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SPORTS MEDICINE

Higher compliance to a neuromuscular injury prevention program improves overall injury rate in male football players

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Abstract

Purpose The 11+injury prevention program has been shown to decrease injury rate. However, few studies have investigated compliance and if it is correlated to time loss. The purpose of this study was to (1) analyze how differences in compliance may impact injury rate and (2) if compliance may impact time loss due to injury.

Methods This study was a Level 1 prospective cluster randomized controlled trial conducted in NCAA men's football (soccer) teams that examined the efficacy of the 11+injury prevention program. The two outcome variables examined were number of injuries and number of days missed from competition. Twenty-seven teams ($n=675$ players) used the 11+program. Compliance, injuries and time loss were recorded. There were three compliance categories, low (LC, 1–19 doses/season), moderate (MC, 20–39 doses/season), and high (HC, > 40 doses/season).

Results There was a significant difference among the groups for injuries, $p=0.04$, ${}_{p}\eta^{2}=0.23$. The LC group [mean (M) = 13.25, 95% confidence interval (CI) 9.82–16.68, injury rate (IR) = 10.35 ± 2.21] had a significantly higher injury rate than the HC group ($M=8.33$, 95%CI 6.05–10.62, IR = 10.35 ± 2.21), $p=0.02$. The MC group ($M=11.21$, 95%CI 9.38–13.05, IR = 8.55 ± 2.46) was not significantly different than the LC group, $p=0.29$, but was significantly greater than the HC group, $p=0.05$. When examined as a continuous variable, compliance was significantly negatively related to injury rate ($p=0.004$). It was also significantly negatively related to number of days missed ($p=0.012$).

Conclusions When compliance was high, there was a significant reduction in injury and time loss. This evidence reinforces the importance of consistent injury prevention program utilization. Clinically, these findings have important implications when discussing the importance of consistent utilization of an injury prevention protocol in sport.

Level of evidence Level 1—Randomized controlled trial (RCT).

Keywords Injury prevention · Compliance · 11+ · Football (soccer) · Program fidelity

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Introduction

Efforts to design and implement effective injury prevention and reduction programs in sport have been researched in the medical community for several decades [8, 11, 14, 17, 19, 22, 24, 25, 31]. The success of such community-based programs is multifactorial and are predicated upon the identification of the injury risk, analyzing the mechanism of injury, education of the coaches and players, the qualitative content of the injury prevention program, and the fidelity, compliance and adherence to the prescribed evidence-based program, where compliance refers to an individual conforming to a recommended intervention with respect to dosage, frequency and timing and adherence refers to a process that is influenced by environment, social context, personal knowledge, motivation, skill and available resources [9, 18, 20, 30]. Once a program has been scientifically vetted, the sports medicine community is compelled, from a public health perspective, to increase awareness that such programs do indeed exist. Clinicians must stress the critical nature of the inclusion, adoption and adherence to such programs into the existing sports training repertoire [4, 5, 7].

Despite the numerous publications that discuss the notion of injury prevention and reduction in sport, only a few studies have thoroughly discussed how the role of program integrity, adherence, and compliance may directly impact the efficacy of such programs [1, 13, 15, 23]. This is a critical aspect to analyzing the overall fidelity of an injury prevention program. In some research circumstances, if compliance was not deemed adequate, it is impossible to ascertain scientifically if it was a failing of the content of the actual prevention protocol, or if the compliance to the program was so inordinately low, that the neuromuscular training benefit of the prevention program was nullified, respectively [27, 28].

The aim of this study was to characterize differences in compliance in competitive male football players and to determine if variability in compliance to a neuromuscular training program (11+) would impact injury rate. Additionally, this study assessed if a correlation existed between high compliance to the 11+ program and a decrease in time lost due to injury during competitive play and training. This study is necessary to stress the importance of consistent utilization of injury prevention programs to address the steady rise in injury associated with sport.

Materials and methods

This study was a prospective cluster randomized controlled trial, which was conducted in 27 of 61 Division I and Division II NCAA men's football (football) teams. Human ethics internal review board approval and informed consent was obtained through Quorum IRB (Seattle, WA, 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.

Intervention

The 11+ is an injury prevention program designed as a dynamic warm-up program to address lower extremity injury incurred in the sport of football for athletes over the age of 14. It is a 20-min field-based program that consists of 15 exercises divided into three separate components: running exercises (8 min) that encompass cutting, change of direction, decelerating and proper landing techniques, strength, plyometric and balance exercises (10 min) that focus on core strength, eccentric control and proprioception, and running exercises (2 min) to conclude the warm-up and prepare the athlete for athletic participation. There are three progressions (level 1, level 2, level 3) that increase the difficulty for each respective exercise. This allows for both individual and team progression throughout the course of the competitive season. In this specific study, the FIFA 11+ program served as the intervention program over the course of one competitive collegiate football season [24].

Participants

Sixty-five institutions were randomly assigned and completed the intervention study during one competitive football 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 was utilized. For the compliance aspect of the study, only the intervention teams that utilized the 11+ program as their dynamic warm-up completed the study were utilized (27 teams, $N = 675$) (Fig. 1).

Operational definitions

The following operational definitions were used during the injury data entry phase of the study. An injury was reported if a player was unable to participate fully in a scheduled game or training session. The player's return to play date was entered when the player was fully able to participate in a game or training session. All injuries were entered by Certified Athletic Trainers using The International Statistical Classification of Diseases and Related Health Problems (ICD-9) coding system. The severity of injury was defined utilizing the UEFA injury definition guidelines which was

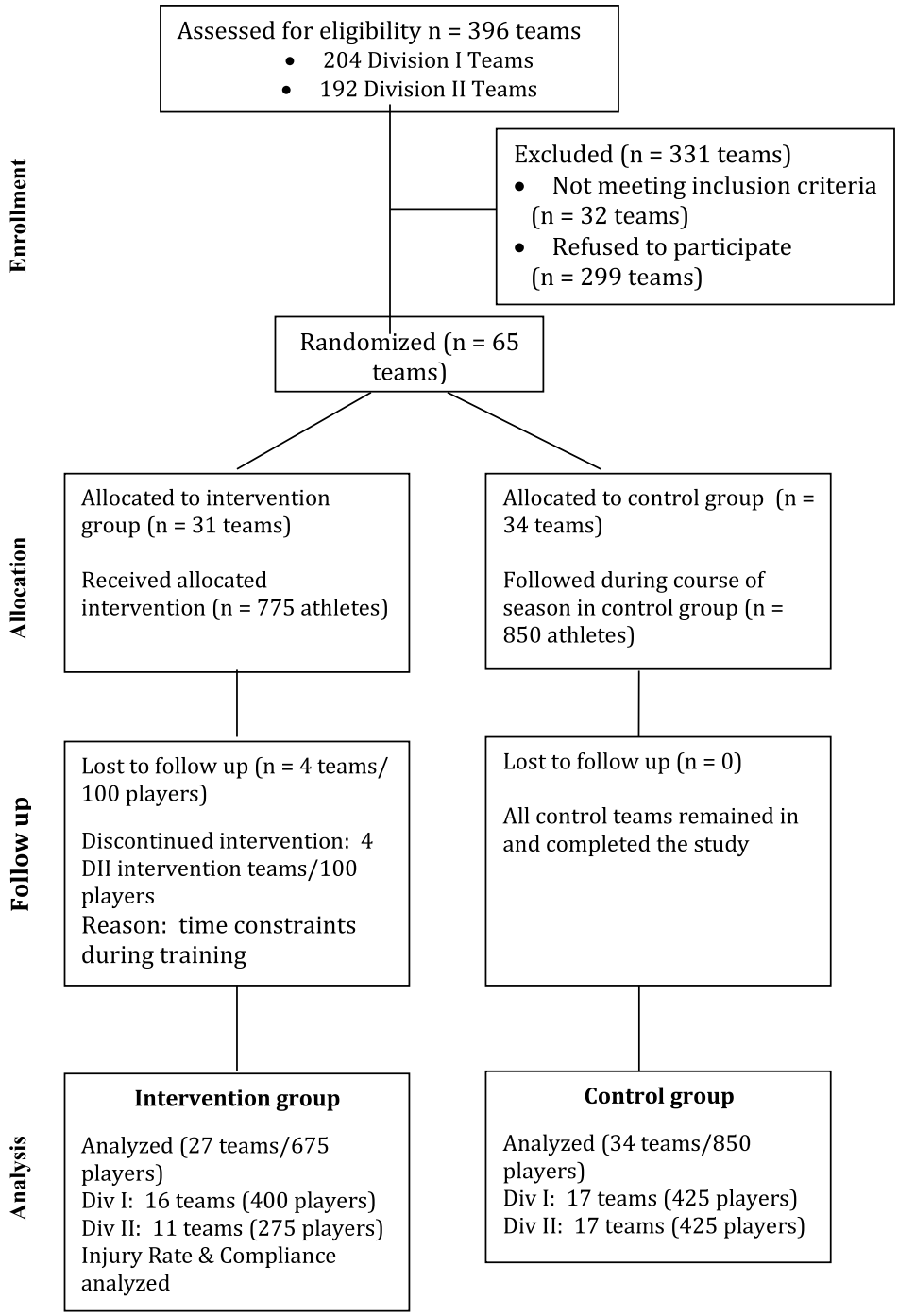

Fig. 1 Description of NCAA team randomization and study flow

dictated by the amount of time missed from active participation (Table 1) [10].

Data collection

An internet-based injury surveillance data collection system was utilized (HealtheAthlete™, Overland Park, Kansas) by every enrolled institution in the study. 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. Only the intervention teams using the 11+ prior to games and training were analyzed for the compliance phase of the study. Upon the completion of the competitive football season, the injury, athletic exposure and compliance data entry

Table 1 Operational definitions used to define the parameters of the injury

Term	Operational definition used to identify injury
Reportable injury	Any injury sustained by a player during a scheduled game or training session which caused the athlete to be unable to fully participate and seek treatment by the Certified Athletic Trainer
Time loss due to injury	An injury which caused an athlete to miss a subsequent training session or game
Exposure	Participation in a game or training session
Severity of injury	The number of days absent from soccer participation; minimal (1–3 days), mild (4–7 days), moderate (8–28 days), or severe (> 28 days)
Return to participation	The day the player was able to return to full participation in training and/or game situation

was confirmed by each certified athletic trainer (ATC) and verified with their individual institution's data collection system for accuracy and thoroughness. During the season, the research team monitored the team and individual compliance of the program weekly. If compliance within the IG was deemed less than optimal, an email was sent by a member of the research team to the individual institution. If the institution did not respond within 14 days, a research member contacted the team to encourage improvement in data entry and/or adherence to the program. At the completion of the season, compliance was analyzed and stratified by utilization consistency into tertile categories and by month of utilization and on a continuum.

Human ethics internal review board approval and informed consent was obtained through Quorum Internal Review Board (IRB # 26182/1) (Seattle, WA, USA).

Statistical analysis

This manuscript is based on an exploratory post hoc analysis of the data collected from the 11+ Intervention group (IG) in a larger randomized controlled trial [24]. All statistical analyses were conducted utilizing IBM SPSS for Windows version 23 (Armonk, NY). Descriptive and inferential tests were used to compare levels of compliance within the IG, including t tests, χ^2 tests, and generalized linear regression models (GLM), with logit link function and Poisson distribution for injury count data between groups. Descriptive data for compliance, exposures and injury rates (IR) are presented as means (M) with standard errors (SE) and 95% confidence intervals (CI). P values of 0.05 or less were considered significant. The summary measure for injury rate (IR) was calculated according to the formula: $IR = n/e$, where n is defined as the number of injuries during the data collection period and e is the number of exposures expressed in number of games or trainings participated in. Relative rate ratios (RR), with their associated 95% confidence intervals, were calculated using the injury incidence for each compliance group. Analyses of variance (ANOVAs) were utilized to analyze the main effect of compliance (three levels) on both injury rate and time loss due to injury. All effects were deemed statistically significant with a p value of $p < 0.05$. Tukey's post hoc analysis was utilized to analyze within group differences when a main effect was identified. χ^2 tests were used to compare categorical variables within the compliance subgroups. A GLM regression model was used to analyze compliance as a continuous variable with respect to injury rate and days lost due to injury.

Cohen's d effect sizes were calculated and defined when compared to the following: small $d = 0.20$, medium $d = 0.5$, and large $d = 0.8$. Power calculations were performed, a priori, using preliminary data and G*Power software version 3.1.0 (Universität Düsseldorf, Düsseldorf, Germany). Using a generalized linear model with Tweedie distribution and logit link function, with p value = 0.05 and power = 0.80, it was determined that a relative risk of 1.1 could be detected with a total sample size of 125.

Results

Of the thirty-one teams in the intervention cohort, 27 teams ($N = 675$) completed the research study and, thus, compliance was analyzed using a per-protocol analysis. Injuries and time loss due to injury during the entire season were tracked within this cohort.

Team compliance

Twenty-seven intervention teams completed the FIFA 11+ injury prevention program over the course of the season (August through late November or early December, depending on the success of the team in the NCAA tournament). The total number of utilizations of the FIFA 11+ equated to 886 sessions (mean 32.8 ± 12.1 sessions, range 11–64, median = 32). There were 1304 overall team exposures in the IG (405 games and 899 training sessions) over the course of the season, translating into an average of 2.2 FIFA 11+ utilizations over the course of the season per week. Compliance was determined to be low for teams using the program ≤ 1 time per week (LC: 1–19 doses/season), moderate for > 1 and < 2 utilizations per week (MC: 20–39 doses/season) or

Table 2 Tertiles of team compliance and utilization of the FIFA 11+Program

Compliance	High ($n=9$ teams/225 athletes)		Moderate ($n=14$ teams/350 athletes)		Low ($n=4$ teams/ 100 athletes)	
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range
Teams						
1st half of season	26.6 ± 7.7	20–45	17.0 ± 4.2	12–25	8.3 ± 3.3	6–13
2nd half of season	19.2 ± 2.2	18–24	12.4 ± 3.9	9–21	7.5 ± 3.1	5–12
Entire season	45.8 ± 7.5	40–64	29.4 ± 5.9	21–39	15.8 ± 3.6	11–19

The mean values represent the number of FIFA 11+sessions performed during distinct and in totality for the competitive season, presented with SD and ranges of utilization

Table 3 Injury risk amongst teams stratified into tertiles of compliance

Compliance	# Teams/# athletes	Injury count (M ± SD)	Injury rate (IR)	Rate ratio (95% CI)	*p* value
High	9/225 athletes	8.3 ± 3.5	6.4 ± 2.7	–	–
Moderate	14/350 athletes	11.2 ± 3.2	8.6 ± 2.5	1.3 (1.1–1.7)	0.009
Low	4/100 athletes	13.3 ± 3.2	10.4 ± 2.2	1.6 (1.3–2.1)	< 0.001

The data represents number of teams, number of athletes, mean injury count with standard deviation, injury rate (IR), rate ratio with 95% confidence interval (CI). The high compliance group is the reference group

high for ≥ 2 utilizations per week (HC: >39 doses per season,), predicated on a 19.4-week season. Four teams were categorized in the low tertile (15.8 ± 3.6 doses/season, range 11–19 days, median = 16.5), 14 teams in the moderate tertile (29.4 ± 5.9 doses/season, range 21–39 days, median = 29.5), and 9 teams were categorized in the high tertile (45.8 ± 7.5 doses/season, range 40–64 days, median = 43) (Table 2). The utilization in the first half of the season (August and September) exceeds that of the utilization in the second half of the season (October, November and December) secondary to the fact that many teams' season were concluded in mid-November after being eliminated from conference tournament play. The decreased dosage of FIFA 11+in the second half of the season does not necessarily reflect a decrease in utilization of the program (Table 2).

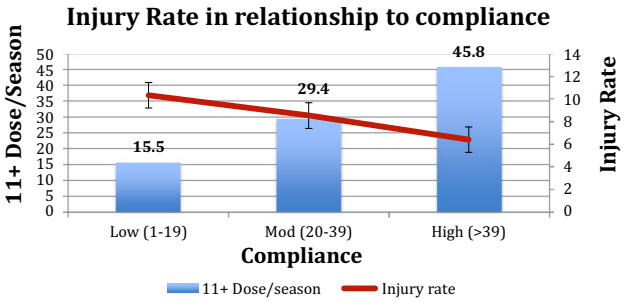

Fig. 2 Injury rates in relationship to compliance with the FIFA 11+program. The bars represent the level of compliance: Low compliance = 1–19 utilizations ($n=4$ teams), moderate compliance = 20–39 utilizations ($n=14$ teams) and high compliance = > 39 utilization ($n=9$ teams) of the FIFA 11+ (error bars depict standard deviation), $p=0.004$

Compliance and injury rate

There were 53 injuries in 4 LC teams ($M=13.3$, IR = 10.34 ± 2.2, RR = 1.6(1.3–2.1), $p<0.001$), 157 injuries in 14 MC teams [$M=11.2$, IR = 8.6 ± 2.5. RR = 1.3 (1.1–1.7), $p=0.009$] and 75 injuries in 9 HC teams ($M=8.3$, IR = 6.4 ± 2.7) (Table 2). There was a main effect within the groups for injury rate, $f(2,24)=3.6$, $p=0.043$, ${}_{p}\eta^2=0.231$. Upon post hoc analysis, the LC group ($M=13.3$, 95% CI 9.8–16.7, IR = 10.4 ± 2.2) had a significantly higher injury rate than the HC group ($M=8.3$, 95% CI 6.1–10.6, IR = 6.4 ± 2.7), $p<0.001$. The MC group ($M=11.2$, 95% CI 9.4–13.1, IR = 8.6 ± 2.5) was not significantly different than the LC group, $p=0.291$, but was significantly greater than the HC group, $p=0.009$. When examined as a continuous variable, compliance was significantly negatively related to injury rate ($b=-1.6$, $t=-3.2$, $p=0.004$, $R^2=0.029$) (Table 3; Fig. 2).

Compliance and time loss due to injury

Compliance was also significantly negatively related to number of days missed, which served as a proxy for severity of injury ($b=-2.8$, $t=-2.7$, $p=0.012$, $R^2=0.23$). The LC teams reported 9.6 ± 2.8 days lost to injury compared to 11.9 ± 5.7 for the MC teams and 7.6 ± 4.8 days lost for the HC teams ($F=3.35$, $p=0.012$) (Fig. 3). Within the high compliance group, there was a lower injury rate and a

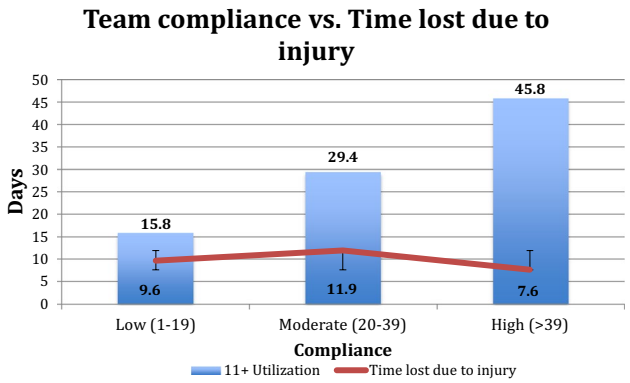

Fig. 3 Team compliance compared to time lost due to injury. Utilization of FIFA 11+ stratified by team compliance (low, moderate and high) compared to time lost due to injury. The high compliance teams had significantly fewer days lost due to injury compared to the MC and LC compliance groups ($p = 0.012$)

decreased severity of injury, demonstrated by a decrease in time loss due to injury (Table 4; Fig. 3).

There was a significant difference among the compliance groups on the average number of days missed per injury by team, $f(2,24) = 3.35$, $p = 0.05$, ${}_{p}\eta^2 = 0.218$. It should be noted that the partial eta squared (${}_{p}\eta^2$) was equal to 0.218, meaning that the effect for the group differences recorded in days lost due to injury per team accounted for 21.8% of the variance plus error variance. Furthermore, there was a similar pattern noted when analyzing compliance compared to days lost to injury and compliance compared to injury rate. The LC group had the second highest number of days missed ($M = 127.3 \pm 54.1$, 95% CI 60.0–194.6) and the MC group reported the highest number of days missed ($M = 133.3 \pm 76.6$, 95% CI 97.3–169.2). The HC group had the fewest days missed per team ($M = 63.2 \pm 46.1$, 95% CI 18.4–108.1) and fewest days lost per injury ($M = 7.6 \pm 4.8$, 95% CI 8.2–12.5) (Table 4). Additionally, there was one potential outlier in the data for the MC group; a contact ACL/meniscal injury that occurred in the first game of the season resulting in 106 days of time loss (within the parameters of the data collection). Since we hypothesize that the benefit of performing an injury prevention program is not realized in the first week of utilization, we performed a secondary analysis with this one injury removed from the dataset. Once removed, there is a significant difference amongst compliance groups, with the HC having significantly fewer days lost to injury than both LC, $p = 0.009$, and MC, $p = 0.018$ groups, respectively.

Discussion

The most important finding of this present study, that corroborated findings by previous researchers, is high compliance to the 11+ injury prevention program demonstrated lower injury rates throughout the competitive season [26–28]. There is an inverse correlation between compliance and injury rate and severity of injury; which was reflected in fewer days lost due to injury. High compliance to the 11+ program resulted in fewer injuries and decreased severity of injury.

Compliance and injury risk

The teams with high compliance (HC) completed the FIFA 11+ nearly three times as frequently as the LC teams and nearly one and one-half times as frequently as the MC teams. When the exposure–response relationship was analyzed, the preventative impact of the program seemed to improve as the number of doses increased throughout the season. The injury rate was lowest in the HC group compared to the MC and the LC groups (Table 2). Thus, a statistically significant inverse relationship exists between compliance and injury rate; the more compliant the teams were to utilizing the FIFA 11+ program, the lower the injury rate reported. In addition, when the entire intervention group was compared to a control group that did not utilize the 11+ program, there was an overall injury reduction of 46.1% [24]. However, when the HC group was compared to the control group, there was a 57.5% decrease in overall injury rate. This supports the

Table 4 FIFA 11+ utilization compared to injury rate and time loss due to injury

	Compliance				95% CI	Std. Error	*p* value
	Low (1–19)	Moderate (20–39)	High (> 39)	Total			
11+ Utilization	15.8 ± 3.6	29.4 ± 5.9	45.8 ± 7.5	32.8 ± 12.1	28.0 + 37.6	2.3	< 0.001
Injury rate	13.3 ± 3.2	11.2 ± 3.2	8.3 ± 3.5	10.6 ± 3.6	9.1–12.0	0.7	0.004
Time lost to injury							
By team	127.3 ± 54.1	133.3 ± 76.6	63.2 ± 46.1	109.0 ± 70.8	81.0–137.1	13.6	0.01
Per Injury	9.6 ± 2.8	11.9 ± 5.7	7.6 ± 4.8	10.3 ± 5.4	8.2–12.5	1.1	0.01

Data represents mean/standard deviation, 95% confidence interval (CI), standard error (std. error), and *p* value. Significance ($p < 0.05$) was reached for FIFA 11+ utilization, injuries within compliance groups, and time lost due to injury (stratified by team and per injury)

notion that as the dosage of the FIFA 11+ increases over the course of the season, the preventative benefit also increases.

The overall utilization of the FIFA 11+ was 32.8 ± 12.1 doses per season and 2.0 ± 0.7 doses per week. The recommended dosage was 2 sessions per week. Despite the LC and MC teams performing the program fewer times than the recommended dosage, both groups still experienced a reduction in injuries and fewer days lost to injury compared to the control group [24]. Recent systematic reviews of the FIFA 11+ program noted that athletes with high compliance to the FIFA 11+ injury prevention program resulted in a 35–39% reduction in injury risk [3, 29]. In addition, the athletes using the FIFA 11+ program demonstrated significant improvements in neuromuscular and motor performance when the structured warm-up was utilized at least 1.5 times per week [3]. This supports the premise that FIFA 11+ program is indeed an effective manner unto which football-related injury might be prevented.

Compliance and time lost due to injury

The high compliance group experience fewer days lost to injury per team and fewer days lost to each individual injury compared to the low and moderate compliance groups. When compliance was analyzed as a continuous variable, this was also a statistically significant finding. Earlier research articles that demonstrated similar findings, have corroborated this evidence. In one of the initial studies analyzing the effectiveness of the FIFA11+ program in young female football players, there was a significantly lower risk of injuries overall overuse injuries, and severe injuries in the IG compared to the CG [25]. In a small cohort study conducted in men's football over one season, the IG demonstrated a reduction in the relative risk of lower extremity injury of 72% and time lost due to lower extremity injury ($p < 0.01$) [12]. These studies, in addition to others that have utilized alternative neuromuscular training programs, have shown proven efficacy in reduction of injury rate, severity of injury and time lost due to injury [6, 11, 16, 17, 19]. However, despite very thorough implementation strategies, compliance continues to be an obstacle in optimal program adherence [4].

The compliance conundrum

Despite very promising research detailing the efficacy of the FIFA 11+ in male and female football athletes [12, 22, 24, 25], compliance and program adherence by players and coaches continues to be problematic across sport. Compliance and adherence to injury prevention protocols has been discussed in the literature, but acceptable levels of program adherence in sport continue to elude sports medicine researchers [18, 26–28]. In a recent survey of youth male football teams analyzing the awareness and utilization of the FIFA 11+ program, 61% of respondents had heard of the FIFA 11+ program, but only 28% reported using the program in some form (fully or modified versions). Interestingly, when the respondents were queried on who ultimately holds responsibility for injury prevention efforts, there was significant variability in the responses: 35% indicated that the head coach held the ultimate responsibility, 24% the player, and 24% the fitness coach [21]. Bahr et al. reported that despite the fact that 88% of Champions League and Norwegian Premier League teams being aware of the existence of hamstring injury prevention methodology, only 16 teams (10.7%) were fully compliant and 9 teams (6%) were partially compliant with the proposed intervention. This resulted in a startling 225 teams (83.3.%) of the teams being deemed completely non-compliant [2]. This research elucidates the magnitude of the work that stands before the sports medicine community. This study has important implications when discussing the importance of consistent utilization of an injury prevention protocol in sport.

This study was conducted in male football (soccer) players and only was conducted over the course of one season. The NCAA collegiate football (soccer) season only extends from August to December, and is significantly shorter than other competitive and professional seasons around the world. Unannounced site visits were not conducted during this data collection due to the vast geographic expanse of the study population (entire United States). Due to the nature of the NCAA substitution rule, the researchers analyzed exposure using athletic exposure versus playing hour as a unit of analysis. The researchers were only able to analyze compliance by team, and not by individual participant. Individual compliance to the program was not collected during the data collection phase. The low compliance group was limited to four teams and the 11+ utilizations ranged from 11 to 19. This may represent inter-team differences, which can affect the overall comparison between groups. This was overcome by including the analysis of compliance on a continuum.

Conclusions

The athletes utilizing the FIFA 11+ as their dynamic warm-up program with high compliance demonstrated a significant reduction in injury rate and time loss due to injury. The higher the consistency in the adherence to the program, the greater the benefit to the individual athlete with respect to decreased injury risk and severity of injury. This corroborates the research finding found in earlier studies conducted in men and women, globally [22, 25–27]. As researchers continue to revise and improve injury prevention and reduction efforts, there should be equal emphasis placed on analyzing optimal strategies to encourage optimal

implementation and utilization by athletes, coaches and medical staffs universally.

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Compliance with ethical standards

Conflict of interest One of the authors (HJS-G) received a PhD Research Grant from Simbex, Inc (less than 10,000 USD); and is a research consultant to Major League Soccer's M-MARC program (less than 10,000 USD) unrelated to this work. One of the authors (AA) received a Grant from the National Institutes of Arthritis and Musculoskeletal and Skin Diseases (R01-AR048212) (less than 10,000 USD) and the Foundation for Physical Therapy–Promotion of Doctoral Studies I Scholarship (less than 10,000 USD). One of the authors (BRM) received funding from FIFA to support the completion of this study (see below); and is a consultant to Athrex, RTI, Exactech, and DePuy Mitek. The institution (Santa Monica Orthopaedic Group) of one or more of the authors (HJS-G, BRM) has received funding from FIFA's (Fédération Internationale de Football Association) F-MARC Program (2012) for the initial publication (10,000–100,000 USD).

Ethical approval This study received Internal Review Board (IRB) and Human Ethics approval.

Informed consent Informed consent was obtained through Quorum Internal Review Board (IRB # 26182/1) (Seattle, WA, USA).

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