.[32, 34, 77, 110, 139] However, the use of this program, and other like it, continue to suffer with respect to widespread adoption and implementation throughout the soccer community at large.[47, 114, 132] The rationale that coaches provide for refusing to implement injury prevention programs include; time constraints, boredom with using a consistent warm-up, lack of sport specificity and lack of player commitment or belief in the program.[142, 143] However, if the vernacular of injury prevention could include, or supplant, the notion of performance enhancement with respect to improving winning percentage, perhaps coaches, managers and players would be more likely to utilize this type of program with more consistency and with adequate adherence and fidelity.

Prior research has demonstrated that team performance (games won) is often negatively correlated to injury rate. [69, 133] In addition, increased injury rates that impact the highest ranked players are deemed detrimental to team success.[144, 145] This may be due to more minutes of athletic exposure, more games being played, player position vulnerability, and player being subject to more consistent contact or fouling.[146, 147] Player availability, particularly in late season and post-season play, is considered paramount to a coaching staff. The premise that an injury prevention program may improve player availability is a concept that should be emphasized when attempting to facilitate consistent program implementation. We are not suggesting that utilizing a neuromuscular training program, such as the FIFA 11+, improves overall athleticism or enhances a player's level of inherent skill. However, with improved overall player durability and mitigating risk to injury, a player has an advantage and an opportunity to be available to play more consistently throughout the competitive season. This improvement in overall player availability may guide and assist a coaching and managerial staff in strategizing for in-season and post-season play more consistently.

Limitations

The limitations of this study include the fact that this study was only conducted for one competitive season, and performance was only tracked for that season, accordingly. Individual compliance was not tracked for each player. Compliance was tracked as a team.

Conclusions

The FIFA 11+ has the capacity to improve overall team performance in comparison to an age and skill matched control group. In addition, the higher the compliance to the FIFA 11+ program, the more favorable the team performance was, (i.e. more wins and fewer losses). These findings may be persuasive for organizations to encourage coaching staffs to incorporate an injury prevention protocol into their existing training regimen.

Chapter 5

ANALYSIS OF A SINGLE-LEG SQUAT TEST OVER THE COURSE OF A COMPETITIVE SEASON IN FEMALE SOCCER PLAYERS

Introduction

The single-leg squat test (SLST) has been used as a functional assessment tool to identify neuromuscular deficits associated with higher risk for lower limb injury, including patellofemoral pain and anterior cruciate ligament (ACL) injury.[148, 149] Larger dynamic knee valgus kinematics and lumbopelvic instability have been directly correlated to increased risk of knee injury.[150-154] Subjects who went on to incur a knee injury demonstrated increased knee abduction, hip adduction, hip internal rotation, hip anteversion, decreased hip and knee flexion angles and increased medio-lateral displacement during a SLST, compared to their uninjured counterparts [155-157] Despite its' ubiquitous use as a clinical test, the SLST has demonstrated only average inter and intra-tester reliability and sensitivity to predict specific risk without the use of a more robust 3-D motion analysis laboratory testing protocol.[158-160] Clinical assessment of medio-lateral displacement during the SLST, however, is a reliable during 2-D analysis allowing for a more robust extrapolation to a larger cohort.[161] Kinematic and kinetic analysis of the SLST is a reliable method of analysis with a relatively low standard error of measurement (SEM).[161]

The analysis of the SLST performance is not isolated to identifying underlying pathology or injury risk to the knee joint. The presence of femoral acetabular impingement, hip muscle pain, iliopsoas tightness and fatigue are all variables that impact the qualitative performance of the SLST.[162, 163] Hip abduction, adduction and extension strength has been shown to play a significant protective role in frontal plane knee motion.[164] Proper SLST performance demands optimal activation of the lateral hip musculature, including the anterior and posterior fibers of the gluteus medius.[148] The SLST test has demonstrated the ability to detect frontal and transverse plane deficits at the ankle and hip, thus lending itself to be an appropriate functional screening tool.[165] Poor performance of the SLST has been correlated with decreased ipsilateral hip abduction strength, decreased single-leg hop distance and lower IKDC functional outcome scores.[149] Furthermore, single-leg testing maneuvers have been shown to be an adequate predictor performance assessment and cost effective substitute for more sophisticated and laborious motion laboratory analysis.[166]

Dynamic valgus (collapse of the lower limb characterized by hip adduction and hip internal rotation, usually when in a hips-flexed position as well as knee abduction) during a SLST is correlated to deficiencies in the hip. The frontal plane knee angle was predicted by the interaction between hip abductor and hip IR moments.[167] Surface electromyography studies have demonstrated the significant role that the gluteus medius and the gluteus maximus have in frontal and transverse plane knee stability.[168, 169] Hip muscle function, including hip abduction, hip external rotation and hip extension peak forces, were positively correlated with SLST performance, with the correlations being statistical significant in females.[170]

The purpose of this study was to analyze the biomechanical impact of the FIFA 11+ on the performance of the single-leg squat test in female collegiate soccer players compared to an age and skill matched control group. The study analyzed bilateral hip, knee and ankle kinematics during a dynamic SLST. Segment kinematics were compared in the frontal, sagittal and transverse planes. We hypothesized the following:

- Hypothesis 5.1: The athletes using the FIFA 11+ program would demonstrate improvements in hip kinematics over the course of the season compared to their pre-season assessment and compared to the control group.
- Hypothesis 5.2: The athletes using the FIFA 11+ program would demonstrate improvements in knee kinematics over the course of the season compared to their pre-season assessment and compared to the control group.
- Hypothesis 5.3: Athletes using the FIFA 11+ would demonstrate decreased Peak Knee Abduction Moments (PKAM) and joint angles consistent with decreased dynamic valgus at the knee.

Methods

The subjects for this study were recruited from local universities in close geographic proximity to the motion analysis laboratory. Two Division I and one Division II NCAA collegiate soccer teams were recruited for the study and subsequently enrolled. The study was approved by both the University of Delaware's and Wilmington University's Internal Review Boards (IRB), respectively (Appendix B and C). Each athlete voluntarily agreed to the terms of the study and submitted written informed consent prior to participating in the dynamic testing. The inclusion criteria included all eligible female soccer athletes currently in good academic standing included on the active roster for the current season. Exclusion criteria included any athlete the may have incurred a recent injury or a post-surgical status that would prohibit them from participating in the testing protocol.

Demographic information was collected for each individual upon receiving voluntary informed consent. Height, weight, player position, number of years playing soccer, the year in which the subject began to specialize in the sport of soccer, and injury history was collected during the pre-testing protocol. Injuries that occurred during the season were recorded during the post-season testing protocol.

The single-leg squat was performed bilaterally and was analyzed during both the preseason and post-season, respectively. Motion analysis of the maneuver was assessed using an eight infrared camera motion analysis system (VICON; Oxford Metrics Ltd, London, England). Twenty-two sixteen-millimeter spherical retro-reflective markers were placed bilaterally on each acromion, each iliac crest in alignment with the greater trochanter, the greater trochanter of each femur, lateral and medial femoral condyles, lateral and medial malleolus and the distal head of the 1st and 5th metatarsal bones, and two markers on the posterior heel. Rigid theromoplastic shells with four markers were affixed using Velcro elastic wraps to the trunk (along the paraspinals), pelvis, lateral thighs, and lateral shanks to track the motion of these segments during dynamic testing. Weigh, height, pelvic depth and acromion width were recorded for each subject for input into the biomechanical model. The markers were affixed solely by one researcher (AA), in order to avoid inter-rater reliability issues. A standing calibration was performed to identify joint centers and to create the segment coordinate system. Two force platforms were also utilized during the analysis and recorded ground reaction forces at 1080Hz (Bertec, Worthington, Ohio, USA). The subjects were instructed to wear tight fitting athletic or compression gear in order to expose the joint(s) of interest and to also wear new or gently worn athletic shoes in order to ensure proper tread for dynamic movement control during testing. All verbal instructions for the single leg squat were provided by one researcher (HSG), in order to maintain methodological continuity.

The single leg squat was performed by having the athlete stand on top of an 8-inch box firmly secured to one of the force plates. The subject was instructed to place the right foot fully on the box and let the left foot approximate the box by 50%. To begin the activity, the subject would advance their left leg forward and perform three single leg squats on the right limb in succession. The subject would return their left leg back to the top of the box and step down off of the box, fully clearing the force plate in use. The athlete would then repeat the activity on their left lower extremity. The subjects were given verbal instructions by one researcher (HSG) and were allowed to practice the single-leg squat one time prior to the analysis commencing. One trial of three successive single leg squats was performed on each limb.

Data Analysis

Kinematic and kinetic data were low pass filtered at 6 Hz and 40 Hz respectively using a second order Butterworth filter. Markers were labeled using Vicon Nexus software (v 1.8.5, VICON, Oxford Metrics Ltd, London, England). If signal gaps occurred due to marker drop out, the software's spline filling algorithm was utilized. In the event that the gaps were persistent and deemed too large for the algorithm to fill, the trial was excluded from the final analysis. Visual3D software was used for the kinematic and inverse dynamic post-processing analyses (Visual 3D, C-Motion Inc., Germantown, Maryland, USA). To remain consistent with the existing literature, moments were calculated as external moments: hip flexion, hip adduction, hip internal rotation, knee extension, and knee adduction were represented as positive values. Variables of interest included peak hip and knee angles and external moments in the frontal, sagittal and transverse planes.

Statistical Analysis

All statistical analyses were conducted utilizing SPSS for Macintosh, Version 24 (Armonk, NY: IBM Corporation) and Microsoft Excel for Mac, 2011 (Redmond, Washington, USA). Means and standard deviations of each variable of interest was calculated in Excel. T-tests were used to compare the demographic variables of the control versus the intervention group (age. height, weight, pelvic depth). One-way ANOVA's were used to analyze age of beginning soccer play and years of soccer experience. Chi-square tests of independence were used to compare year of eligibility, leg dominance and position by group. MANOVA statistical tests were performed to determine if there were biomechanical differences within joint angles and moments between the CG and IG, respectively. Levene's test was used to assess the homogeneity of variance between the groups. If statistical difference were identified, one-way ANOVA's were utilized to identify which variable (pre-test versus post-test) was contributing to the statistically different MANOVA. The effect sizes of each variable were tested using partial eta (η) squared within and between groups (0.01 = small effect, 0.06 = medium effect, and 0.14 = large effect),

Results

Sixty-nine subjects completed the biomechanical testing at two time points and were included in this analysis. Forty-eight of the subjects from two Division I soccer teams were part of the intervention group (IG) and were using the FIFA 11+ program as their dynamic warm-up throughout the course of the season. Twenty-one of the subjects from one Division II soccer team served as the control group (CG) and were not utilizing the proposed intervention. Demographic analysis, including age, height, weight and pelvic depth revealed that there were no significant differences between the IG and the CG. There was a significant difference between the groups for the age of beginning soccer play, with the IG (Division I) starting earlier in life to the CG (Division II) (Table 4). There was no significant difference in year of eligibility, player position, or leg dominance, between the IG and CG groups (Table 5).

Demographic Variables	Intervention	Control	P value
# of subjects (N)	48	21	-
Age (Mean ± SD)	20.10 ± 2.0	19.93 ± 4.52	0.73
Height (inches ± SD)	65.81 ± 2.03	65.10 ± 2.62	0.22
Weight (kg ± SD)	63.71 ± 5.96	63.54 ± 8.13	0.92
Pelvic Depth (inches ± SD)	17.06 ± 1.11	17.00 ± 1.59	0.85
Age starting soccer (years ± SD)	4.67 ± 1.48	6.1 ± 2.43	0.004*
Age of sport designation (years ± SD)	14.51 ± 3.88	13.1 ± 5.15	0.22

Table 10 Demographic information regarding the Control Group and the Intervention Group. There was a significant difference between groups for age of beginning soccer play (p=0.004). .

	Intervention	Control	P value
Year of Eligibility	N=48	N=21	0.19
Redshirt	2 / 4.2%	1 / 4.8%	
Freshman	14 / 29.2%	6 / 28.6%	

Sophomore	16 / 33.4%	2 / 9.5%	
Junior	8 / 16.7%	8 / 38.1%	
Senior	8 / 16.7%	4 / 19.0%	
Position	**Intervention**	**Control**	**P value**
Forward	10 / 20.8%	6 / 28.6%	0.41
Midfielder	18 / 37.5%	4 / 19.0%	
Defender	14 / 29.2%	9 / 42.9%	
Goalkeeper	6 / 12.5%	2 / 9.5%	
Leg Dominance	**Intervention**	**Control**	**P value**
Right	39 / 81.3%	20 / 95.2%	0.31
Left	8 / 16.7%	1 / 4.8%	
Bilateral	1 / 2.1%	0 / 0%	

Table 11 Stratification of player by year of eligibility, player position and leg dominance. There was no significant difference between groups for year of eligibility (p = 0.19), player position (p = 0.41) or by leg dominance (p = 0.31)

Between Group Analysis: Single leg squat

Significant time*group interactions were found for hip flexion angle ($F(2,95)$ = 7.214, p=0.001), hip extensor moment ($F(2,95)$ = 6.829, p=0.002), hip adduction angle ($F(2,95)$ = 3.70, p=0.028), hip abductor moment ($F(2,95)$ = 5.858, p =0.004), hip internal rotation angle ($F(2,95)$ = 7.19, p=0.001), peak knee flexion angle ($F(2,95)$ = 3.085, p=0.05 and peak knee abduction angle ($F(2,95)$ = 5.136, p=0.008. There were significant differences between the groups during post-test analysis for hip flexion angle, hip extensor moment and hip adductor angle, hip internal rotation angle and knee abduction angle. Compared to the pre-test measurements, the IG had a within group increase of 14.78%, in hip flexion angle, a 22.72% increase in hip extensor moment, and a 30.21% decrease in hip internal rotation. (Table 12)

Post-hoc analysis demonstrated that there was a significant difference in post-test hip flexion angles ($p<0.001$), but not in pre-test measurements ($p=0.813$). There was a significant increase in hip flexion angles in the IG, with the IG demonstrating an 14.78% increase in hip flexion angle compared to a 12.71% decrease in hip flexion angle in the CG over the course of the season ($p=0.001$). (Table 12)

There was a significant difference in post-test hip extensor moment, $F(1,96) = 13.973$; $p < 0.001$; partial $\eta 2 = .125$), bur not in pre-test measurements ($F(1,96) = 1.081$, $p = 0.301$, partial $\eta 2 = .011$). There was a significant increase in hip extensor moment in the IG, with the IG demonstrating a 22.7% increase in hip extensor moment ($p=0.002$) compared to a 18.4% decrease in the CG ($p=0.873$).

There was a significant difference in post-test hip adduction angle: $F(1,96) =5.447$, $p = 0.022$; partial $\eta 2 = 0.054$) bur not in pre-test measurements ($F(1,96) < 0.001$, $p = 0.999$; partial $\eta 2 < 0.001$). There was a significant difference in hip adduction angle with the CG demonstrating a 19.3% decrease in hip adduction angle ($p=0.998$) compared to a 2.4% increase in the IG ($p=0.007$),

There was a significant difference between groups in pre-test hip abduction moment ($F(1,96)=.208$, $p=0.005$), but not for post-test ($F(1,96)=1.886$, $p=0.173$). There was a significant difference in post-test right hip abductor moment within the IG, with the IG demonstrating a 41.3% increase in hip abduction moment ($p=0.092$)) compared to a 6.9% increase in the CG ($p=0.172$).

There was a significant difference in hip IR angle between groups for both the pre-test ($F(1,96)=7.19$, $p=0.004$) and the post-test ($F(1,96)=7.892$, $p=0.007$) measurements. Both the CG and the IG demonstrated significant decreases in hip IR angles throughout the course of the competitive season, with the CG demonstrating a 31.8% decrease (p=0.027) and the IG demonstrating a 30.2% decrease (p = 0.002).

There was a significant difference between groups in pre-test peak knee flexion angle (F(1,96)=4.60, p=0.035), but not for post-test measures (F(1,96)=0.688, p=0.409). The IG demonstrated a 3.4% increase in peak knee flexion angle (p=0.007) compared to a 5.9% decrease in the CG (p=0.046).

There was a significant difference between groups in knee abduction angle (F(1,96) = 5.136, p=0.008) There was a significant decrease in right knee abduction angle in the IG when comparing pre-test values to post-test, with the IG demonstrating a 22.3% decrease in knee abduction over the course of the season (p=0.015). The CG demonstrated a 16.9% increase in knee abduction over the courses of the season (p=0.006) (Table 12,, Figure 3)

There were no significant group*time interactions found for hip internal rotation moment (p=0.86), peak knee flexion moment (p=0.79), or knee abduction moment (p=0.547).

Variable	**Control (M±SD)**		**Intervention (M±SD)**		**P value**	**partial η2**
	Pre	**Post**	**Pre**	**Post**		
Hip Flexion Angle (°)	40.90±13.41	35.70±9.09	40.18±12.13	47.15±12.43	0.001	0.132
Hip Extension Moment (Nm/kgm)	-0.76±0.33	-0.62±0.24	-0.85±0.36	-1.10±0.58	0.002	0.126
Hip Adduction Angle (°)	13.87±6.79	11.19±5.17	13.87±5.77	14.23±5.41	0.028	0.072
Hip Abduction	-0.61±0.19	-0.57±0.18	-0.49±0.17	-0.83±0.91	0.004	0.11

Moment (Nm/kgm) *						
Peak Hip IR Angle (°)	7.08±5.08	4.82±4.99	11.32±5.20	7.90±5.56	0.001	0.131
Hip IR Moment (Nm/kgm)	0.05±0.02	0.04±0.02	0.04±0.03	0.04±0.05	0.86	0.003
Peak Knee Flexion Angle (°)**	-77.27±9.66	-72.72±9.11	-72.01±10.26	-74.58±9.31	0.05	0.061
Peak Knee Flexion Moment (Nm/kgm)	1.11±0.19	1.03±0.30	0.97±0.27	0.99±0.26	0.079	0.052
Peak Knee Abduction Angle (°)**	-0.30±3.312	-1.77±3.77	2.09±3.58	0.46±3.74	0.008	0.098
Peak Knee Abduction Moment (Nm/kgm) ***	-0.10±0.09	-0.11±0.08	-0.12±0.06	-0.10±0.07	0.547	0.013

Table 12 Mean, Standard Deviation, P value and Effect size (partial η2) for pre and post-test kinetic and kinematic variables of the hip and knee during the single leg squat test. * Negative hip moment values indicate a hip abduction moment. ** Negative peak knee angle values indicate knee flexion (x) and knee abduction (y). ***Negative peak knee moments indicate knee extensor moment and knee adductor moment.

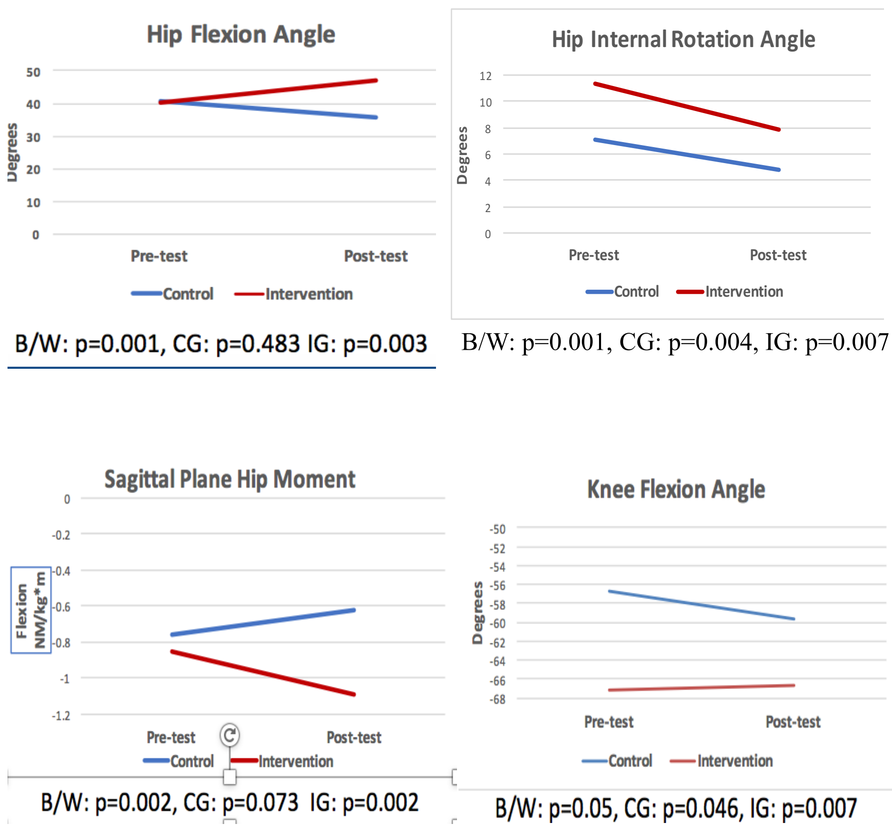

Figure 3 Kinetic and Kinematic analysis of Single Leg Squat maneuver for hip and knee variables.

Discussion

This study investigated the potential influence that the FIFA 11+ injury prevention program to positively alter the kinetics and kinematics of female soccer players performing a single leg squat after using the FIFA 11+ as their dynamic warm-up throughout the course of a competitive season. In previous publications, the program has demonstrated its' ability to decrease the rate of soccer related injury in male and female soccer players.[32, 34, 45, 77] However, despite the program demonstrating efficacy within the sporting community, the mechanistic understanding of its' ability to favorably modify movement has not been investigated to date.

The results of this study suggest that the FIFA 11+ program may positively impact the kinetics and kinematics of the lower extremity during a single leg squat test, predominantly by affecting the hip. There were significant main effects (group*time) found for seven different variables: hip flexion angle, hip extensor moment, hip adduction angle and moment, and hip internal rotation angle, peak knee flexion angle and knee abduction angle; with the intervention group demonstrating favorable changes and improved biomechanics over the course of the season compared to the control group. During the within-group analysis, there were favorable statistical differences found for the right lower extremity for hip flexion angle, hip extensor moment, hip adduction moment, hip internal rotation angle, and peak knee flexion angle when comparing the pre to post-test values. These findings suggest that with consistent utilization and high program fidelity, the FIFA 11+ may favorably address some of the biomechanical risk factors that may exist in the female collegiate soccer population.

The single leg squat test has been used to prospectively assess risk and determine readiness for return to sport.[171-174] This test has been shown to be predictive of frontal and sagittal plane knee mechanics after knee surgery.[171, 175] The single leg squat also serves as a reliable and valid test that is also a cost-effective option to more sophisticated motion analysis testing.[166] Single leg squats have been positively correlated to assessing hip and trunk muscle function, particularly in female athletes.[170] In addition, hip abduction strength has been shown to be a significant predictor of the variation in frontal plane projection angle.[176] Gluteus maximus activation has been theorized to modulate frontal plane knee kinematics during single leg squats.[177]

The FIFA 11+ program was designed in 2007 by an international group of clinical researchers imbedded in the sport of soccer.[34] The premise of the program was to design a dynamic injury prevention warm-up program to address the incidence of soccer related injury. Unlike other injury prevention programs that are specific to one injury type (i.e, ACL injury [24, 28, 49]), the approach to the FIFA 11+ was holistic in nature, and not specific to decreasing the incidence of any one type of injury to a specific joint. The contents of the program have a heavy emphasis on core/trunk control and control of the proximal segment of the lower extremity. The founders of the program thought that by emphasizing core, trunk and hip control, the program may mitigate risk to the lower extremity. The program has been shown to be an optimal warm-up program that optimally increases core temperature, oxygen uptake and lactate.[112] Upon performing positron emission tomography (PET) scans of athletes utilizing the FIFA 11+ program, F-fluorodeoxyglucose (FDG) uptake was significant increased in the rectus abdominus, the gluteus medius and the gluteus minimus.[111] Upon performing isokinetic testing of the quadriceps and hamstring muscles in young male soccer players utilizing the FIFA 11+, researchers found that the 11+ increased concentric and eccentric hamstring strength, but did not show statistical differences in quadriceps concentric or eccentric strength compared to a control group not utilizing the program[178]. The FIFA 11+ has been shown to have positive effects on 10 and 20-meter sprint times, vertical jump height and agility testing. Furthermore, soccer player using the program three times per week for nine weeks demonstrated improved neuromuscular control and the time-to-stabilization while performing the sitting posture test.[113] These studies reinforce the notion that the qualitative elements of the FIFA 11+ have a heavy emphasis on core, trunk and proximal segment (hip and pelvis) stability.

The results of this investigation suggest that the FIFA 11+ protocol may have favorable effects on the kinetics and kinematics of the hip in female collegiate soccer players that are utilizing the protocol. The athletes in the intervention group using the FIFA 11+ did not, however, demonstrate many statistically favorable changes in the knee joint, with the exception of knee abduction angle. There were significant and favorable findings found in the IG for hip flexion angle, hip extensor moment, hip abduction moment, peak knee flexion angle and knee abduction angle. Both the IG and the CG demonstrated favorable changes in hip IR angle. The relationship between proximal hip control and frontal plane deficiencies of the knee has been well established.[162, 164, 169, 179, 180] Prior research has demonstrated that neuromuscular training programs that emphasize the lateral and posterior hip musculature resulted in a decreased incidence of knee injuries in female athletes.[24, 28, 29, 124] The FIFA 11+ has therapeutic exercises included in the protocol that target the lateral and posterior hip musculature.[91] In this study, the favorable changes reported in the hip, including improvements in hip extensor moment, hip abduction moment, and decreases in hip internal rotation angle are critical components to achieving dynamic knee stability distally. If the proximal segment (hip) is demonstrating favorable kinetic and kinematic changes, the lower limb will, ostensibly, demonstrate a decrease risk profile (i.e. decreased dynamic valgus).[180]

Although there the data in this study revealed significant positive findings found in the hip joint, there may be several reasons for why these favorable biomechanical findings did not manifest in the knee. The length of the NCAA collegiate soccer season is significantly truncated compared to international, professional and club soccer seasons; 16 weeks versus 10 months. [42, 70, 181] Due to the nature of the condensed season, it is very challenging, from a neuromuscular perspective, to impart a positive benefit or change to pathokinematic movement patterns. In a study performed in female collegiate soccer players, there was a statistically significant decrease in ACL injuries in the second half of the season compared to the first half in players using an ACL injury prevention program.[24] This study elucidates and highlights the critical nature of having optimal time to allow an injury prevention program to manifest its' benefits by virtue of decreased injury incidence rates or favorable changes in kinetic and kinematic motion analysis. Additionally, researchers have found significant differences in muscle activation and isokinetic strength patterns between male and female soccer players.[67, 182] Females have demonstrated faulty frontal plane kinematics, with decreased activation of hip abduction and increases in hip adduction. These differences also have implications with respect to injury rate with respect to leg dominance, as females have demonstrated a statistically significant propensity to sustain and ACL injury to their non-dominant limb compared to males, who are more likely to sustain an ACL injury to their dominant limb.[50, 68, 74, 183] Therefore, there may be a need to develop sex specific injury prevention program that specifically target the biomechanical deficits most commonly demonstrated in a population; specific to sport, sex, level of competition and age.

Limitations

There are several limitations to this current study. The biomechanical analysis was only conducted in female athletes. There were only three teams included in the analysis, two intervention teams and one control. The intervention teams were both Division I teams, while the control team was a Division II team. There may be a selection bias with respect to level of play by comparing the Division I to II athletes. Furthermore, there was no direct oversight of the implementation of the FIFA 11+ injury prevention intervention. The FIFA 11+ training materials were given to the intervention teams and their Certified Athletic Trainer prior to the beginning of the season. The control group received the materials at the culmination of the study.

Conclusions

The FIFA 11+ program has demonstrated its' ability to initiate favorable biomechanical changes in the hip and knee while performing a single leg squat. Female soccer players utilizing the FIFA 11+ program consistently throughout the course of the season demonstrated improvements in dynamic lateral hip control by demonstrating increased hip flexion, increased hip extensor moments, increased hip abduction moments, and decreased hip internal rotation angle. There were no significant differences in the kinetic and kinematic measurement made at the knee joint. Further research is suggested to study the biomechanical efficacy of the program in male soccer players. Furthermore, additional studies to investigate whether longer exposure, duration and/or increased frequency of performance of the FIFA 11+

program would improve the kinetic and kinematic biomechanical measurements made at the knee as meaningfully as the hip.

Chapter 6

ANALYSIS OF CHANGES TO A TRIPLE HOP MANEUVER OVER THE COURSE OF A COMPETITIVE SEASON IN FEMALE SOCCER PLAYERS

The single leg triple hop test (THT) is a challenging dynamic movement assessment tool that has high functional and clinical utility in assessing power, muscular strength, joint stability, proprioception and neuromuscular control.[184] The THT is widely utilized to assess post-injury or post-operative status, readiness for return to play, limb asymmetry and to, potentially, prospectively identify high-risk athletes by identifying aberrant biomechanical movement patterns.[185-187] The test has been shown to be a valid and reliable measure of lower limb performance[186, 188, 189].including assessing knee flexion excursion upon landing, and has been shown to be a useful clinical tool to predict lower limb strength and power.[190, 191] decreased single-leg hop distance has been correlated with decreased ipsilateral hip abduction strength and poor performance of the single leg squat test.[149] It has also been directly correlated to patient-reported outcome scores, such as KOOS and IKDC.[192] The test requires minimal equipment, is cost effective and can be performed on the playing surface that is native to the athlete's competitive environment.

Single leg triple hop tests can be tested objectively and provide the clinician with important kinetic and kinematic criteria for assessing overall joint stability. Single leg hop tests that simply assess a quantitative outcome measure in distance covered, may not be a useful tool in assessing potential risk.[193] On the contrary, greater single leg hop distances has been correlated with increased risk of injury in male basketball players[194] and was not predictive of dynamic valgus malalignment in young male and female athletes.[195] Hop tests for distance, in isolation, did not provide sufficient evidence about deficiencies in lower extremity strength in isolated muscle groups.[196] A prospective study analyzing injury rates in female military cadets did, however, find a correlation between single leg hop distance and risk of injury.[197] Combining the distance outcomes (quantitative) with a kinetic and kinematic assessment (qualitative) may provide a more comprehensive analysis of the testing protocol.

The qualitative assessment of the THT performance may require sophisticated motion analysis instrumentation and a skilled clinician that can analyze the functional outcomes in order to identify and address the faulty biomechanics that underlie suboptimal movement patterns.[198, 199] The qualitative assessment of the single leg hop test may supersede the quantitative aspect to the test with its' ability to reliably detect biomechanical deficits and injury risk.[200-202] Upon comparing 3D motion analysis of kinetics and kinematics of the THT with 2D video analysis, good correlation exist between the two.[203] This has important implications for clinicians as we try to extrapolate the findings of the motion analysis assessment to field or clinic-based testing.

The single leg THT is often included in a larger battery of tests to analyze function.[186, 187, 194, 204] In this particular study, we are utilizing this test as one of six functional movement tests to analyze the biomechanical changes that are realized after implementing the FIFA 11+ injury prevention protocol to replace an existing dynamic warm-up in competitive collegiate soccer players. The program has previously shown the ability to increase THT distance by 8.3% in male competitive soccer players.[205]

The purpose of this study was to analyze the biomechanical impact of the FIFA 11+ on the performance of the single-leg hop test in Division I and Division II female collegiate soccer players compared to an age and skill matched control group. The study analyzed bilateral hip and knee kinematics during three trials of a dynamic single-leg hop test. Segment kinematics were compared in the frontal, sagittal and transverse planes. We hypothesized the following:

- Hypothesis 5.1: The athletes using the FIFA 11+ program would demonstrate improvements in hip kinetics and kinematics over the course of the season compared to their pre-season assessment and compared to the control group.
- Hypothesis 5.2: The athletes using the FIFA 11+ program would demonstrate improvements in knee kinetics and kinematics over the course of the season compared to their pre-season assessment and compared to the control group.
- Hypothesis 5.3: Athletes using the FIFA 11+ program would demonstrate decreased Peak Knee Abduction Moments (PKAM) and joint angles consistent with decreased dynamic valgus at the knee.
- Hypothesis 5.4: Athletes using the FIFA 11+ program would demonstrate decreased vGRF's upon initial contact of a single leg hop test compared to a control group.

Methods

The subjects for this study were recruited from local universities in close geographic proximity to the motion analysis laboratory. Two Division I and one Division II NCAA collegiate soccer teams were recruited for the study and subsequently enrolled. The study was approved by both the University of Delaware's and Wilmington University's Internal Review Boards (IRB), respectively (Appendix B and C). Each athlete voluntarily agreed to the terms of the study and submitted written informed consent prior to participating in the dynamic testing. The inclusion criteria included all eligible female soccer athletes currently in good academic standing included on the active roster for the current season. Exclusion criteria included any athlete that was currently injured or had a post-surgical status that would prohibit them from participating in the testing protocol.

Demographic information was collected for each individual upon receiving voluntary informed consent. Height, weight, player position, number of years playing soccer, the year in which the subject began to specialize in the sport of soccer, and injury history was collected during the pre-testing protocol. Injuries that occurred during the season were recorded during the post-season testing protocol.

The triple hop test (THT) was performed bilaterally and was analyzed during the preseason and post-season, respectively. Motion analysis of the maneuver was assessed using an eight infrared camera motion analysis system (VICON; Oxford Metrics Ltd, London, England). Twenty-two sixteen-millimeter spherical retro-reflective markers were placed bilaterally on each acromion, each iliac crest in alignment with the greater trochanter, the greater trochanter of each femur, lateral and medial femoral condyles, lateral and medial malleolus and the distal head of the 1st and 5th metatarsal bones, and two markers on the posterior heel. Rigid theromoplastic shells with four markers were affixed using Velcro elastic wraps to the trunk (along the paraspinals), pelvis, lateral thighs, and lateral shanks to track the motion of these segments during dynamic testing. Weight, height, pelvic depth and acromion width were recorded for each subject for input into the biomechanical model. The markers were affixed solely by one researcher (AA), in order to avoid inter-rater reliability issues. A standing calibration was performed to identify joint centers and to create the segment coordinate system. Two force platforms were also utilized during the analysis and recorded ground reaction forces at 1080Hz (Bertec, Worthington, Ohio, USA). The subjects were instructed to wear tight fitting athletic or compression gear in order to expose the joint(s) of interest and to also wear new or gently worn athletic shoes in order to ensure proper tread for dynamic movement control during testing. All verbal instructions for the single leg squat were provided by one researcher (HSG), in order to maintain methodological continuity.

The triple hop test was performed by having the subject stand on one limb on the force plate. The subject was instructed to hop three successive times on one leg for maximal distance to determine the subject's hopping ability in the laboratory. A red six-inch cone was placed to delineate the approximate distance covered. The subject was then given one test trial to learn the task and to identify the proper landing position on the force plate. To begin the activity, the subject lined up next to the red cone standing on the right limb. Three single leg hops were performed in succession for maximal distance. The third landing was made on the force plate, with the foot completely clearing the perimeter of the plate in order to ensure thorough motion analysis. The subject repeated the task two more times on the right leg and three times on their left lower extremity. The subjects were given verbal instruction by one research (HSG) and were allowed to practice the THT one time following the determination of distance covered. Three trials were collected for each limb.

Data Analysis

Kinematic and kinetic data were low pass filtered at 6 Hz and 40 Hz respectively using a second order Butterworth filter. Markers were labeled using Vicon Nexus software (v 1.8.5, VICON, Oxford Metrics Ltd, London, England). If signal gaps occurred due to marker drop out, the software's spline filling algorithm was utilized. In the event that the gaps were persistent and deemed too large for the algorithm to fill, the trial was excluded from the final analysis. Visual3D software was used for the kinematic and inverse dynamic post-processing analyses (Visual 3D, C-Motion Inc., Germantown, Maryland, USA). To remain consistent with the existing literature, moments were calculated as external moments: hip flexion, hip adduction, hip internal rotation, knee extension, and knee adduction were represented as positive values. Variables of interest included peak hip and knee angles and external moments in the frontal, sagittal and transverse planes.

Statistical Analysis

All statistical analyses were conducted utilizing SPSS for Macintosh, Version 24 (Armonk, NY: IBM Corporation) and Microsoft Excel for Mac, 2011 (Redmond, Washington, USA). Means and standard deviations of each variable of interest were calculated in Excel. T-tests were used to compare the demographic variables of the control versus the intervention group (age. height, weight, pelvic depth). One-way ANOVA's were used to analyze age of beginning soccer play and years of soccer experience. Chi-square tests of independence were used to compare year of eligibility, leg dominance and position by group. MANOVA statistical tests were performed to determine if there were biomechanical differences within joint angles and moments between the CG and IG, respectively. Levene's test was used to assess the homogeneity of variance between the groups. If statistical difference were identified, one-way ANOVA's were utilized to identify which variable (pre-test versus post-test) was contributing to the statistically different MANOVA. The effect sizes of each variable were tested using partial eta (η) squared within and between groups (0.01 = small effect, 0.06 = medium effect, and 0.14 = large effect),

Results

Sixty-nine subjects completed the biomechanical testing at two time points and were included in this analysis. Forty of the subjects from two Division I soccer teams were part of the intervention group (IG) and were using the FIFA 11+ program as their dynamic warm-up throughout the course of the season. Twenty-one of the subjects from one Division II soccer team served as the control group (CG) and were not utilizing the proposed intervention. Demographic analysis, including age, height, weight and pelvic depth revealed that there were no significant differences between the IG and the CG.

Between Group Analysis: Triple Hop Test

Significant time*group interactions were found for hip flexion angle ($F(2,104) = 38.725$, $p<0.001$), hip extensor moment ($F(2,104) = 12.794$, $p<0.001$), hip adduction angle ($F(2,104) = 6.301$, $p=0.003$), hip internal rotation angle ($F(2,104) = 11.242$, $p<0.001$), peak knee flexion angle ($F(2,104) = 15.697$, $p<0.001$, peak knee flexion moment ($F(2,104) = 5.551$, $p=0.005$) and peak knee abduction angle ($F(2,104) = 8.314$, $p<0.001$).

There were significant differences between the groups during post-test analysis for peak hip flexion angle ($F(2,104)=31.129$, $p<0.001$), hip extensor moment ($F(2,104)=14.074$, $p<0.001$) and hip adductor angle ($F(2,104)=8.523$, $p<0.004$), hip internal rotation angle ($F(2,104)=14.093$, $p<0.001$), peak knee flexion angle ($F(2,104)= 9.155$, $p=0.003$), peak knee flexion moment ($F(2,104)=6.648$, $p=0.011$), and knee abduction angle ($F(2,104)=11.961$, $p=0.011$).

There were significant differences between groups in both pre-test ($F(2,104) = 78.708$, $p<0.001$) and post-test ($F(2,104)=78.708$, $p<0.001$) hip flexion angles. There was a slight decrease in peak hip flexion angle in the IG (9.01%, $p=0.78$) compared to a small increase in hip flexion angle in the CG (5.4%, $p=0.07$). The mean difference in hip flexion angle between groups, however, significantly favored the IG, with the IG averaging 17.43 more degrees of hip flexion compared to the CG. (Table 13).

There was a significant between group difference in hip flexor moments for both the pre-test ($F(1,105) = 18.175$, $p<0.001$) and post-test ($F(1,105) = 14.074$, $p<0.001$) measurements, with the IG demonstrating a greater hip flexor moment than the CG. (Table 13) There was no significant within group differences (IG: $p=0.15$, CG: $p=0.10$).

There were significant between group difference in hip adductor angle for both the pre-test ($F(1,105)=8.697$, $p<0.001$) and post-test (F(1,105, $p<0.004$), with both groups demonstrating a non-significant decrease in hip adductor angle over the course of the season (IG: 15.2% decrease, $p=0.10$ versus CG: 29.0% decrease, $p=0.07$).

There were significant between group difference in hip internal rotation angle for both the pre-test ($F(1,105)=15.562$, $p<0.001$) and post-test ($F(1,105)=14.093$, $p<0.001$) measurements, with both groups demonstrating a significant difference in hip internal rotation over the course of the season (IG: 32.8%, $p<0.001$ versus CG: 43.9% decrease, $p=0.011$)

There were significant between group differences in peak knee flexion angles for both the pre-test ($F(1,105)=28.991$, $p<0.001$) and post-test ($F(1,105)=9.155$, $p=0.003$) measurements. There was no statistical change in within group measurement (IG: $p=0.73$ versus CG: $p=0.23$). However, similar to the findings in hip flexion, the mean difference of knee flexion angle between groups, however, significantly favored the IG, with the IG averaging 10.37 more degrees of hip flexion that the CG. (Table 13, Figure 4).

There were significant between group differences in peak knee flexion moments for the post-test ($F(1,105)=6.648$, $p=0.011$) , but not the pre-test ($F(1,105)=1.636$, $p=0.204$) measurements. There was no significant difference in post-test knee flexion moment for the IG ($p=0.09$) or the CG ($p=0.23$).

There were significant between group differences in peak knee abduction angle for both the pre-test ($F(1,105)=16.459$, $p<0.001$) and the post-test ($F(1,105)=18.619$, $p<0.001$) measurements. There was a significant increase in knee abduction angle in the CG (67.2% increase, $p=0.001$) , but not in the IG ($p=0.09$). Furthermore, the CG demonstrated a positive value for knee adduction during the pre-test and a negative value during the post-test, demonstrating and increase in knee abduction. The IG maintained and knee adduction angle during the course of the competitive season. (Table 13)

There were no significant between group differences in peak knee abduction moment for both the pre-test ($F(1,105)=1.647$, $p=0.202$) and the post-test ($F(1,105)=1.778$, $p=0.185$) measurements.

Variable	Intervention (M±SD)		Control (M±SD)		P value	partial η2
	Pre	Post	Pre	Post		
Hip Flexion Angle (°)	55.10±14.13	50.19±15.96	30.90±10.23	32.75±10.73	<0.001	0.427
Hip Extension Moment (Nm/kgm)	-0.83±0.50	-0.82±0.67	-0.40±0.39	-0.35±0.24	<0.001	0.197
Hip Adduction Angle (°)	9.55±5.41	8.09±6.04	6.27±4.66	4.58±4.46	0.003	0.108
Hip Abduction Moment (Nm/kgm)*	-0.89±0.36	-0.83±0.35	-1.01±0.18	-1.46±2.06	0.051	0.056
Peak Hip IR Angle (°)	11.02±5.57	7.40±4.97	6.49±4.88	3.64±3.93	<0.001	0.178
Hip IR Moment (Nm/kgm)	-0.03±0.05	-0.15±0.51	-0.03±0.04	-0.03±0.05	0.354	0.02
Peak Knee Flexion Angle (°) **	-67.10±9.49	-66.63±11.25	-56.73±7.78	-59.67±9.57	<0.001	0.232
Peak Knee Flexion Moment (Nm/kgm)	1.54±0.31	1.67±0.51	1.62±0.25	1.38±0.56	0.005	0.096
Peak Knee Abduction Angle (°)**	7.31±6.05	4.20±5.71	2.29±5.06	-0.75±4.48	<0.001	0.214
Peak Knee Abduction Moment (Nm/kgm)***	-0.88±0.36	-1.46±0.86	-1.01±0.18	-0.83±0.35	0.18	0.032

Table 13 Mean, Standard Deviation, P value and Effect size (partial η2) for pre and post-test kinetic and kinematic variables of the triple hop test. * Negative hip moment values indicate a hip abduction moment. ** Negative peak knee angle values indicate knee flexion (x) and knee abduction (y). ***Negative peak knee moments indicate knee extensor moment and knee adductor moment.

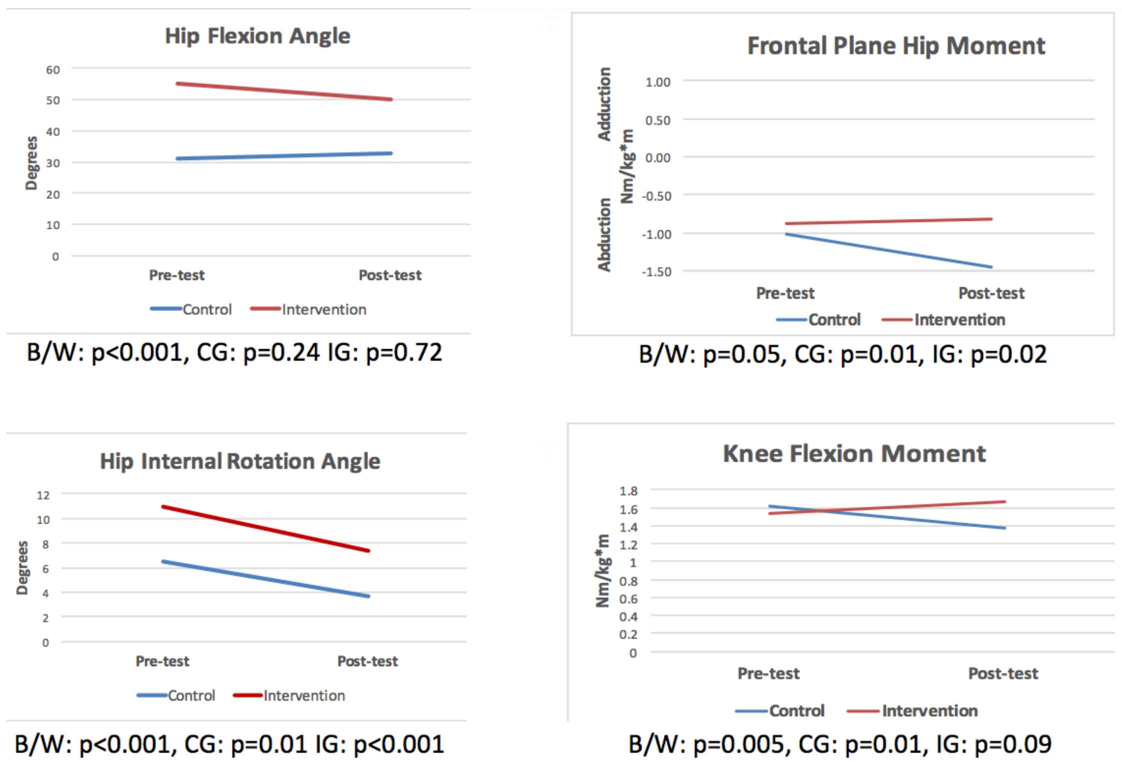

Figure 4 Kinetic and Kinematic variables of Triple Hop for knee and hip variables.

Peak vertical ground reaction forces (vGRF) were normalized for height (meters) and body weight (kg). There was no statistical difference between pre and post-test peak vGRF between groups (F(2,52)= 0.220, p=0.804) (Table 13)

Time of Testing	Control	Intervention	P value	Partial η2
	Mean±SD N/kg*m	Mean±SD N/kg*m		
Pre-test	2203.44±591.76	2275.77±498.45	0.891	<0.001
Post-test	2093.44±435.42	2250.64±558.36	0.507	0.009

Table 14 Peak vertical GRFs (vGRF) normalized for height and weight for pre and post-test analysis of the triple hop test

Discussion

This study investigated the effect of the FIFA 11+ injury prevention program has on the kinetics and kinematics of female soccer players performing a triple hop test after using the FIFA 11+ as their dynamic warm-up throughout the course of a competitive season. In previous publications, the program has demonstrated its' ability to decrease the rate of soccer related injury in male and female soccer players.[32, 34, 45, 77] An understanding of how of if the program effectively modifies faulty movement patterns has not been elucidated to date.

The results of this study suggest that the FIFA 11+ program may positively impact the hip and knee kinetics and kinematics of the lower extremity during a triple hop test. There were significant main effects (group*time) found for seven different variables: hip flexion angle, hip extensor moment, hip adduction angle and moment, peak knee flexion angle, peak knee flexion moment and peak knee abduction angle; with the intervention group demonstrating favorable changes and improved biomechanics over the course of the season compared to the control group. During the within-group analysis, there were favorable statistical changes demonstrated by decreased hip internal rotation angle, decreased hip internal rotation moment, and decreased knee abduction moment for the IG. (Table 13). Additionally, there were significant differences between groups for both knee and hip flexion angles, with the IG demonstrating significantly greater knee and hip flexion at both the pre-test and post-testing sessions. After normalizing for height and weight, there were no significant differences found between groups for peak vertical ground reaction forces (vGRF). (Table 14) These findings support the notion that the FIFA 11+ significantly alters hip and knee kinetics and kinematics when performing a single leg triple hop test.

The FIFA 11+ program was designed by an international group of clinical researchers imbedded in the sport of soccer.[34] The impetus to design the program emanated from the body of research examining the rising rate of soccer related injury.[61, 69, 85, 206] The contents of the program have a heavy emphasis on core/trunk control and control of the proximal segment of the lower extremity. The founders of the program thought that by emphasizing core, trunk and hip control, the program may mitigate risk to the lower extremity. The program has been shown to be an optimal warm-up program that optimally prepares the athlete for competition.[112] The FIFA 11+ has been shown to have positive effects on sprint testing, vertical jump performance, agility testing, improvements in neuromuscular control and time to stabilization.[113] These studies reinforce the concept that the components of the FIFA 11+ heavily emphasize neuromuscular control and dynamic lower limb stability.

The results of this investigation suggest that the FIFA 11+ protocol may have favorable effects on the kinetics and kinematics of the hip and knee in female collegiate soccer players that are utilizing the protocol. The athletes in the intervention group using the FIFA 11+ demonstrated statistically favorable changes in the hip and knee joints. There were significant and favorable findings found in the IG for hip internal rotation angle and moment, and knee abduction moment. In addition, the hip and knee flexion angles in the IG exceeded that of the CG for both the pre and post-testing session. This has important implication with respect to injury risk, including ACL injury risk. Analysis of ACL injuries occurring in the sport of soccer have been shown to occur with the hip and knee at or near full extension, particularly when playing in a defensive role.[68, 74] In addition, ACL injury risk is increased during single leg landing activities that are performed with inadequate flexion of the knee and hip. The goal of this body of work is to prospectively identify female collegiate athletes who demonstrate poor sagittal plane landing kinematics to mitigate injury risk in the future, The ultimate goal is prevention, or reduction, of injury rate.

Hip internal rotation and decreased lateral hip strength are complicit with dynamic knee valgus and have been identified as risk factors for ACL injury in females.[152, 207, 208] Athletes that have sustained an ACL injury and have successfully returned to play continue to demonstrate deficits of the lateral hip, including decreased hip external rotation strength.[209] Deficiencies in gluteus maximus and gluteus medius strength have been associated with increased valgus at the knee in women. [210] Female soccer players with increased hip external rotation strength have improved control of the lower extremity during single leg landing and dynamic cutting tasks. This research continues to establish the important relationship between lateral and posterior hip strength and lower extremity landing mechanics. The FIFA 11+ protocol includes several exercises that target the lateral and posterior hip.

[91] The findings in this study support prior research that demonstrates decreased risk to injury by virtue of utilizing the FIFA 11+ with high compliance. [34, 79]

Limitations

There are several limitations to this current study. The biomechanical analysis was only conducted in female athletes. There were only three teams included in the analysis, two intervention teams and one control. The intervention teams were both Division I teams, while the control team was a Division II team. There may be a selection bias with respect to level of play by comparing the Division I to II athletes. Furthermore, there was no direct oversight of the implementation of the FIFA 11+ injury prevention intervention. The FIFA 11+ training materials were given to the intervention teams and their Certified Athletic Trainers prior to the beginning of the season.

Conclusions

The FIFA 11+ program resulted in favorable biomechanical changes in the hip and knee while performing a triple hop test. Female soccer using the FIFA 11+ program throughout the course of the season demonstrated improvements in dynamic lateral hip control by demonstrating decreased hip internal rotation angle, decreased hip internal rotation moment, and decreased knee abduction moment. These biomechanical findings support the notion that the FIFA 11+ program may provide a protective benefit to the athletes who perform the program consistently.

Chapter 7

IMPLICATIONS FOR EFFECTIVELY IMPLEMENTING THE FIFA 11+ PROGRAM

Purpose

The overall goals of this body of work were to expand the existing literature and 1) evaluate the efficacy of an injury prevention program (FIFA 11+) in a large scale randomized controlled trial involving sixty-one NCAA male collegiate soccer teams, 2) identify how the FIFA 11+ program may effectively reduce the rate of ACL injury, 3) identify how program compliance affects injury rate and overall soccer team performance, and 4) to analyze the kinetic and kinematic biomechanical changes associated with the utilization of the FIFA 11+ over a competitive season in collegiate soccer players across Division I and II. Specifically, we aimed to identify what biomechanical variables were being favorably changed by virtue of implementing the program. The central hypotheses were 1) the FIFA 11+ program would reduce injury in the intervention cohort, 2) high compliance to the program will allow for a further decrease in injury rate, and 3) the athletes utilizing the FIFA 11+ protocol would demonstrate improvements in a biomechanical testing protocol compared to a age and skill matched control group.

Efficacy of the FIFA 11+ Program in Male Collegiate Soccer Players

Aim 1: Determine the efficacy of the FIFA 11+ injury prevention program in Division I and Division II male collegiate soccer players.

Hypothesis 1.1: Athletes utilizing the FIFA 11+ program as their dynamic warm-up will demonstrate lower game and practice injury rates compared to their age and skill matched control counterparts.

Hypothesis 1.2: Athletes utilizing the FIFA 11+ program as their dynamic warm-up will demonstrate decreased severity of injury, translating to a decrease in time loss secondary to injury, compared to the control group.

Hypothesis 1.3: Athletes in the intervention group utilizing the FIFA 11+ program will demonstrate a decrease in injury rate (IR) on the day of actual utilization compared to days that the program is not utilized.

Hypothesis 1.4: Athletes utilizing the FIFA 11+ program will demonstrate a lower rate of ACL injuries compared to their age and skill matched control counterparts.

The findings in Aim 1 corroborated prior evidence in female soccer players that suggested that the FIFA 11+ program is an effective tool to decrease soccer injury in men. The program is a cost-effective and time efficient training program to reduce the risks associated with playing the sport of soccer. The program also illustrated that as program fidelity and compliance improve, injury rates decline further. The findings in Chapter 3 illustrate the importance of consistent and cohesive program implementation in order to reap the benefit of injury reduction. Our hypothesis for Aim 1 was supported. Athletes using the FIFA 11+ program demonstrated lower injury rates compared to a control group. Severity of injury was also decreased, demonstrated by the truncated time loss due to injury compared to injuries that occurred in the control group. The day of utilization of the FIFA 11+ protocol demonstrated lower injury rates and a decreased time loss due to injury compared to days when the program was not utilized, suggesting a cortical control component to the program. In addition, soccer players that utilized the FIFA 11+ program demonstrated a lower rate of ACL injury. Further research is needed to identify the optimal dosage of the program and to determine if this program is effective in the collegiate female and professional soccer player.

Comparison of Tertiles of Compliance with respect to Injury Rate

Aim 2: Determine how variation in compliance impacts the ability of an injury prevention program to impart its' benefit onto the athletes and the overall success of a soccer campaign.

Hypothesis 2.1: Teams with higher compliance to the FIFA 11+ program will demonstrate lower injury rates throughout the course of a competitive season.

Hypothesis 2.2: Teams with higher compliance to the FIFA 11+ program will experience decreased time loss due to injury than teams with moderate or lower compliance to the protocol.

Hypothesis 2.3: Teams with higher compliance to the FIFA 11+ program will demonstrate an improvement in their overall win-loss record compared to the control team and to the teams with low(er) compliance to the prevention program.

Compliance, program fidelity and adherence to injury prevention protocols continue to beleaguer the medical community. Despite an abundance of research that supports the efficacy, safety and cost-effectiveness of injury prevention protocols, the rate of utilization is seemingly low. Improvements to program delivery and dissemination have made these programs freely and widely available, on a global scale. The findings in chapter 2 highlight how impactful high compliance to the FIFA 11+ can be. Our hypotheses in Aim 2 were fully supported. The high compliance teams implementing the program demonstrated lower injury rates, endured fewer days lost to injury and demonstrated a higher win and lower loss percentage with respect to team performance. These critical and beneficial aspects of the program can potentially be used to broaden the public health message and encourage more widespread use of injury prevention methodology.

Aim 3: Quantify biomechanical differences between a baseline pre and post-season single leg squat and triple hop testing assessment in collegiate soccer players

Hypothesis 3.1: Players participating in the FIFA 11+ dynamic warm-up will demonstrate favorable biomechanical changes in sagittal plane kinetics and kinematics during the single leg squat and triple hop tests compared to the control group.

Hypotheses 3.2: Players participating in the FIFA 11+ dynamic warm-up will demonstrate favorable biomechanical changes in frontal plane kinetics and kinematics of hip and knee during the single leg squat and triple hop tests compared to the control group.

A significant body of literature has substantiated the merits of injury prevention implementation over the past three decades. There is a scarcity of work, however, that analyzes the mechanistic underpinnings of what the intervention is actually accomplishing from a biomechanical perspective. Mechanism of injury and the prospective identification of high-risk movement patterns are at the forefront of many clinicians' minds. The findings of chapters 5 and 6 elucidated the biomechanical protective changes that are realized by the individuals performing the FIFA 11+ program. Both of the hypotheses were supported; there were favorable kinetic and kinematic changes found in the intervention group in both the frontal and sagittal planes during both tasks. These findings are elucidating the nature or how an effective injury prevention program imparts its' benefit unto the athletes that perform it. By analyzing the changes demonstrated in the intervention group, and the biomechanics that remained unaltered or deficient, we can continue to redesign, refine and improve upon the existing neuromuscular training protocols. These data are a critical element to the injury reduction puzzle, and will allow researchers to analyze and examine shortcomings in the existing prevention protocols.

Clinical Relevance

The overarching theme of this dissertation was to establish the efficacy of the FIFA 11+ in the male collegiate soccer player and to further understand the biomechanical mechanism that allow these programs to be successful. The program has demonstrated its' ability to reduce injury rates and severity of injury. Program compliance is paramount; the more consistently the program was utilized, the greater the injury prevention benefit was imparted onto the athlete. Furthermore, the ability for the athlete to stay healthy and available for selection throughout the competitive season seemingly allowed teams to perform more favorably. The benefits of sport participation are numerous, and far outweigh the risks. The likelihood of incurring an injury by virtue of participating in soccer should not be underestimated. As clinicians and researchers, we must collectively recognize the risks associated with sport and implement the prevention protocols that have published to date. The information provided in this dissertation may help reduce the incidence of soccer related injuries.

We recognize the need for optimal program adherence and additional randomized controlled trials to continue to elucidate the etiology, mechanism of injury and the need for continued biomechanical analysis of athletes to address the deficits that may inhibit their overall athletic performance and their ability to enjoy a functional, healthy and active lifestyle.

REFERENCES

1. Dvorak, J., Junge, A., *F-MARC Football Medicine Manual: 1994-2005.* Federation Internationale de Football Association, 2005: p. 81-93.
2. FIFA. *270 Million people active in football*. 2006; Available from: http://www.fifa.com/mm/document/fifafacts/bcoffsurv/bigcount.statspackage_7024.pdf.
3. Bizzini M, I.F., Dvorak J, Bortolan L, Schena F, Modena R, Junge A. , *Physological and performance responses to the "FIFA 11+" (part 1): is it an appropriate warm-up? Part 1.* J Sports Sci., 2013. **31**(13): p. 481-90.
4. Bureau, U.S.C. *Participation in Selected Sports Activities: 2009*. 2012; Available from: https://www.census.gov/compendia/statab/2012/tables/12s1249.pdf.
5. Morris, B. *Why is the U.S. So good at women's soccer?* 2015 [cited 2015 12/13/2015]; Available from: http://fivethirtyeight.com/datalab/why-is-the-u-s-so-good-at-womens-soccer/.
6. MLSsoccer.com, *MLS Commissioner Don Garber covers it all in annual address*. Feb. 27, 2013: MLSsoccer.com.
7. Jeffrey, T.P. *Football is the Top Sport in U.S: 1,088,158 High School Players*. 2014 [cited 2015 12/13/2015]; Available from: http://cnsnews.com/news/article/terence-p-jeffrey/football-top-sport-us-1088158-high-school-players.
8. NCAA, *Estimated Probability of Competing in Athletics Beyond the High School Interscholastic Level.* NCAA Research, 2012.
9. McErlain, E. *CSC Study on NCAA Soccer Highlights Opportunity Gap Between Male and Female Players*. 2010 [cited 2015 12/13/2015]; Available from: http://savingsports.blogspot.com/2010/06/soccer-opportunity-gap-in-pictures.html.
10. Arendt, E. and R. Dick, *Knee injury patterns among men and women in collegiate basketball and soccer. NCAA data and review of literature.* Am J Sports Med, 1995. **23**(6): p. 694-701.
11. Bailey R, E.L., *Incidence of injuries among male soccer players in the first team of the University of the Free State in the Coca Cola League – 2007. 2008 season.* SA J Sports Med, 2009. **21**(1): p. 3-6.
12. Brophy, R.H., H.J. Silvers, and B.R. Mandelbaum, *Anterior cruciate ligament injuries: etiology and prevention.* Sports Med Arthrosc, 2010. **18**(1): p. 2-11.

13. Caraffa, A., et al., *Prevention of anterior cruciate ligament injuries in soccer. A prospective controlled study of proprioceptive training.* Knee Surg Sports Traumatol Arthrosc, 1996. **4**(1): p. 19-21.
14. Cerulli, G., et al., *Proprioceptive training and prevention of anterior cruciate ligament injuries in soccer.* J Orthop Sports Phys Ther, 2001. **31**(11): p. 655-60; discussion 661.
15. Chandy, T., Grana, WA, *Secondary school athletic injury in boys and girls: A three year comparison. .* The Physician and Sportsmedicine, 1985. **13**: p. 106-111.
16. Ekstrand, J. and J. Gillquist, *Soccer injuries and their mechanisms: a prospective study.* Med Sci Sports Exerc, 1983. **15**(3): p. 267-70.
17. Junge, A., et al., *Prevention of soccer injuries: a prospective intervention study in youth amateur players.* Am J Sports Med, 2002. **30**(5): p. 652-9.
18. McLean, S.G., et al., *Sagittal plane biomechanics cannot injure the ACL during sidestep cutting.* Clin Biomech (Bristol, Avon), 2004. **19**(8): p. 828-38.
19. Morgan, B.E. and M.A. Oberlander, *An examination of injuries in major league soccer. The inaugural season.* Am J Sports Med, 2001. **29**(4): p. 426-30.
20. Agel J, E.T., Dick R. , *Descriptive epidemiology of collegiate men's soccer injuries: National Collegiate Athletic Association Injury Surveillance System,1988-1989 through 2002-2003.* J Athl Train., 2007. **42**(2): p. 270-7.
21. Bollars, P., et al., *The effectiveness of preventive programs in decreasing the risk of soccer injuries in Belgium: national trends over a decade.* Am J Sports Med, 2014. **42**(3): p. 577-82.
22. Daneshjoo, A., et al., *The effects of injury prevention warm-up programmes on knee strength in male soccer players.* Biol Sport, 2013. **30**(4): p. 281-8.
23. Ekstrand, J., et al., *Considerably decreased amount of soccer injuries after introduction of a preventive program.* Lakartidningen, 1983. **80**(17): p. 1803-4, 9.
24. Gilchrist, J., et al., *A randomized controlled trial to prevent noncontact anterior cruciate ligament injury in female collegiate soccer players.* Am J Sports Med, 2008. **36**(8): p. 1476-83.
25. Hagglund, M., M. Walden, and I. Atroshi, *Preventing knee injuries in adolescent female football players - design of a cluster randomized controlled trial [NCT00894595].* BMC Musculoskelet Disord, 2009. **10**: p. 75.
26. Hagglund, M., M. Walden, and J. Ekstrand, *Injuries among male and female elite football players.* Scand J Med Sci Sports, 2009. **19**(6): p. 819-27.
27. Malinzak, R.A., et al., *A comparison of knee joint motion patterns between men and women in selected athletic tasks.* Clin Biomech (Bristol, Avon), 2001. **16**(5): p. 438-45.
28. Mandelbaum, B., et al., *Effectiveness of a neuromuscular and proprioceptive training program in preventing anterior cruciate ligament injuries in female*

athletes - 2-year follow-up. American Journal of Sports Medicine, 2005. **33**(7): p. 1003-1010.
29. Myklebust, G., et al., *Prevention of anterior cruciate ligament injuries in female team handball players: a prospective intervention study over three seasons.* Clin J Sport Med, 2003. **13**(2): p. 71-8.
30. Myklebust, G., et al., *Prevention of noncontact anterior cruciate ligament injuries in elite and adolescent female team handball athletes.* Instr Course Lect, 2007. **56**: p. 407-18.
31. Ostenberg, A. and H. Roos, *Injury risk factors in female European football. A prospective study of 123 players during one season.* Scand J Med Sci Sports, 2000. **10**(5): p. 279-85.
32. Owoeye, O.B., et al., *Efficacy of the FIFA 11+ Warm-Up Programme in Male Youth Football: A Cluster Randomised Controlled Trial.* J Sports Sci Med, 2014. **13**(2): p. 321-8.
33. Pfeiffer, R.P., et al., *Lack of effect of a knee ligament injury prevention program on the incidence of noncontact anterior cruciate ligament injury.* J Bone Joint Surg Am, 2006. **88**(8): p. 1769-74.
34. Soligard, T., et al., *Comprehensive warm-up programme to prevent injuries in young female footballers: cluster randomised controlled trial.* Bmj, 2008. **337**: p. a2469.
35. Hewett TE, M.G., Ford KR. , *Reducing knee and anterior cruciate ligament injuries among female athletes: a systematic review of neuromuscular training interventions.* J Knee Surg., 2005. **18**(1): p. 82-8.
36. Fernandez, W.G., E.E. Yard, and R.D. Comstock, *Epidemiology of lower extremity injuries among U.S. high school athletes.* Acad Emerg Med, 2007. **14**(7): p. 641-5.
37. Ekstrand, J. and J. Gillquist, *The avoidability of soccer injuries.* Int J Sports Med, 1983. **4**(2): p. 124-8.
38. Fuller, C.W., et al., *Consensus statement on injury definitions and data collection procedures in studies of football (soccer) injuries.* Clin J Sport Med, 2006. **16**(2): p. 97-106.
39. Hagglund, M., M. Walden, and J. Ekstrand, *Lower reinjury rate with a coach-controlled rehabilitation program in amateur male soccer: a randomized controlled trial.* Am J Sports Med, 2007. **35**(9): p. 1433-42.
40. Koutures, C.G. and A.J. Gregory, *Injuries in youth soccer.* Pediatrics, 2010. **125**(2): p. 410-4.
41. Commission, U.C.P.S., *National Electronic Injury Surveillance System Data [2006 data]*, C.P.S. Commission, Editor. 2007: Washington, DC: US.
42. Agel J, E.T., Dick R, *Descriptive epidemiology of collegiate men's soccer injuries: National Collegiate Athletic Association Injury Surveillance System.* J Athl Train, 2007. **42**(2): p. 270-7.

43. Hootman, J.M., R. Dick, and J. Agel, *Epidemiology of Collegiate Injuries for 15 Sports: Summary and Recommendations for Injury Prevention Initiatives.* Journal of Athletic Training, 2007. **42**(2): p. 311-319.
44. Yard, E.E., C.L. Collins, and R.D. Comstock, *A comparison of high school sports injury surveillance data reporting by certified athletic trainers and coaches.* J Athl Train, 2009. **44**(6): p. 645-52.
45. Grooms, D.R., et al., *Soccer-specific warm-up and lower extremity injury rates in collegiate male soccer players.* J Athl Train, 2013. **48**(6): p. 782-9.
46. Steffen, K., et al., *Evaluation of how different implementation strategies of an injury prevention programme (FIFA 11+) impact team adherence and injury risk in Canadian female youth football players: a cluster-randomised trial.* Br J Sports Med, 2013. **47**(8): p. 480-7.
47. Steffen, K., et al., *Preventing injuries in female youth football--a cluster-randomized controlled trial.* Scand J Med Sci Sports, 2008. **18**(5): p. 605-14.
48. Faude, O., et al., *Risk factors for injuries in elite female soccer players.* Br J Sports Med, 2006. **40**(9): p. 785-90.
49. Hewett TE, L.T., Riccobene JV, Noyes FR. , *The effect of neuromuscular training on the incidence of knee injury in female athletes. A prospective study.* Am J Sports Med. 1999, 1999. **27**(6): p. 699-706.
50. Brophy, R., et al., *Gender influences: the role of leg dominance in ACL injury among soccer players.* Br J Sports Med, 2010. **44**(10): p. 694-7.
51. Griffin, L.Y., et al., *Noncontact anterior cruciate ligament injuries: risk factors and prevention strategies.* J Am Acad Orthop Surg, 2000. **8**(3): p. 141-50.
52. Griffin, L.Y., et al., *Understanding and preventing noncontact anterior cruciate ligament injuries: a review of the Hunt Valley II meeting, January 2005.* Am J Sports Med, 2006. **34**(9): p. 1512-32.
53. Alentorn-Geli, E., et al., *Prevention of non-contact anterior cruciate ligament injuries in soccer players. Part 2: a review of prevention programs aimed to modify risk factors and to reduce injury rates.* Knee Surg Sports Traumatol Arthrosc, 2009. **17**(8): p. 859-79.
54. Alentorn-Geli, E., et al., *Prevention of non-contact anterior cruciate ligament injuries in soccer players. Part 1: Mechanisms of injury and underlying risk factors.* Knee Surg Sports Traumatol Arthrosc, 2009. **17**(7): p. 705-29.
55. Alentorn-Geli E, M.J., Samuelsson K, Musahl V, Karlsson J, Cugat R, Myer GD, *Prevention of anterior cruciate ligament injuries in sports. Part I: systematic review of risk factors in male athletes.* Knee Surg Sports Traumatol Arthrosc, 2014. **22**(1): p. 3-15.
56. Alentorn-Geli E, M.J., Samuelsson K, Musahl V, Karlsson J, Cugat R, Myer GD, *Prevention of non-contact anterior cruciate ligament injuries in sports. Part II: systematic review of the effectiveness of prevention programmes in male athletes.* Knee Surg Sports Traumatol Arthrosc, 2014. **22**(1): p. 16-25.

57. Croisier, J., *Factors associated with recurrent hamstring injuries.* . Sports Med, 2004. **34**(10): p. 681-695.
58. Arnason, A., et al., *Prevention of hamstring strains in elite soccer: an intervention study.* Scand J Med Sci Sports, 2008. **18**(1): p. 40-8.
59. Arnason, A., et al., *Soccer injuries in Iceland.* Scand J Med Sci Sports, 1996. **6**(1): p. 40-5.
60. Ekstrand, J., et al., *Incidence of soccer injuries and their relation to training and team success.* Am J Sports Med, 1983. **11**(2): p. 63-7.
61. Ekstrand, J., M. Hagglund, and M. Walden, *Epidemiology of muscle injuries in professional football (soccer).* Am J Sports Med, 2011. **39**(6): p. 1226-32.
62. Engebretsen, A.H., et al., *Intrinsic risk factors for groin injuries among male soccer players: a prospective cohort study.* Am J Sports Med, 2010. **38**(10): p. 2051-7.
63. Engebretsen, A.H., et al., *Intrinsic risk factors for hamstring injuries among male soccer players: a prospective cohort study.* Am J Sports Med, 2010. **38**(6): p. 1147-53.
64. Giza E, M.K., Farrell L, Zarins B, Gill T. , *Injuries in women's professional soccer.* British Journal of Sports Medicine 2005. **39**: p. 212-6.
65. Hagglund, M., et al., *Methods for epidemiological study of injuries to professional football players: developing the UEFA model.* Br J Sports Med, 2005. **39**(6): p. 340-6.
66. Kristenson, K., et al., *The Nordic Football Injury Audit: higher injury rates for professional football clubs with third-generation artificial turf at their home venue.* Br J Sports Med, 2013. **47**(12): p. 775-81.
67. Brophy, R.H., et al., *Differences between sexes in lower extremity alignment and muscle activation during soccer kick.* J Bone Joint Surg Am, 2010. **92**(11): p. 2050-8.
68. Brophy, R.H., et al., *Defending Puts the Anterior Cruciate Ligament at Risk During Soccer: A Gender-Based Analysis.* Sports Health, 2015. **7**(3): p. 244-9.
69. Ekstrand, J., M. Hagglund, and M. Walden, *Injury incidence and injury patterns in professional football: the UEFA injury study.* Br J Sports Med, 2011. **45**(7): p. 553-8.
70. Dick, R., J. Agel, and S.W. Marshall, *National Collegiate Athletic Association Injury Surveillance System commentaries: introduction and methods.* J Athl Train, 2007. **42**(2): p. 173-82.
71. Mandelbaum, B.R., et al., *Effectiveness of a neuromuscular and proprioceptive training program in preventing anterior cruciate ligament injuries in female athletes: 2-year follow-up.* Am J Sports Med, 2005. **33**(7): p. 1003-10.
72. Giza, E., H.J. Silvers, and B.R. Mandelbaum, *Anterior cruciate ligament tear prevention in the female athlete.* Curr Sports Med Rep, 2005. **4**(3): p. 109-11.
73. Salgado, E., F. Ribeiro, and J. Oliveira, *Joint-position sense is altered by football pre-participation warm-up exercise and match induced fatigue.* Knee, 2015. **22**(3): p. 243-8.

74. Walden, M., et al., *Three distinct mechanisms predominate in non-contact anterior cruciate ligament injuries in male professional football players: a systematic video analysis of 39 cases.* Br J Sports Med, 2015. **49**(22): p. 1452-60.
75. Junge, A., et al., *Countrywide campaign to prevent soccer injuries in Swiss amateur players.* Am J Sports Med, 2011. **39**(1): p. 57-63.
76. Lohmander, L.S., et al., *High prevalence of knee osteoarthritis, pain, and functional limitations in female soccer players twelve years after anterior cruciate ligament injury.* Arthritis Rheum, 2004. **50**(10): p. 3145-52.
77. Silvers-Granelli, H., et al., *Efficacy of the FIFA 11+ Injury Prevention Program in the Collegiate Male Soccer Player.* Am J Sports Med, 2015.
78. Soligard, T., et al., *Compliance with a comprehensive warm-up programme to prevent injuries in youth football.* Br J Sports Med, 2010. **44**(11): p. 787-93.
79. Steffen, K., et al., *High adherence to a neuromuscular injury prevention programme (FIFA 11+) improves functional balance and reduces injury risk in Canadian youth female football players: a cluster randomised trial.* Br J Sports Med, 2013. **47**(12): p. 794-802.
80. Carling, C., F. Le Gall, and G. Dupont, *Are physical performance and injury risk in a professional soccer team in match-play affected over a prolonged period of fixture congestion?* Int J Sports Med, 2012. **33**(1): p. 36-42.
81. Dellal, A., et al., *The effects of a congested fixture period on physical performance, technical activity and injury rate during matches in a professional soccer team.* Br J Sports Med, 2015. **49**(6): p. 390-4.
82. Frank, B.S., J. Register-Mihalik, and D.A. Padua, *High levels of coach intent to integrate a ACL injury prevention program into training does not translate to effective implementation.* J Sci Med Sport, 2015. **18**(4): p. 400-6.
83. Gabbett, T.J., *The training-injury prevention paradox: should athletes be training smarter and harder?* Br J Sports Med, 2016. **50**(5): p. 273-80.
84. Gatterer, H., et al., *Effects of the performance level and the FIFA "11" injury prevention program on the injury rate in Italian male amateur soccer players.* J Sports Med Phys Fitness, 2012. **52**(1): p. 80-4.
85. Emery, C.A., et al., *Risk of injury and concussion associated with team performance and penalty minutes in competitive youth ice hockey.* Br J Sports Med, 2011. **45**(16): p. 1289-93.
86. Gabbett, T.J., *Influence of injuries on team playing performance in Rugby League.* J Sci Med Sport, 2004. **7**(3): p. 340-6.
87. Otten, M.P. and T.J. Miller, *A BALANCED TEAM WINS CHAMPIONSHIPS: 66 YEARS OF DATA FROM THE NATIONAL BASKETBALL ASSOCIATION AND THE NATIONAL FOOTBALL LEAGUE.* Percept Mot Skills, 2015. **121**(3): p. 654-65.
88. Inklaar, H., et al., *Injuries in male soccer players: team risk analysis.* Int J Sports Med, 1996. **17**(3): p. 229-34.

89. McCall, A., et al., *Injury risk factors, screening tests and preventative strategies: a systematic review of the evidence that underpins the perceptions and practices of 44 football (soccer) teams from various premier leagues.* Br J Sports Med, 2015. **49**(9): p. 583-9.
90. McCall, A., et al., *Risk factors, testing and preventative strategies for non-contact injuries in professional football: current perceptions and practices of 44 teams from various premier leagues.* Br J Sports Med, 2014. **48**(18): p. 1352-7.
91. Bizzini, M. and J. Dvorak, *FIFA 11+: an effective programme to prevent football injuries in various player groups worldwide-a narrative review.* Br J Sports Med, 2015. **49**(9): p. 577-9.
92. Agel, J., E.A. Arendt, and B. Bershadsky, *Anterior cruciate ligament injury in national collegiate athletic association basketball and soccer: a 13-year review.* Am J Sports Med, 2005. **33**(4): p. 524-30.
93. Agel, J. and J. Schisel, *Practice injury rates in collegiate sports.* Clin J Sport Med, 2013. **23**(1): p. 33-8.
94. Arendt, E.A., J. Agel, and R. Dick, *Anterior cruciate ligament injury patterns among collegiate men and women.* J Athl Train, 1999. **34**(2): p. 86-92.
95. Azubuike, S.O. and O.H. Okojie, *An epidemiological study of football (soccer) injuries in Benin City, Nigeria.* Br J Sports Med, 2009. **43**(5): p. 382-6.
96. Ekstrand J, H.M., Fuller CW. , *Comparison of injuries sustained on artificial turf and grass by male and female elite football players.* Scand J Med Sci Sports., 2010. **21**(6): p. 824-32.
97. Chappell, J.D., et al., *Effect of fatigue on knee kinetics and kinematics in stop-jump tasks.* Am J Sports Med, 2005. **33**(7): p. 1022-9.
98. Hewett, T.E., Ford, K. R., Hoogenboom, B. J., & Myer, G. D. , *Understanding and preventing acl injuries: Current biomechanical and epidemiologic considerations – update 2010.* North American Journal of Sports Physical Therapy, 2010. **5**(4): p. 234-251.
99. Hewett, T.E., S.L. Di Stasi, and G.D. Myer, *Current concepts for injury prevention in athletes after anterior cruciate ligament reconstruction.* Am J Sports Med, 2013. **41**(1): p. 216-24.
100. Olsen, O.E., et al., *Exercises to prevent lower limb injuries in youth sports: cluster randomised controlled trial.* Bmj, 2005. **330**(7489): p. 449.
101. Fuller, C.W., et al., *'Football for Health'--a football-based health-promotion programme for children in South Africa: a parallel cohort study.* Br J Sports Med, 2010. **44**(8): p. 546-54.
102. Bengtsson, H., J. Ekstrand, and M. Hagglund, *Muscle injury rates in professional football increase with fixture congestion: an 11-year follow-up of the UEFA Champions League injury study.* Br J Sports Med, 2013. **47**(12): p. 743-7.

103. Engebretsen, A.H., et al., *Prevention of injuries among male soccer players: a prospective, randomized intervention study targeting players with previous injuries or reduced function.* Am J Sports Med, 2008. **36**(6): p. 1052-60.
104. Faude, O., et al., *Injuries in female soccer players: a prospective study in the German national league.* Am J Sports Med, 2005. **33**(11): p. 1694-700.
105. Griffin, L.Y., et al., *Understanding and preventing noncontact anterior cruciate ligament injuries - A review of the Hunt Valley II Meeting, January 2005.* American Journal of Sports Medicine, 2006. **34**(9): p. 1512-1532.
106. Junge, A. and J. Dvorak, *Soccer injuries: a review on incidence and prevention.* Sports Med, 2004. **34**(13): p. 929-38.
107. Torg, J.S., G. Stilwell, and K. Rogers, *The effect of ambient temperature on the shoe-surface interface release coefficient.* Am J Sports Med, 1996. **24**(1): p. 79-82.
108. Bizzini, M., A. Junge, and J. Dvorak, *Implementation of the FIFA 11+ football warm up program: how to approach and convince the Football associations to invest in prevention.* Br J Sports Med, 2013. **47**(12): p. 803-6.
109. van Beijsterveldt AM, v.d.P.I., Krist MR, Schmikli SL, Stubbe JH, Frederiks JE, Backx FJ. , *Effectiveness of an injury prevention programme for adult male amateur soccer players: a cluster-randomised controlled trial.* Br J Sports Med., 2012. **Dec;46**(16): p. 1114-8.
110. Longo, U.G., et al., *The FIFA 11+ program is effective in preventing injuries in elite male basketball players: a cluster randomized controlled trial.* Am J Sports Med, 2012. **40**(5): p. 996-1005.
111. Nakase, J., et al., *Whole body muscle activity during the FIFA 11+ program evaluated by positron emission tomography.* PLoS One, 2013. **8**(9): p. e73898.
112. Bizzini, M., et al., *Physiological and performance responses to the "FIFA 11+" (part 1): is it an appropriate warm-up?* J Sports Sci, 2013. **31**(13): p. 1481-90.
113. Impellizzeri, F.M., et al., *Physiological and performance responses to the FIFA 11+ (part 2): a randomised controlled trial on the training effects.* J Sports Sci, 2013. **31**(13): p. 1491-502.
114. Bizzini M, J.A., Dvorak J. , *Implementation of the FIFA 11+ football warm up program: how to approach and convince the Football associations to invest in prevention.* Br J Sports Med., 2013. **Aug;47**(12): p. 803-6.
115. NCAA. *Rules of the Game: 2014 and 2015 Rules and Interpretations*. 2014; Available from: http://ncaasoccer.arbitersports.com/front/106254/Site/Area/Rules-of-the-Game.
116. Gordon MD, S.M., *Anterior cruciate ligament injuries.* Orthopaedic Knowledge Update Sports Medicine III, ed. G. JG. 2004, Rosemont, IL: American Academy of Orthopaedic Surgeons.
117. Albright JC, C.J., Graf BK, *Knee and leg: soft tissue trauma*. Orthopaedic Knowledge Update 6, ed. B. JH. Vol. 6. 1999, Rosemont, IL. : American Academy of Orthopaedic Surgeons.

118. Stanley, L.E., et al., *Sex Differences in the Incidence of Anterior Cruciate Ligament, Medial Collateral Ligament, and Meniscal Injuries in Collegiate and High School Sports: 2009-2010 Through 2013-2014.* Am J Sports Med, 2016. **44**(6): p. 1565-72.
119. Chhadia, A.M., et al., *Are meniscus and cartilage injuries related to time to anterior cruciate ligament reconstruction?* The American Journal of Sports Medicine, 2011. **39**(9): p. 1894-1899.
120. Dumont, G.D., et al., *Meniscal and chondral injuries associated with pediatric anterior cruciate ligament tears: relationship of treatment time and patient-specific factors.* The American Journal of Sports Medicine, 2012. **40**(9): p. 2128-2133.
121. Magnussen, R.A., et al., *Time from ACL injury to reconstruction and the prevalence of additional intra-articular pathology: is patient age an important factor?* Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA, 2013. **21**(9): p. 2029-2034.
122. Lohmander, L.S., et al., *The long-term consequence of anterior cruciate ligament and meniscus injuries: osteoarthritis.* Am J Sports Med, 2007. **35**(10): p. 1756-69.
123. Walden, M., M. Hagglund, and J. Ekstrand, *High risk of new knee injury in elite footballers with previous anterior cruciate ligament injury.* Br J Sports Med, 2006. **40**(2): p. 158-62; discussion 158-62.
124. Hewett, T.E., G.D. Myer, and K.R. Ford, *Reducing knee and anterior cruciate ligament injuries among female athletes: a systematic review of neuromuscular training interventions.* J Knee Surg, 2005. **18**(1): p. 82-8.
125. Boden, B.P., et al., *Video analysis of anterior cruciate ligament injury: abnormalities in hip and ankle kinematics.* Am J Sports Med, 2009. **37**(2): p. 252-9.
126. Dragoo, J.L., et al., *Incidence and risk factors for injuries to the anterior cruciate ligament in National Collegiate Athletic Association football: data from the 2004-2005 through 2008-2009 National Collegiate Athletic Association Injury Surveillance System.* Am J Sports Med, 2012. **40**(5): p. 990-5.
127. Dragoo, J.L., H.J. Braun, and A.H. Harris, *The effect of playing surface on the incidence of ACL injuries in National Collegiate Athletic Association American Football.* Knee, 2013. **20**(3): p. 191-5.
128. Nigg, B.M. and M.R. Yeadon, *Biomechanical aspects of playing surfaces.* J Sports Sci, 1987. **5**(2): p. 117-45.
129. Olsen, O.E., et al., *Relationship between floor type and risk of ACL injury in team handball.* Scand J Med Sci Sports, 2003. **13**(5): p. 299-304.
130. Torg, J.S., T.C. Quedenfeld, and S. Landau, *The shoe-surface interface and its relationship to football knee injuries.* J Sports Med, 1974. **2**(5): p. 261-9.

131. Sugimoto, D., et al., *Compliance with neuromuscular training and anterior cruciate ligament injury risk reduction in female athletes: a meta-analysis.* J Athl Train, 2012. **47**(6): p. 714-23.
132. Bahr, R., K. Thorborg, and J. Ekstrand, *Evidence-based hamstring injury prevention is not adopted by the majority of Champions League or Norwegian Premier League football teams: the Nordic Hamstring survey.* Br J Sports Med, 2015. **49**(22): p. 1466-71.
133. Podlog, L., et al., *Time trends for injuries and illness, and their relation to performance in the National Basketball Association.* J Sci Med Sport, 2015. **18**(3): p. 278-82.
134. Kerr, Z.Y., et al., *Comprehensive Coach Education and Practice Contact Restriction Guidelines Result in Lower Injury Rates in Youth American Football.* Orthop J Sports Med, 2015. **3**(7): p. 2325967115594578.
135. McDuff, D.R. and M. Garvin, *Working with sports organizations and teams.* Int Rev Psychiatry, 2016. **28**(6): p. 595-605.
136. Ekstrand, J., M. Walden, and M. Hagglund, *Hamstring injuries have increased by 4% annually in men's professional football, since 2001: a 13-year longitudinal analysis of the UEFA Elite Club injury study.* Br J Sports Med, 2016. **50**(12): p. 731-7.
137. Penuel, W. and B. Means, *Implementation variation and fidelity in an Inquiry Science Program: analysis of GLOBE data reporting patterns.* J Res Sci Teaching, 2004. **41**.
138. O'Brien, J. and C.F. Finch, *The implementation of musculoskeletal injury-prevention exercise programmes in team ball sports: a systematic review employing the RE-AIM framework.* Sports Med, 2014. **44**(9): p. 1305-18.
139. Barengo, N.C., et al., *The impact of the FIFA 11+ training program on injury prevention in football players: a systematic review.* Int J Environ Res Public Health, 2014. **11**(11): p. 11986-2000.
140. Myer, G.D., et al., *Trunk and hip control neuromuscular training for the prevention of knee joint injury.* Clin Sports Med, 2008. **27**(3): p. 425-48, ix.
141. Myer, G.D., et al., *A pilot study to determine the effect of trunk and hip focused neuromuscular training on hip and knee isokinetic strength.* Br J Sports Med, 2008. **42**(7): p. 614-9.
142. Bellg, A., et al., *Enhancing treatment fidelity in health behaviour change studies: Best practices and recommendations from the NIH Behavior Change Consortium.* Health Psychol, 2004. **23**.
143. Hahn, E., et al., *Efficacy of training and fidelity of implementation of the life skills training program.* J School Health, 2002. **72**.
144. Eirale, C., Tol, J.L., Farooq, A., Smiley, F. and Chalabi, H., *Low injury rate strongly correlates with team success in Qatari professional football.* . British Journal of Sports Medicine, 2013(47): p. 807-808.

145. Dvorak, J., et al., *Risk factor analysis for injuries in football players. Possibilities for a prevention program.* Am J Sports Med, 2000. **28**(5 Suppl): p. S69-74.
146. Hagglund, M., et al., *Injuries affect team performance negatively in professional football: an 11-year follow-up of the UEFA Champions League injury study.* Br J Sports Med, 2013. **47**(12): p. 738-42.
147. McGill, S.M., Andersen, J.T. and Horne, A.D., *Predicting performance and injury resilience from movement quality and fitness scores in a basketball team over 2 years.* Journal of Strength and Conditioning Research, 2012(26): p. 1731-1739.
148. Crossley, K.M., et al., *Performance on the single-leg squat task indicates hip abductor muscle function.* Am J Sports Med, 2011. **39**(4): p. 866-73.
149. Hall, M.P., et al., *Neuromuscular Evaluation With Single-Leg Squat Test at 6 Months After Anterior Cruciate Ligament Reconstruction.* Orthop J Sports Med, 2015. **3**(3): p. 2325967115575900.
150. Edmondston, S., et al., *Symmetry of trunk and femoro-pelvic movement responses to single leg loading tests in asymptomatic females.* Man Ther, 2013. **18**(3): p. 231-6.
151. Graci, V., L.R. Van Dillen, and G.B. Salsich, *Gender differences in trunk, pelvis and lower limb kinematics during a single leg squat.* Gait Posture, 2012. **36**(3): p. 461-6.
152. Herrington, L., *Knee valgus angle during single leg squat and landing in patellofemoral pain patients and controls.* Knee, 2014. **21**(2): p. 514-7.
153. Hopper, L.S., N. Sato, and A.L. Weidemann, *Single-leg squats can predict leg alignment in dancers performing ballet movements in "turnout".* Open Access J Sports Med, 2016. **7**: p. 161-166.
154. Kulas, A.S., T. Hortobagyi, and P. DeVita, *Trunk position modulates anterior cruciate ligament forces and strains during a single-leg squat.* Clin Biomech (Bristol, Avon), 2012. **27**(1): p. 16-21.
155. Willson, J.D., M.L. Ireland, and I. Davis, *Core strength and lower extremity alignment during single leg squats.* Med Sci Sports Exerc, 2006. **38**(5): p. 945-52.
156. Noehren, B., J. Scholz, and I. Davis, *The effect of real-time gait retraining on hip kinematics, pain and function in subjects with patellofemoral pain syndrome.* Br J Sports Med, 2011. **45**(9): p. 691-6.
157. Horan, S.A., et al., *Lower-limb kinematics of single-leg squat performance in young adults.* Physiother Can, 2014. **66**(3): p. 228-33.
158. Ageberg, E., et al., *Validity and inter-rater reliability of medio-lateral knee motion observed during a single-limb mini squat.* BMC Musculoskelet Disord, 2010. **11**: p. 265.
159. Munro, A., L. Herrington, and M. Carolan, *Reliability of 2-dimensional video assessment of frontal-plane dynamic knee valgus during common athletic screening tasks.* J Sport Rehabil, 2012. **21**(1): p. 7-11.

160. Nakagawa, T.H., et al., *Test-retest reliability of three-dimensional kinematics using an electromagnetic tracking system during single-leg squat and stepping maneuver.* Gait Posture, 2014. **39**(1): p. 141-6.
161. Alenezi, F., et al., *The reliability of biomechanical variables collected during single leg squat and landing tasks.* J Electromyogr Kinesiol, 2014. **24**(5): p. 718-21.
162. Cheatham, S.W., et al., *Hip Musculoskeletal Conditions and Associated Factors That Influence Squat Performance: A Systematic Review.* J Sport Rehabil, 2017: p. 1-31.
163. Austin, A.B., et al., *Identification of abnormal hip motion associated with acetabular labral pathology.* J Orthop Sports Phys Ther, 2008. **38**(9): p. 558-65.
164. Claiborne, T.L., et al., *Relationship between hip and knee strength and knee valgus during a single leg squat.* J Appl Biomech, 2006. **22**(1): p. 41-50.
165. Earl, J.E., S.K. Monteiro, and K.R. Snyder, *Differences in lower extremity kinematics between a bilateral drop-vertical jump and a single-leg step-down.* J Orthop Sports Phys Ther, 2007. **37**(5): p. 245-52.
166. Henriksson, T., et al., *Laboratory- and field-based testing as predictors of skating performance in competitive-level female ice hockey.* Open Access J Sports Med, 2016. **7**: p. 81-8.
167. Bittencourt, N.F., et al., *Foot and hip contributions to high frontal plane knee projection angle in athletes: a classification and regression tree approach.* J Orthop Sports Phys Ther, 2012. **42**(12): p. 996-1004.
168. Bolgla, L., et al., *Trunk and hip electromyographic activity during single leg squat exercises do sex differences exist?* Int J Sports Phys Ther, 2014. **9**(6): p. 756-64.
169. Boudreau, S.N., et al., *Hip-muscle activation during the lunge, single-leg squat, and step-up-and-over exercises.* J Sport Rehabil, 2009. **18**(1): p. 91-103.
170. Burnham, J.M., et al., *Relationship of Hip and Trunk Muscle Function with Single Leg Step-Down Performance: Implications for Return to Play Screening and Rehabilitation.* Phys Ther Sport, 2016. **22**: p. 66-73.
171. Raisanen, A., et al., *Single-Leg Squat as a Tool to Evaluate Young Athletes' Frontal Plane Knee Control.* Clin J Sport Med, 2016. **26**(6): p. 478-482.
172. Marshall, B.M., et al., *Can a Single-Leg Squat Provide Insight Into Movement Control and Loading During Dynamic Sporting Actions in Patients With Athletic Groin Pain?* J Sport Rehabil, 2016. **25**(2): p. 117-25.
173. Fernandes, T.L., et al., *Evaluation of static and dynamic balance in athletes with anterior cruciate ligament injury - A controlled study.* Clinics (Sao Paulo), 2016. **71**(8): p. 425-9.
174. Ugalde, V., et al., *Single leg squat test and its relationship to dynamic knee valgus and injury risk screening.* Pm r, 2015. **7**(3): p. 229-35; quiz 235.
175. Kline, P.W., et al., *Clinical Predictors of Knee Mechanics at Return to Sport after ACL Reconstruction.* Med Sci Sports Exerc, 2016. **48**(5): p. 790-5.

176. Stickler, L., M. Finley, and H. Gulgin, *Relationship between hip and core strength and frontal plane alignment during a single leg squat.* Phys Ther Sport, 2015. **16**(1): p. 66-71.
177. Hollman, J.H., et al., *Frontal and transverse plane hip kinematics and gluteus maximus recruitment correlate with frontal plane knee kinematics during single-leg squat tests in women.* Clin Biomech (Bristol, Avon), 2014. **29**(4): p. 468-74.
178. Daneshjoo, A., et al., *The effects of injury preventive warm-up programs on knee strength ratio in young male professional soccer players.* PLoS One, 2012. **7**(12): p. e50979.
179. Lubahn, A.J., et al., *Hip muscle activation and knee frontal plane motion during weight bearing therapeutic exercises.* Int J Sports Phys Ther, 2011. **6**(2): p. 92-103.
180. Weeks, B.K., C.P. Carty, and S.A. Horan, *Kinematic predictors of single-leg squat performance: a comparison of experienced physiotherapists and student physiotherapists.* BMC Musculoskelet Disord, 2012. **13**: p. 207.
181. Dick, R., et al., *Descriptive epidemiology of collegiate women's soccer injuries: National Collegiate Athletic Association Injury Surveillance System, 1988-1989 through 2002-2003.* J Athl Train, 2007. **42**(2): p. 278-85.
182. Brophy, R.H., et al., *The core and hip in soccer athletes compared by gender.* Int J Sports Med, 2009. **30**(9): p. 663-7.
183. Ruedl, G., et al., *Leg dominance is a risk factor for noncontact anterior cruciate ligament injuries in female recreational skiers.* Am J Sports Med, 2012. **40**(6): p. 1269-73.
184. Sekir, U., et al., *Reliability of a functional test battery evaluating functionality, proprioception, and strength in recreational athletes with functional ankle instability.* Eur J Phys Rehabil Med, 2008. **44**(4): p. 407-15.
185. Bampouras, T.M. and S. Dewhurst, *A comparison of bilateral muscular imbalance ratio calculations using functional tests.* J Strength Cond Res, 2017.
186. Bolgla, L.A. and D.R. Keskula, *Reliability of lower extremity functional performance tests.* J Orthop Sports Phys Ther, 1997. **26**(3): p. 138-42.
187. Cacolice, P.A., et al., *THE USE OF FUNCTIONAL TESTS TO PREDICT SAGITTAL PLANE KNEE KINEMATICS IN NCAA-D1 FEMALE ATHLETES.* Int J Sports Phys Ther, 2015. **10**(4): p. 493-504.
188. Reid, A., et al., *Hop testing provides a reliable and valid outcome measure during rehabilitation after anterior cruciate ligament reconstruction.* Phys Ther, 2007. **87**(3): p. 337-49.
189. Ross, M.D., B. Langford, and P.J. Whelan, *Test-retest reliability of 4 single-leg horizontal hop tests.* J Strength Cond Res, 2002. **16**(4): p. 617-22.
190. dos Reis, A.C., et al., *Kinematic and Kinetic Analysis of the Single-Leg Triple Hop Test in Women With and Without Patellofemoral Pain.* J Orthop Sports Phys Ther, 2015. **45**(10): p. 799-807.

191. Hamilton, R.T., et al., *Triple-hop distance as a valid predictor of lower limb strength and power.* J Athl Train, 2008. **43**(2): p. 144-51.
192. Reinke, E.K., et al., *Hop tests correlate with IKDC and KOOS at minimum of 2 years after primary ACL reconstruction.* Knee Surg Sports Traumatol Arthrosc, 2011. **19**(11): p. 1806-16.
193. Brumitt, J., et al., *PRESEASON JUMP AND HOP MEASURES IN MALE COLLEGIATE BASKETBALL PLAYERS: AN EPIDEMIOLOGIC REPORT.* Int J Sports Phys Ther, 2016. **11**(6): p. 954-961.
194. Brumitt J, H.B., Manske RC, *Lower extremity functional tests and risk of injury in division iii collegiate athletes.* Int J Sports Phys Ther., 2013. **8**: p. 216-227.
195. Schmitz, R.J., S.J. Shultz, and A.D. Nguyen, *Dynamic valgus alignment and functional strength in males and females during maturation.* J Athl Train, 2009. **44**(1): p. 26-32.
196. Kollock, R., et al., *Measures of functional performance and their association with hip and thigh strength.* J Athl Train, 2015. **50**(1): p. 14-22.
197. Kodesh, E., et al., *Examination of the Effectiveness of Predictors for Musculoskeletal Injuries in Female Soldiers.* J Sports Sci Med, 2015. **14**(3): p. 515-21.
198. Myer, G.D., et al., *Utilization of modified NFL combine testing to identify functional deficits in athletes following ACL reconstruction.* J Orthop Sports Phys Ther, 2011. **41**(6): p. 377-87.
199. Padua, D.A., et al., *The Landing Error Scoring System (LESS) Is a valid and reliable clinical assessment tool of jump-landing biomechanics: The JUMP-ACL study.* Am J Sports Med, 2009. **37**(10): p. 1996-2002.
200. Petschnig, R., R. Baron, and M. Albrecht, *The relationship between isokinetic quadriceps strength test and hop tests for distance and one-legged vertical jump test following anterior cruciate ligament reconstruction.* J Orthop Sports Phys Ther, 1998. **28**(1): p. 23-31.
201. Rambaud, A., P. Samozino, and P. Edouard, *Functional tests can they help in the decision to return to sports after anterior cruciate ligament? Example with Hop tests.* Ann Phys Rehabil Med, 2016. **59s**: p. e19-e20.
202. Hoog, P., et al., *FUNCTIONAL HOP TESTS AND TUCK JUMP ASSESSMENT SCORES BETWEEN FEMALE DIVISION I COLLEGIATE ATHLETES PARTICIPATING IN HIGH VERSUS LOW ACL INJURY PRONE SPORTS: A CROSS SECTIONAL ANALYSIS.* Int J Sports Phys Ther, 2016. **11**(6): p. 945-953.
203. Herrington, L., et al., *The reliability and criterion validity of 2D video assessment of single leg squat and hop landing.* J Electromyogr Kinesiol, 2017. **34**: p. 80-85.
204. McCunn, R., et al., *THE INTRA- AND INTER-RATER RELIABILITY OF THE SOCCER INJURY MOVEMENT SCREEN (SIMS).* Int J Sports Phys Ther, 2017. **12**(1): p. 53-66.

205. Ayala, F., et al., *Training Effects of the FIFA 11+ and Harmoknee on Several Neuromuscular Parameters of Physical Performance Measures.* Int J Sports Med, 2017. **38**(4): p. 278-289.
206. Ekstrand, J., et al., *Hamstring muscle injuries in professional football: the correlation of MRI findings with return to play.* Br J Sports Med, 2012. **46**(2): p. 112-7.
207. Hewett, T.E., et al., *Biomechanical measures of neuromuscular control and valgus loading of the knee predict anterior cruciate ligament injury risk in female athletes: a prospective study.* Am J Sports Med, 2005. **33**(4): p. 492-501.
208. Hewett, T.E., et al., *Longitudinal Increases in Knee Abduction Moments in Females during Adolescent Growth.* Med Sci Sports Exerc, 2015.
209. Kline, P.W., et al., *Hip external rotation strength predicts hop performance after anterior cruciate ligament reconstruction.* Knee Surg Sports Traumatol Arthrosc, 2017.
210. Hollman, J.H., et al., *Relationships between knee valgus, hip-muscle strength, and hip-muscle recruitment during a single-limb step-down.* J Sport Rehabil, 2009. **18**(1): p. 104-17.

Appendix A

FIFA 11+ PROGRAM

Appendix B

IRB DOCUMENT FOR CHAPTERS 1 - 4

Quorum
REVIEW IRB
www.QuorumReview.com

1601 Fifth Avenue,
Suite 1000
Seattle, WA 98101

T | 206-448-4082
T | 877-472-9883
F | 206-448-4193

Notice of Approval

Dear Silvers:

Quorum Review has reviewed and approved the material that was submitted regarding the above referenced study. Enclosed please find a Notice of Approval and stamped consent form in support of the Board's approval.

Your site's approval for this study expires on May 1, 2013. Quorum Review will provide you with a Site Status Report form four weeks prior to the due date. Per FDA and other regulatory agency regulations research activity may not continue on or after the expiration date shown on the Notice of Approval without prior review and approval.

Please note that documents helpful to your site (including Participant Recruitment and Safety Reporting Guidance, Safety Report Forms, the California Bill of Rights (for CA sites) etc.) can be found on Quorum Review's website at www.quorumreview.com. Current and historical Board Rosters can be found on the Quorum OnQ Portal at https://onq.quorumreview.com/Library/.

If you have any questions, please don't hesitate to contact the Site Support Team at (206) 448-4082. Thank you for using Quorum Review.

Enclosure

CC:

Quorum Review File # *26182/1*

Quorum
REVIEW IRB
www.QuorumReview.com

1601 Fifth Avenue,
Suite 1000
Seattle, WA 98101

T | 206-448-4082
T | 877-472-9883
F | 206-448-4193

NOTICE OF APPROVAL

Approval Date: May 1, 2012

Expiration begins on: May 1, 2013

Study Title: Assessment of an injury prevention program in male soccer athletes
Protocol Number: FIFA-NCAA-0611
Sponsor: Santa Monica Sports Research Foundation
Principal Investigator: Holly J. Silvers MPT

This approval includes:

The Protocol, dated 06/14/11 (date received)
The Principal Investigator
Information and Consent Form, Version 1, dated 05/01/12

The following report is necessary:

Site Status Report due by: 3/17/2013

CC:

Quorum Review File # 26182/1
See page 2 for additional conditions of this approval.

Quorum
REVIEW IRB
www.QuorumReview.com

1601 Fifth Avenue,
Suite 1000
Seattle, WA 98101

T | 206-448-4082
T | 877-472-9883
F | 206-448-4193

Quorum Review approvals are provided to Principal Investigators contingent upon the continuing approval of the underlying protocol and also subject to the following conditions:

Quorum Review regards the Principal Investigator as responsible for the conduct of research trials at his/her site and all associated research facilities. Specific responsibilities of the Principal Investigator include ensuring:

- supervision of all research activity at the site and facilities in accordance with Quorum Review policy, applicable laws, guidelines and the ethical principles outlined in the Belmont Report
- conduct of research according to the research protocol as approved by Quorum Review and any restrictions or conditions placed on the study by Quorum Review
- use of the most recently Quorum Review -approved, stamped informed consent form
- provision of a Quorum Review -approved consent form in the participant's first language
- subjects who are unable to read may only be enrolled if a Quorum Review approved consent form contains the witness statement and signature lines
- subjects requiring a legally authorized representative may only be enrolled if a Quorum Review approved consent form contains a legally authorized representative statement and signature lines
- prospective approval by Quorum Review of changes in research activity including protocol amendments and/or consent form revisions prior to implementation, changes in Principal Investigator, change in research site, and addition of research facilities to a previously approved site
- prompt reporting to Quorum Review of the completion of research
- prospective approval by Quorum Review of all advertisements and recruiting materials prior to use
- prompt reporting to Quorum Review of serious adverse events, major protocol deviations/violations, and other unanticipated problems involving risks to participants or others
- prompt reporting to Quorum Review of updated safety information and significant findings or information during the course of research which may relate to a participant's willingness to continue participation in the research
- timely submission of required progress reports
- all participants are aware that the research is investigational
- maintenance of adequate records in accordance with national, federal, state, provincial and local regulations
- maintenance of open communication with participants regarding participant requests for additional information or concerns about the research
- compliance with all requirements specified in the Quorum Handbook

---

Quorum Review IRB is an appropriately constituted research ethics board as required by regulation. This research was reviewed and approved by the Board in accordance with pertinent authorities, including but not limited to, the ICH Guidelines for Good Clinical Practice, U.S. Food and Drug Administration (21 CFR Parts 50 and 56), U.S. Department of Health and Human Services (45 CFR Part 46), the ethical principles outlined in the Belmont Report, the Canadian Food and Drug Regulations (Part C, Division 5), Part 4 of the Canadian Natural Health Products Regulations, and the Tri-Council Policy Statement (TCPS). This approval and the views of the Board have been documented in writing and certified by the Board Chair.

Stephen J. Rosenfeld, M.D., M.B.A.
Quorum Review IRB Chairperson or authorized designee

1601 Fifth Avenue,
Suite 1000
Seattle, WA 98101

T | 206-448-4082
T | 877-472-9883
F | 206-448-4193

Approval is not valid without the presence of the Chairperson's or authorized designee's stamp

INFORMATION AND CONSENT FORM

Study Title: ***Assessment of an injury prevention program in male soccer athletes***

Study #: ***FIFA-NCAA-0611***

Sponsor: ***Santa Monica Sports Research Foundation/FIFA***

Study Doctor: ***Holly J. Silvers, MPT***
Santa Monica Sports Research Foundation
2020 Santa Monica Blvd., Fl. 4, Santa Monica, CA 90404

Telephone Number: ***(310) 829-2663***

After Office Hours: ***(310) 871-2823***

For California participants: Before you read this consent form, you should read and sign a copy of the California Experimental Subject's Bill of Rights. Ask the study staff for a copy of this document if you haven't already received one.

The research group called Santa Monica Sports Research Foundation would like to know if you would like to be part of a research study.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

WHAT IS THIS STUDY ABOUT?

Researchers want to find out more about an injury prevention exercise program that has been used to study injuries in competitive soccer players. The exercise program is called the FIFA 11+ Injury Prevention Program.

Some people who agree to join the study will use the research exercise program two to three times per week prior to soccer practice.

The main purpose of this study is to see if, by performing the exercise program, injury rates will be lower throughout the 2012 season.

The study will compare the effects of performing the FIFA 11+ exercise program before practice to other soccer player study participants who will not be performing the exercise program.

It is planned that about 120 NCAA Men's Division I and II soccer teams (approximately 2600 to 3120 people) playing competitive soccer will be included this study.

HOW DOES THE EXERCISE PROGRAM WORK?

The study will use exercises as a warm-up program to some people's soccer practice. The exercises will be used to determine whether or not injuries may be reduced during regular season practice and game schedule. The program will take approximately 20 minutes to complete and will be conducted 2 to 3 times per week during the Fall, 2012 season. For participants who use the FIFA 11+ program exercises, this will be done instead of your usual warm-up exercises.

WHAT IS MY ALTERNATIVE TO BEING IN THIS STUDY?

You do not have to be in this study to get help to prevent injuries related to playing soccer. Some other things you may be able to do are:

- participate in other exercise programs.
- participate in the exercise program that you were performing in the past.

You should discuss your alternatives to participating in this research with the study staff. In addition, you may discuss your options with your regular health care provider.

WHO IS PAYING FOR THIS STUDY?

A company called Santa Monica Sports Research Foundation, the sponsor of the study, is paying for this study.

The address is: 2020 Santa Monica Blvd, 4th Floor, Santa Monica, CA 90404.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There is no cost to you for participating in the study.

HOW LONG WILL I BE IN THE STUDY?

The study will begin in August, 2012 and finish in December, 2012. You will be in the study for approximately 5 months (the duration of one soccer season).

WHAT WILL HAPPEN DURING THIS STUDY?

Your certified athletic trainer and coach will administer certain exercises to do prior to your soccer practices.

Teams will be assigned by chance (like flipping a coin) to 1 of the following study groups:

- Group 1: Group 1 will perform the FIFA 11+ program exercises. This will take approximately 20 minutes to complete. The program will be completed 2 to 3 times per week prior to practice.
- Group 2: Group 2 will be considered a control group. You will do the same warm-up program that you have been doing in the past, under the direction of your coach.

Your team has an equal chance of being in either of the study groups. Neither you nor your coach nor the study doctor or study staff will be able to pick which study group you are in.

Players who do not want to be in the study will perform their normal warm-up routine. While you are in the study, you must:

- Follow the instructions you are given.
- Tell the study staff about any changes in your health or the way you feel.
- Tell the study staff if you want to stop being in the study at any time.

What happens when I enter the study?

After you sign this form, the study staff will do the things listed below. If you would like more information about when the tests and procedures will be done, ask the study doctor or study staff.

- Demographic Questions: Ask you to give personal information, such as your name, date of birth, race, height, weight, leg dominance and field position.
- Health and Medication Questions: Ask you to answer questions about your health, your medical history, and the medications you take.
- Height, Weight: See how tall you are, and see how much you weigh.
- Questionnaires: Ask you to fill out questionnaires about your prior injury history.

What else will happen during this study?

Your athletic trainer will enter all injuries that occur while practicing or playing soccer throughout the season in a secure database. The collected information includes injury type, location in the body and the injury's severity. If you become injured while in this study, your name and other personal information will not be included in the database.

What else should I know about the study procedures?

Estimate of the expected recovery time of the participant after the experiment: You are not expected to need any time to recover from participating in this study.

WILL BEING IN THIS STUDY HELP ME?

The study is being done to see if injury rates in soccer can be decreased, but there is no guarantee that being in this study will help you. Your risk of injury may not decrease while you are in this study.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

What can happen if I participate in the exercise study?

All studies carry a risk of side effects. Some people who have participated in the exercise study:

- Have not seen a decrease in injury
- Have seen no change in the risk of injury

There is a potential for injury that exists during the performance of any warm up routine, including the FIFA 11+ program.

Ask the study staff if you have questions about the risks you read about in this consent form.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study

There is a risk of loss of confidentiality of your information that is used in this study. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I AM IN THIS STUDY?

It is possible that you could have problems and side effects of the exercise program that nobody knows about yet, which include your injuries being worse.

WILL I RECEIVE ANY NEW INFORMATION DURING THE STUDY?

If the study staff learns any new information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

WILL I RECEIVE PAYMENT?

As a collegiate athlete, you will not receive payment for participation in the study. Your certified athletic trainer will receive a small payment at the end of the season for their work associated with filing all of the paperwork and updating the injury reports on a weekly basis.

DO I HAVE TO BE IN THIS STUDY?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits. If you want to stop being in the study, tell the study staff.

The study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You do not follow directions about the study.
- The sponsor stops the study for any reason.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. The study doctor or study staff may ask you to participate in some procedures or tests to help you leave the study safely and/or to collect more information for the study. If you were assigned to the group performing the FIFA 11+ program exercises, you will return to your normal warm-up routine.

Individual team members do not have to be in this study. No one should influence or pressure you to be in this study. A team member's decision to be in the study, or to leave the study early, will not affect the team member's position or team benefits.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your confidentiality will be protected as required by law and according to any policies the study center or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared and copied as needed for the study. The forms will be kept in a secure site and in a locked file cabinet.

The study staff or sponsor may use some facts about your being in this study in books, magazines, journals, and scientific meetings. If this happens, no one will use your name or other information that could be used to identify you.

WHO CAN I TALK TO ABOUT THIS STUDY?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

> *Quorum Review is located in Seattle, Washington.*
> *Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.*
> *Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).*

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

This section explains who will use and share your private health information if you agree to be in this study. If you do not sign this form, you cannot be in the study.

During the study, the study doctor and study staff will use, collect, and share health information about you (your "records"). Your records may include any information about you that the study doctor needs to do the study and other identifying information about you, such as your name, address, phone number, or social security number. Your records will include:

- medical records
- medical history
- interviews and/or questionnaires
- information from other procedures you have as part of the study

Your health information will be used or shared when required by law. Your records may be used and shared with these people for the following purposes:

- The study doctor and study staff to conduct the research described in this consent form.
- The sponsor, Santa Monica Sports Research Foundation; people who work with or for the sponsor; and other researchers involved in this study. These people will use your records to review the study and to check the safety and results of the study.
- Others required by law to review the quality and safety of research, including: the U.S. Food and Drug Administration, Department of Health and Human Services (DHHS), Office of Human Research Protections, other government agencies in the United States and other countries, and Quorum Review.

There are national and state laws that make the study doctor protect the privacy of your records. However, you do not have a guarantee of absolute privacy because of the need to share your information. After the study doctor shares your records with the sponsor and others, the laws may no longer protect the privacy of your records. The sponsor or others may share your records with other people who do not have to protect the privacy of your records. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes.

No publication or public presentation about the research described in this consent will reveal your identity without permission from you.

You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

You can cancel this authorization to use and share your records at any time. If you want to cancel your authorization, you must write a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study.

Even if you cancel your authorization and leave the study early, the study doctor and study staff will still be able to use and share your records that they have already collected as described above.

This authorization to use and share your records expires in 50 years. You will receive a signed copy of this form.

_______________________________________ __________________

Signature of Participant *Date*

CONSENT

I have read this form, and I have been able to ask questions about this study. The study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study. I agree to allow the use and sharing of my study-related records as described above.

By signing this form, I have not given up any of my legal rights as a research participant. I will get a signed copy of this consent form for my records.

____

Printed Name of Participant

_______________________________________ __________________

Signature of Participant *Date*

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

____

Printed Name of Person Explaining Consent

_______________________________________ __________________

Signature of Person Explaining Consent *Date*

Appendix C

IRB DOCUMENT FOR CHAPTERS 5 AND 6

University of Delaware Informed Consent Form

Title of Project: Biomechanical Analysis of the FIFA 11+ Injury Prevention Program
Principal Investigator (s): Holly J. Silvers, PT
Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach, has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team will utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*
- *Every player on your team will be invited to participate. You have the option not to participate in the study.*
- *The testing will take approximately 2 hours. The testing will occur once during preseason and again at the conclusion of the fall (men) and spring seasons (mend and women) for a total of 4-6 hours. In addition, your team will utilize the FIFA 11+ Program as a dynamic warm-up twice a week. This will replace your traditional warm-up and will require no additional time from you as a player.*
- *Upon your approval, a member of the research team will schedule you for a session in the motion analysis lab to be tested at your convenience. A follow-up testing will be scheduled at the end of the fall and spring seasons.*

WHAT WILL YOU BE ASKED TO DO

- *During the season, you will perform the FIFA 11+ warm-up program twice a week. This will replace your traditional warm-up program and will require no additional time from you. You can view the program in its' entirety here: http://f-marc.com/11plus/home/*
- *Any injury that you incur during the course of the season will be collected.*
- *The number of completed FIFA 11+ warm-ups throughout the course of the season will also be collected.*
- *The movement testing will take place in the motion analysis laboratory on the Star Campus, University of Delaware. The testing will occur once in August, 2014 (men), once during December, 2014 – February, 2015 (men and women), in May, 2015 (men and women), August, 2015 and December, 2015 (for men and women) . Each testing session will take approximately 2 hours.*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *There are no foreseeable risks from participating in the study. The FIFA 11+ warm-up is a well-researched program and has been shown to decrease the number of soccer related injuries and time loss associated with injury.*
- *There is always a small risk associated with movement analysis or participating in an injury prevention program. However, we expect these risks to be minimal or non-existent.*
- *There are no financial risks associated with your participation. The only foreseeable discomfort may be associated with the time devoted to the actual testing process (2 hours for 3 sessions – one in August, one in December, 2014 – February, 2015, and once in May, 2015)*

WHAT ARE THE POTENTIAL BENEFITS?

- *The potential benefit for participating in the research project is that your risk of soccer related injury may potentially be decreased.*

- *The other potential benefits include a more thorough understanding of how the FIFA 11+ program helps to reduce injury in soccer players.*
- *The future benefits include a better scientific understanding of how the FIFA 11+ program helps to decrease injury by slight changes to movement patterns in competitive soccer players. This knowledge is very important to the medical community that works directly with soccer players.*

HOW WILL CONFIDENTIALITY BE MAINTAINED?

- *Your identity will be protected during the course of the study. You will be assigned a unique identifying code number and your name will not be associated with any data that the research team collects. A list will be created to link the code number to the participant. Only the primary investigator (Holly Silvers) will have access to this and this will be kept in a secured file (password protected).*
- *The data that we collect in the lab and the injury data collected throughout the course of the season will be stored in an excel worksheet and will be password secured. Any data that we collect on paper will be stored in a locked filing cabinet in the BIOMS office on the Star Campus, University of Delaware. The records will be stored for three years.*
- *Only the research team will have access to the video recordings of your movement analysis. This data will be stored on a secured hard drive and will be password protected. Your file will be saved with a unique identifier and will not include your name or date of birth. This data will be stored for seven years and will only be used for research purposes. Recordings will be permanently destroyed at this time.*
- *The data will be reported in a manuscript form and will not include your name, age, date of birth or any unique identifier. The data will be grouped together and analyzed. Upon completion, the data will be submitted to a scientific journal for publication.*
- *There is always a risk that confidentiality may be breached. However, the research team will do everything possible to ensure that this in minimized; including the removal of your name, date of birth, position and jersey number from every file, assigning you with a unique identifying code, keeping all of the files password secured, and keeping any written documentation in a locked-secured cabinet.*

***"We will make every effort to keep all research records that identify you confidential to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared*. "**

Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

- *No other research organization will have access to these records.*

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

- *There are no financial costs associated with your participation*

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

- *There is no compensation associated with your participation, in accordance with NCAA rules and regulations.*

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid and medical treatment at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the institution that you attend or are employed by, or the Women's or Men's soccer program at the NCAA member institution.

As a student-athlete, if you decide not to take part in this research, your choice will have no effect on your academic status or with your status as a player on the Men's soccer team.

If you are indeed injured during the course of the study, you have the option to have your medical care provided by the University of Delaware's Athletic Department. You may also see private treatment through your private insurance.
In the event you incur a season ending injury during the course of the season, your participation in the study will end.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Holly Silvers at 310 871-2823 or via email: hollys@udel.edu. If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at 302-831-2137.

Your signature below indicates that you are voluntarily agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

__________________________________ _______________

Signature of Participant Date

____

Printed Name of Participant

Appendix D

IRB DOCUMENT FOR CHAPTERS 5 AND 6 (WILMINGTON UNIVERSITY)

WILMINGTON UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)
RECORD AND REVIEW OF RESEARCH PROTOCOL

Contact Information

Principal Investigator: Silvers-Granelli (Last) Holly (First) Jacinda (Middle)

Address: 540 South College Avenue – BIOMS Department (2nd Floor)

City Newark State DE Zip 19713

Phone: Day 310 871 2823 Evening 310 899 0897 Cell 310 871 2823

E-Mail: hollysilverspt@gmail.com FAX: 888 853 0707

Project status

This research is for (check one):

Doctoral Dissertation/Capstone x Practicum _____
Master's Thesis/Capstone _____ Undergraduate _____

Other (specify) _____

This research proposal is (check one):

New _____ **Renewal** _____ **Re-**evaluation x (IRB approval received at the University of Delaware – requesting expedited review for Wilmington University's participation as a control team.)

Instructor or assigned faculty sponsor: Lynn Snyder-Mackler, PT, ATC, ScD

Project Information

Title of study: Biomechanical Analysis of the FIFA 11+ Injury Prevention Program

Research purpose or issue:
Soccer is the number one played sport globally. However, there are risks associated with playing the sport of soccer, which include injuries to the ankle, knee, hip and torso (Griffin, 2005). Researchers have created injury prevention programs that help to reduce the risk of ACL injury while participating in the sport of soccer (Mandelbaum, 2005, Gilchrist, 2008). The FIFA 11+ injury prevention program in a soccer specific warm-up designed to decrease

all types of soccer related injury (Soligard, 2008, Silvers-Granelli, 2015). The program has demonstrated the ability to decrease severe injury and significant time loss due to injury in female soccer players. More recently, researchers expanded the scope of the FIFA 11+ program and analyzed its' ability to decrease injuries in the collegiate male soccer athlete. In that study, the rate of soccer related injury was decreased by 52% compared to an age and skill-matched control group (Silvers-Granelli, 2015). The purpose of this study is to analyze the biomechanical changes occurring within collegiate male soccer players as a result of participating in the FIFA 11+ program throughout the course of one-competitive soccer season compared to an age and skill-matched control group.

Population to be studied: Gender M & F Age 18-25 Race/ethnicity all

Number of groups and number of participants in each group:
N=150: 75 men and 75 women (1 intervention team and 1 control team for males and 1 intervention team and 1 control team for women)

How participants will be selected:
Division I and Division II local NCAA soccer teams (within a 60 mile radius of the University of Delaware's biomechanics laboratory) will be invited to participate. Ms. Silvers, the primary investigator on the protocol, gave a lecture at the National Collegiate Athletic Association (NCAA) regarding the efficacy of the FIFA 11+ in reducing soccer related injury (January, 2015). Following this lecture, several area coaches approached her about being part of the study. The subject pool will include male and female soccer players participating in Division I or Division II soccer, between the ages of 18-25 (N = 150). The rosters are a publicly known group of individuals available on the NCAA Athletic websites and the University Athletics website, respectively.

What qualification criteria will be used to include participants in the sample?
All Division I and Division II men's and women's soccer teams within a 60 mile radius of the University of Delaware's biomechanics laboratory will be eligible to participate in the study. Participation is voluntary; by team and by individual.

What criteria will be used to exclude potential participants in the sample?
All Division I and Division II men's and women's soccer players that are currently medically cleared for play by their respective medical teams and in good academic standing are eligible to participate. There are no additional exclusion criteria to the study.

How subjects will be recruited:
After approval from the Head Coach is received, respectively, a script (see below) will be delivered via email to every player on the enrolled University soccer roster between the third week of July and the first week of August. If no response is received, a second email will be generated in the second week of August (same script). If there is no response to the second email, it will be followed up with a phone call. Only three attempts (two by email and one by phone) will be made to reach the individual player in order to avoid coercion and/or harassment of the individual. If no response is made after this time, the researchers will assume that the player is not interested in participating in the research study.

Dear _______ (player name),

My name is Holly Silvers-Granelli. I am currently a PhD student and a practicing physical therapist at the University of Delaware in the Biomechanics and Movement Science Program. I would love to have the opportunity to speak to you regarding a project that we are working on this fall. Your coach, - ____________ (fill in coach's name based on the team), has agreed to be a part of the FIFA 11+ biomechanics assessment protocol this season. We ran a large research trial in women's soccer in Norway in Fall, 2008 and in men's soccer in the Fall, 2012) to look at the effectiveness of the FIFA 11+ as an injury prevention program in soccer players. We found an overall injury reduction of 52%. The research team is curious to see if you might be interested in participating in a study this coming fall. We are interested in doing a biomechanical screening in the Star biomechanics laboratory at the University of Delaware to look at any changes that occur in your movement patterns over the course of one competitive soccer season. We will be testing the following soccer specific movements: cutting, pivoting, decelerating, squatting, lateral shuffling, and a triple hop. There will be several testing dates; one in August, 2016, and December of 2016 (following the conclusion of the study). I would be happy to dialogue with you via email: hollys@udel.edu, hollysilverspt@gmail or via cell: 310 871 2823.

If you have any questions or concerns, please contact me at your convenience. I look forward to speaking with you.

Most sincerely,
Holly Silvers-Granelli

Describe the procedures that the participants will undergo in the proposed research project including the physical location and duration of subject participation. Attach a copy of all research instruments, e.g., surveys, questionnaires, interview questions, etc.:

The FIFA 11+ program is a dynamic soccer specific warm-up developed by researchers to decrease the number of soccer related injuries and time loss due to injury (Soligard, 2008). This program was introduced to the NCAA, including the Men's and Women's University of Delaware soccer team, during a large randomized controlled trial conducted in the Fall, 2012 season. The Men's and Women's coaching staffs and the athletic training staffs have previously agreed to utilize this training warm-up program for the 2014-2016/7 seasons. The researchers are looking to analyze how certain soccer specific movements change over the course of the season while using the FIFA 11+ as a warm-up program. Each student-athlete will then be asked to participate individually by one of the research staff members. This is a voluntary program and their decision to participate is solely the individual player's decision. If the player does indeed agree to participate, a signed informed consent form will be collected for each participating player. If the player decides to not participate, no further action will ensue and there will be no impact to their individual standing on the soccer team.

Prior to the season beginning, the soccer subjects (Male N=75, Female N=75) will be analyzed in the University of Delaware Motion Analysis Laboratory. The movements that will be analyzed via motion capture analysis are soccer specific and will include the following: cutting, pivoting, decelerating, a lateral shuffle, a triple hop and a single leg squat. Peak flexion angle, joint moments for the knee and hip and ground reaction forces will be collected for each respective movement. A password-protected injury surveillance database will be utilized to allow the ATC to upload the injury data after each respective week of the season. The research staff will oversee the compliance data during the course of the season in addition to the injury incidence data entry. At the cessation of the study, the participants will be analyzed once again in the motion analysis laboratory for the post-intervention analysis (Star Campus, University of Delaware). The same motions that were analyzed in August will be re-analyzed in December to see if there were any biomechanical changes imparted onto the athlete as a result of utilizing the FIFA 11+ throughout the course of the 2016 soccer season, or not (with respect to the control group population). All of the FIFA 11+ materials that were dispersed to the intervention group will be shared with the control group at the completion of the study.

Confidentiality and Security *Please answer yes or no to the following questions:*

YES	NO	
x		Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information.
x		Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.)
x		All data is maintained in encrypted and/or password protected digital/electronic files.
x		Individually identifiable information will be securely maintained for three years past the completion of the research, then destroyed rendering the data unusable and unrecoverable.

Please provide further information concerning any "no" answers given above (including cases where a procedure is not applicable). Describe any other procedures you are taking to maintain anonymity, confidentiality, or information security.

A unique three-digit identifier will be randomly assigned to each participant. This code will be utilized on all of the date collection materials (compliance with the FIFA 11+ program, injuries incurred during the season, and the pre-post biomechanical analysis testing protocol). There is always a risk that confidentiality may be breached. However, the research team will do everything feasibly possible to ensure that this is mitigated and minimized; including the removal of the subject's name, date of birth, player position and jersey number from every file, assigning each subject with a unique identifying code, keeping all of the files password secured on a secure University server, and keeping any written documentation in a locked-secured cabinet.

Obligations of Principal Investigator:

HSRC meets on the second Thursday of each month September to May and as needed during the summer months. Protocol must be received two weeks before that date.

Any substantive changes made to the research protocol must be reported to college representatives of the HSRC for review prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

According to federal regulation all data, including signed consent form documents must be retained for a minimum of three years past the completion of the research.

I have read and understand my obligations as an investigator. I certify that the research proposal is accurate and complete.

Print name: Holly Silvers, PT, PhD Candidate

Signature: Holly Silvers Date: July 20, 2016

Instructor or Assigned Faculty Sponsor:

Print name: Lynn Snyder-Mackler

Signature: Lynn Snyder-Mackler Date: July 26 2016

If this research involves collecting information or perceptions from Wilmington University students/employees or access to Wilmington University data, this form must be signed by an appropriate director or executive. The executive signing this form is responsible for conferring with institutional research or other parts of the university which would need to support the research.

(If needed) Director or Executive:

Print name: ____________________

Signature: ____________________ Date: ____________________

Consent Forms

YES_x_ NO ____ Is a consent form included with this study? If so, attach a copy.

YES____ NO _x_ Are child assent forms included with this study? If so, attach a copy.

Minors must provide an affirmative consent to participate by signing a simplified form, unless the principal investigator can provide evidence that the minors are not capable of assenting because of age, maturity, psychological state, or other factors.

Please refer to the informed consent outline and checklist and the assent outline which can be found in the Human Subjects Review Committee section of the Wilmington University website.

Implied consent – For some exempt or expedited research, it is not necessary to have a signed consent form. For example, a relatively short survey of competent adults which is anonymous and deals with noncontroversial topics could use a less formal means of providing information. In such cases, the person's voluntary participation indicates implied consent. Typically, the invitation to participate would be less legal in tone than a consent form but would provide information about the principle investigator, study purpose, voluntary participation, nature/duration of participation, and anonymity/confidentiality.

If implied consent is being used, attach a copy of the invitation.

Who is obtaining consent? *Check all that apply:*

Principal Investigator _x_ Research Assistant____ Other x__ (specify) Co-investigator

How is consent being obtained? Consent will be obtained prior to biomechanical testing in the Star Laboratory, University of Delaware. All of the subjects will have the opportunity to review the protocol and the consent form at length. They will have the personal decision of whether or not they would like to participate in the study. The participant will have the opportunity to cease testing at any time.

What steps are being taken to determine that potential subjects are competent to participate in the decision-making process? The PI will ensure that the subject has a full understanding of what the study entails and what risks/benefits are associated with participation in the study. The PI will ensure that each subject is participating voluntarily under their own free will, and did not feel coerced or pressured to participate in the study.

Wilmington University
Informed Consent Form

Title of Project: *Biomechanical Analysis of the FIFA 11+ Injury Prevention Program*

Principal Investigator (s): Holly J. Silvers, PT

Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team may or may not utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015, and 2016 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*

Participant Initials ________

Wilmington University
Informed Consent Form

Title of Project: *Biomechanical Analysis of the FIFA 11+ Injury Prevention Program*

Principal Investigator (s): Holly J. Silvers, PT

Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team may or may not utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015, and 2016 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*

Participant Initials ________

- *Every player on your team will be invited to participate. You have the option not to participate in the study.*
- *The testing will take approximately 1 hour. The testing will occur once during preseason and again at the conclusion of the fall (men) and spring seasons (men and women) for a total of 4-6 hours. In addition, your team may utilize the FIFA 11+ Program as a dynamic warm-up twice a week. This will replace your traditional warm-up and will require no additional time from you as a player.*

WHAT WILL YOU BE ASKED TO DO?

- *Upon your approval, a member of the research team will schedule you for a session in the motion analysis lab to be tested at your convenience. A follow-up testing will be scheduled at the end of the fall and spring seasons.*
- *During the season, if you are selected as an intervention team, you may or may not perform the FIFA 11+ warm-up program twice a week. This will replace your traditional warm-up program and will require no additional time from you. You can view the program in its' entirety here: http://f-marc.com/11plus/home/*
- *Any injury that you incur during the course of the season will be collected.*
- *The number of completed FIFA 11+ warm-ups throughout the course of the season will also be collected.*
- *The movement testing will take place in the motion analysis laboratory on the Star Campus, University of Delaware. The testing will occur once in August, 2014 (men), once during December, 2014 – February, 2015 (men and women), in May, 2015 (men and women), August, 2015 and December, 2015 (for men and women), and August, 2016 and December, 2016 (men and women) . Each testing session will take approximately less than 1 hour.*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *There are no foreseeable risks from participating in the study. The FIFA 11+ warm-up is a well-researched program and has been shown to decrease the number of soccer related injuries and time loss associated with injury.*
- *There is always a small risk associated with movement analysis or participating in an injury prevention program. However, we expect these risks to be minimal or non-existent.*
- *There are no financial risks associated with your participation. The only foreseeable discomfort may be associated with the time devoted to the actual testing process (2 hours for 3 sessions – one in August, one in December, 2014 – February, 2015, once in May, 2015, and once in August and December, 2016).*

WHAT ARE THE POTENTIAL BENEFITS?

Participant Initials ________

WILMINGTON UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE (HSRC)
PROTOCOL REVIEW

This section is to be completed by the HSR Committee Person.

Principal Investigator: Holly Silvers

Date submitted: 7/28/16

The protocol and attachments were reviewed:

The proposed research is approved as:

____Exempt   X Expedited   ____ Full Committee

The proposed research was approved pending the following changes:

____See attached letter

____Resubmit changes to the HSRC chairperson

The proposed research was disapproved:

____ See attached letter for more information.

HSRC Chair
or Representative   Ruth Norman
Print name

Ruth T. Norman
Signature   Date: 7/28/16

HSRC Chair
Or Representative   Stephanie A. Battis
Print name

SA Battis
Signature   Date: 7/28/16

Wilmington University
Informed Consent Form

Title of Project: *Biomechanical Analysis of the FIFA 11+ Injury Prevention Program*

Principal Investigator (s): Holly J. Silvers, PT

Other Investigators: Amelia Arundale, PT, Ryan Zarzycki, PT, Adam Marmon, PhD, Lynn Snyder-Mackler, PT, ScD, Adam Marmon, PhD

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will be asked to do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything we have not made clear before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn more about the effectiveness of an injury prevention program (The FIFA 11+ program) developed specifically for competitive soccer players. The program has been studied in females and in male NCAA soccer players and has been shown to reduce injury by 52%. Your coach has agreed to utilize the FIFA 11+ program as your warm-up throughout the course of the season. We now would like to understand how it works by analyzing it biomechanically.

- *The study will be conducted in the NCAA using men's and women's soccer players.*
- *We will analyze your movements in the motion analysis lab (Star Campus, University of Delaware). These movements are soccer specific and will include cutting, pivoting, deceleration, a lateral shuffle, a triple hop and a single leg squat.*
- *Your team may or may not utilize the FIFA 11+ warm-up program twice a week throughout the course of the 2014 fall, 2015, and 2016 spring and fall seasons.*
- *Your injuries will be tracked throughout the course of the season. This information will be kept confidential and your name and any unique identifying information will never be disclosed.*
- *This study will be utilized towards completion of a PhD dissertation.*

You are being asked to take part in this study because…

- *You are a soccer player competing as a member of an NCAA Men's or Women's soccer team.*

Participant Initials ________

- *Every player on your team will be invited to participate. You have the option not to participate in the study.*
- *The testing will take approximately 1 hour. The testing will occur once during preseason and again at the conclusion of the fall (men) and spring seasons (men and women) for a total of 4-6 hours. In addition, your team may utilize the FIFA 11+ Program as a dynamic warm-up twice a week. This will replace your traditional warm-up and will require no additional time from you as a player.*

WHAT WILL YOU BE ASKED TO DO?

- *Upon your approval, a member of the research team will schedule you for a session in the motion analysis lab to be tested at your convenience. A follow-up testing will be scheduled at the end of the fall and spring seasons.*
- *During the season, if you are selected as an intervention team, you may or may not perform the FIFA 11+ warm-up program twice a week. This will replace your traditional warm-up program and will require no additional time from you. You can view the program in its' entirety here: http://f-marc.com/11plus/home/*
- *Any injury that you incur during the course of the season will be collected.*
- *The number of completed FIFA 11+ warm-ups throughout the course of the season will also be collected.*
- *The movement testing will take place in the motion analysis laboratory on the Star Campus, University of Delaware. The testing will occur once in August, 2014 (men), once during December, 2014 – February, 2015 (men and women), in May, 2015 (men and women), August, 2015 and December, 2015 (for men and women), and August, 2016 and December, 2016 (men and women) . Each testing session will take approximately less than 1 hour.*

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- *There are no foreseeable risks from participating in the study. The FIFA 11+ warm-up is a well-researched program and has been shown to decrease the number of soccer related injuries and time loss associated with injury.*
- *There is always a small risk associated with movement analysis or participating in an injury prevention program. However, we expect these risks to be minimal or non-existent.*
- *There are no financial risks associated with your participation. The only foreseeable discomfort may be associated with the time devoted to the actual testing process (2 hours for 3 sessions – one in August, one in December, 2014 – February, 2015, once in May, 2015, and once in August and December, 2016).*

WHAT ARE THE POTENTIAL BENEFITS?

Participant Initials ________

- *The potential benefit for participating in the research project is that your risk of soccer related injury may potentially be decreased.*
- *The other potential benefits include a more thorough understanding of how the FIFA 11+ program helps to reduce injury in soccer players.*
- *The future benefits include a better scientific understanding of how the FIFA 11+ program helps to decrease injury by slight changes to movement patterns in competitive soccer players. This knowledge is very important to the medical community that works directly with soccer players.*

HOW WILL CONFIDENTIALITY BE MAINTAINED?

- *Your identity will be protected during the course of the study. You will be assigned a unique identifying code number and your name will not be associated with any data that the research team collects. A list will be created to link the code number to the participant. Only the primary investigator (Holly Silvers) will have access to this and this will be kept in a secured file (password protected).*
- *The data that we collect in the lab and the injury data collected throughout the course of the season will be stored in an excel worksheet and will be password secured. Any data that we collect on paper will be stored in a locked filing cabinet in the BIOMS office on the Star Campus, University of Delaware. The records will be stored for three years.*
- *Only the research team will have access to the video recordings of your movement analysis. This data will be stored on a secured hard drive and will be password protected. Your file will be saved with a unique identifier and will not include your name or date of birth. This data will be stored for seven years and will only be used for research purposes. Recordings will be permanently destroyed at this time.*
- *The data will be reported in a manuscript form and will not include your name, age, date of birth or any unique identifier. The data will be grouped together and analyzed. Upon completion, the data will be submitted to a scientific journal for publication.*
- *There is always a risk that confidentiality may be breached. However, the research team will do everything possible to ensure that this in minimized; including the removal of your name, date of birth, position and jersey number from every file, assigning you with a unique identifying code, keeping all of the files password secured, and keeping any written documentation in a locked-secured cabinet.*

***"We will make every effort to keep all research records that identify you confidential to the extent permitted by law. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared*. "**

Your research records may be viewed by the Wilmington University and the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

- *No other research organization will have access to these records.*

Participant Initials ________

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

- *There are no financial costs associated with your participation*

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

- *There is no compensation associated with your participation, in accordance with NCAA rules and regulations.*

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid and medical treatment at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your refusal will not influence current or future relationships with the institution that you attend or are employed by, or the Women's or Men's soccer program at the NCAA member institution.

As a student-athlete, if you decide not to take part in this research, your choice will have no effect on your academic status or with your status as a player on the Men's soccer team.

- *If you are indeed injured during the course of the study, you have the option to have your medical care provided by the University of Delaware's Athletic Department. You may also see private treatment through your private insurance.*
- *In the event you incur a season ending injury during the course of the season, your participation in the study will end.*

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Holly Silvers at 310 871-2823 or via email: hollys@udel.edu or hollysilverspt@gmail.com.

If you have any questions or concerns about your rights as a research participant, you may contact the Wilmington University Institutional Review Board at University of Delaware Institutional Review Board at 302-831-2137.

Participant Initials ________

Your signature below indicates that you are voluntarily agreeing to take part in this research study. You have been informed about the study's purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

______________________________ ____________

Signature of Participant Date

____

Printed Name of Participant

Participant Initials ________

Appendix E

PERMISSIONS FOR MANUSCRIPT PUBLICATION

Permission to publish Chapter 2 from the American Journal of Sports Medicine, Sage Publications

Thank you for your query. Per the SAGE Journal Author Guidelines (https://us.sagepub.com/en-us/nam/journal-author-archiving-policies-and-re-use) you are allowed to include up to one full article that you have authored in your dissertation. Please note that this permission does not cover any third party material you included in your article and you must credit the original source, SAGE Publications. Please contact us for any further use of the material and congratulations on your dissertation!

All the Best,
Yvonne McDuffee
Rights Coordinator
SAGE Publications Inc.
2455 Teller Road
Thousand Oaks, CA 91320

www.sagepublishing.com
Los Angeles | London | New Delhi
Singapore | Washington DC | Melbourne

https://us.sagepub.com/en-us/nam/journal-author-archiving-policies-and-re-use

Permission to publish Chapter 3 from Clinical Orthopaedics and Related Research, Springer Publications

Dear Holly

I received your voicemail. Congratulations on nearing completion of your PhD. The copyright transfer you would have agreed to when you published in CORR would have been slightly different from the attached version (the attached is for Springer owned journals, CORR is owned by an external society, so the Assoc of Bone and Joint Surgeons owns the copyright to your work) but the conditions noted in the attached would apply.

Including, towards the bottom, is the text I have pasted and highlighted below:

Author retains the right to use his/her article
for his/her further scientific career by including the final published journal article in
other publications such as dissertations and postdoctoral qualifications provided acknowledgement
is given to the original source of publication.

Just cite your article in CORR, and ensure it's not being posted somewhere online that is selling your work again; and you're fine.

My best to you;
Sean

Sean Beppler
Editor
Clinical Medicine
Springer Science + Business Media
Sean.Beppler@Springer.com

400 Market Street | Suite 700 | Philadelphia, PA 19106