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High adherence to a neuromuscular injury prevention program (FIFA 11+) improves functional balance and reduces injury risk in Canadian youth female football players - a cluster randomized trial

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Abstract

Background: A protective effect on injury risk in youth sports through neuromuscular warm-up training routines has consistently been demonstrated. However, there is a paucity of information regarding the quantity and quality of coach-led injury prevention programs and its impact on the physical performance of players.

Objective: The aim of this cluster-randomized controlled trial was to assess whether different delivery methods of an injury prevention program (FIFA 11+) to coaches could improve player performance, and to examine the effect of player adherence on performance and injury risk.

Method: During the 2011 football season (May-August), coaches of 31 Tier 1-3 level teams were introduced to the 11+ through either an unsupervised website or a coach-focused workshop with and without additional on-field supervisions. Playing exposure, adherence to the 11+, and injuries were recorded for female 13-18-year old players. Performance testing included the Star Excursion Balance Test (SEBT), single-leg balance, triple hop, and jumping-over-a-bar tests.

Results: Complete pre- and post-season performance tests were available for 226 players (66.5%). Compared to the unsupervised group, single-leg balance (OR=2.8; 95% CI 1.1-4.6) and the anterior direction of the SEBT improved significantly in the on-field supervised group of players (OR=4.7; 2.2-7.1), while jumping decreased (OR=-5.1;-9.9- -0.2). However, significant improvements in 5 out of 6 reach distances in the SEBT were found, favoring players who highly adhered to the 11+. Also, injury risk was lower for those players (IRR=0.28, 95% CI: 0.10-0.79).

Conclusion: Different delivery methods of the FIFA 11+ to coaches influenced players' physical performance minimally. However, high player adherence to the 11+ resulted in significant improvements in functional balance and reduced injury risk.

Background

Prospective intervention studies consistently demonstrate a protective effect of comprehensive neuromuscular warm-up routines in reducing injury risk among youth team sport participants.¹⁻⁵ Among Norwegian 14- to 16-year old female football players, Soligard et al.³ demonstrated the effectiveness of the FIFA 11+ program in reducing the risk of all injuries by 32%. Soligard et al.⁶ further demonstrated a greater protective effect in players with high adherence to the 11+, estimating a risk reduction of all injuries by 35% for those players participating in at least 1.5 structured warm-up sessions/week.

Previous investigations among youth team sport participants have suffered from moderate or unknown adherence to the warm-up programs.²⁻⁵ These programs were largely delivered by coaches who were initially educated by a physiotherapist or other research personnel. There is a paucity of information regarding the quantity and quality of coach-led injury prevention programs and its impact on the physical performance of players.⁷

It is conceivable that it is easier to motivate coaches and players to follow such exercise programs, not only to prevent injuries, but if there also is a direct performance benefit.⁸⁻¹² It might be expected that by implementing a 15-20 min injury prevention program, physical performance should be improved, however, conflicting outcomes are currently reported.⁸⁻¹³ Testing neuromuscular injury prevention programs regarding their effects on direct performance improvements and intermediate performance outcomes (e.g. reduced injury risk through decreased knee valgus motions¹⁴ or improved functional balance and postural control,¹⁵⁻¹⁸ will add to a better understanding of the mechanisms of successful injury prevention programs in reducing injury risk and improving neuromuscular performance.

If there was a link among injury risk factors, risk reduction and performance outcomes it may facilitate adoption and sustained adherence to successful programs. To our knowledge no investigation has shown a link between improved balance through neuromuscular injury prevention training and reduced injury risk.

The aim of this cluster-randomized controlled trial (RCT) was 1) to assess whether different delivery methods of an injury prevention program (FIFA 11+) to the team could improve physical performance; 2) to relate changes in performance to changes in injury occurrence; and 3) to examine the effect of adherence to the 11+ program on both performance changes and injury risk in a group

of 13-18-year old female football players. Our primary hypothesis was that there would be a difference between the three groups in the change in performance from pre- to post-season performance tests.

Materials and methods

Study population and design

This cohort was part of a larger RCT aimed to investigate the effect of different delivery methods of the 11+ on team and player adherence to the injury prevention program, injury risk, and coaches' and players' knowledge, attitudes, and beliefs to and satisfaction with the intervention (Re-vised manuscript submitted to BJSM). Youth female football teams from the Calgary and Edmonton Minor Football Associations, and The Edmonton Interdistrict Youth Football Association, Alberta, Canada were recruited.

The study population consisted of consenting coaches and female football players (ages 13 to 18 yrs) representing 31 teams from 19 clubs playing in the 2011 outdoor season. We recruited all available teams in the pre-season (April/May 2011), and followed players from these teams for a total of 4.5 months through the regular league play and play-offs (to August 2011).

Before the start of the investigation, all teams received oral and written information about the study. Player assent and parent consent were obtained, and it was emphasized that participation in the project was voluntary. Teams were recruited from the top three levels of play (Tier 1-3) and two age groups (under 16 years [U16], under 18 years [U18]). All players were screened for pre-season injuries (back or lower extremity injuries last 6 weeks) using a medical baseline questionnaire at the start of the study. Player exclusion criteria were: being injured or having had a systemic disease (e.g. cancer, arthritis, heart disease) or neurological disorder (i.e. head injury), which prevented full participation in all organized football activities at the commencement of the 2011 outdoor season.

Teams were randomized to one of two intervention groups or a control group. To avoid contamination, teams were randomized by club to study group, and from the final consenting clubs, there were five clubs in total randomized with 2-6 teams. The randomization of clubs was undertaken by a random number generation conducted by study personnel (CE) not involved directly in recruitment or intervention delivery

The intervention program and delivery methods

The FIFA 11+ is a 20 min warm-up program developed to prevent lower extremity injuries among football players. The 11+ program consists of 15 single exercises, divided into three parts including initial and final running exercises with a focus on cutting, jumping and landing technique (Parts 1 and 3) and strength, plyometrics, agility, and field balance components (Part 2). For each of the six conditioning exercises in Part 2, the 11+ program offers three levels of variation and progression.³

Following baseline performance assessment, coaches from the 11 teams in the control group were solely provided with online access to the 11+ program website (http://f-marc.com/11plus/). They were given no additional information or guidance about the injury prevention program or how to engage their players in it. Coaches from the 10 teams in the regular, coach-focused intervention group were provided with one pre-season coach workshop for the 11 + program by study personnel, and with 11+ material (video, poster detailing the exercises, and website information). In addition to the pre-season 11+ workshop for coaches and other 11+ material (as mentioned above), coaches from the 10 teams in the comprehensive, player-focused intervention group were provided with an assigned 11+ study physiotherapist who taught the 11+ program to the players and was to participate weekly in a practice session to facilitate correct technique and progression of the program components. These coaches led the daily warm-up of their players supported by the team's physiotherapist.

By the end of the pre-season to the beginning of the season, a total of seven workshops were delivered to 35 head and assistant coaches from the 20 intervention teams and to 11+ study physiotherapists participating in the player-focused intervention group.

All participating coaches were asked to carry out the 11+ injury prevention program with their team as a warm-up at the beginning of all practice sessions and Parts 1 and 3 before match play (2-3 times a week). All coaches from all three study groups were given contact information to clarify questions and provide support by telephone when needed.

Exposure, player adherence, and injury registration

From team recruitment into the project (day of workshop for the 20 intervention teams and day of pre-season testing and delivery of the link to the 11+ website for the control teams), teams and players were followed-up weekly by study personnel regarding playing exposure, 11+ participation, and injuries throughout the study period.

All teams identified a team designate who was responsible for daily and individual exposure registration (participation in practices and matches (in minutes), 11+ sessions, including single 11+ exercises). Completeness of data collection was ensured by study personnel on a regular basis. Team and player adherence to the 11+ was based on the number of sessions each team and player completed the 11+ out of the team's total amount of football sessions possible, and on the total number of 11+ exercises completed by each player. An injury was defined as "any injury occurring during football activity resulting in medical attention and/or the removal of the player from the current session and/or subsequent time loss of at least one football session (match or practice) as a direct result of that injury".¹⁹ All injured players were assessed at a practice session by an athletic or physiotherapist within one week of an injury occurrence to confirm the injury and its diagnosis, and were thereafter followed-up to return to play. For any injury resulting in expected time loss of more than one week or any suspected concussion, the injured player was referred to a study sport medicine physician. Injury severity was classified based on the consensus agreement of injury definitions as slight, minimal or mild (0-7 days absence from football), moderate (8-28 days), and severe (>28 days).²⁰ All study therapists and physicians examining the injury, were blinded to study group allocation.

Performance tests

Prior to the randomization and start of the intervention period, all players were asked to take part in a field-based testing procedure to assess specific performance measures. The test battery included four test stations and lasted for approximately 60 minutes. This session also included the completion of a survey regarding safety knowledge, attitudes and behaviors, which is not reported here. Follow-up field-based testing was completed in the final two weeks of the season.

The test session included the Single-leg eyes-closed balance on an Airex Balance Pad® (seconds),¹⁶ the Star Excursion Balance Test (cm),^{17;22} the Single-leg triple hop (cm),²⁴ and the Jump-over-a-bar test (total number of 2-leg jumps in 15 seconds).¹⁰ The test procedures are described in detail in Appendix 1. During the testing, the players received verbal instruction and visual demonstration from the examiner for each of four test stations. All single-limb tests were carried out on both feet, and tests commenced with an assessment of the player's dominant foot (defined as primary kicking leg). All players were measured for height (in 0.5 cm units) and weight (in 0.5 kg units), and tested for balance performance while having their socks on. The remainder of the testing was completed with their shoes on.

Statistical methods

All statistical analyses were conducted in STATA 10.0 (StataCorp, College Station, Texas, USA). The primary hypothesis, that there would be a difference between the three groups in the change in performance from pre- to post-season performance tests, was analyzed by using a linear 3-way mixed regression model (randomization, age group, playing level), using team as the unit of cluster. An intention-to-treat analysis was used including only players with completed pre- and post-tests. All estimates for between-group changes in performance from pre-season to post-season testing were adjusted for age group, playing level, previous injury history and clustering effects.

To explore the potential for a dose-response relationship between adherence to the 11+ and its effect on performance changes and injury risk, a secondary analysis, adjusted for age group and playing level, was used with players being evenly stratified into three groups of adherence tertiles⁶ according to the number of single 11+ exercises completed throughout the season.

Player baseline characteristics are presented as means with standard deviations (SD) or frequencies and percentages. As normally distributed, results from pre-season tests are reported as means with SD, while within-group changes from pre- to post-season tests and between-group differences are given as means with 95% confidence intervals (CI). Injury incidence rates (number of injuries/1000 player hours) were estimated for each of the three randomization groups and adherence groups. Post-hoc analyses (Bonferroni) for between-group differences in performance changes and injury risk are presented with the control and low adherence groups as reference groups.

A Poisson regression model was used to estimate crude and adjusted injury rate ratios (IRR) with corresponding 95% CI for each intervention group compared to the reference group (control group). RRs were also estimated using a similar model to compare the rate of injury based on tertiles of adherence according to the number of 11+ exercises. The level of significance was chosen to be α =0.05, and all tests were two-tailed.

The sample size was chosen to account for cluster randomization, contamination rates, and nonparticipating players for the post-season performance testing. A sample size calculation before study start indicated that 108 players (36 in each group) were necessary to determine a change of 5% from pre- to post-season testing on the jump-over-a bar test (absolute change 2-3 jumps) between groups ($\alpha = f 0.05$, $\beta = 80\%$ power) based on the results (mean 43 jumps) in a recent comparable study.¹⁰

Results

The first pre-season baseline testing was held on April 19 2012, the last post-season testing on September 10 2012. For the 20 intervention teams (10 regular, coach-focused and 10 comprehensive, player-focused intervention teams), the median time to pre-season baseline testing was 5 days following the FIFA 11+ workshop (range = 11 days before to 28 days after the workshop). The median number of therapist supervised sessions for the 10 teams in the comprehensive, playerfocused intervention group was 6 (range = 3 to 8 sessions), corresponding to approximately one visit every two weeks.

The final study sample included 29 teams (n=226 players), as two U18 tier 2 level teams from the regular, coach-focused intervention group were excluded following pre-season testing (Figure 1). These teams were unable to identify a team designate to establish data collection procedures according to the study guidelines. Of the 340 players completing performance baseline testing, 114 players (34%) did not participate in the post-season testing for multiple reasons (moved out of town, were on holiday, or unable to attend follow-up session for other unknown reasons). There were no clinically relevant differences for baseline characteristics or baseline performance between players who did not participate in follow-up performance testing and participating players.

Anthropometric player characteristics and their distribution in the three study groups are presented in Table 1. Following randomization, there were significant differences in the distribution of players by age group and playing level.

Effect of the intervention on performance

The 226 study participants completed the 11+ injury prevention program in 3876 (mean 17.2 [SD 7.3] sessions, range 0-31) out of 4872 possible sessions throughout the study period (79.8%), corresponding to 1.9 (0.8) 11+ sessions per week. The corresponding data for the three study groups in addition to team and player adherence to the 11+ are presented in Table 2. There were no clinically relevant differences between study groups on baseline tests with the exception of 2-leg jump performance (Table 3). For all groups, significant within-group differences and improved crude post-season outcomes were found for all SEBT directions, in addition to an enhanced triple-hop performance for players in the comprehensive, player-focused intervention group. After adjusting player-performance changes were found between the comprehensive, player-focused intervention group and the control group. Single-leg balance (OR=2.8; 95% CI 1.1, to 4.6) and the anterior

direction of the SEBT improved more in the comprehensive, player-focused group (OR=4.7; 2.2 to 7.1), while the number of jumps-over-a-bar improved more, however, in the control group (OR=-5.1; -9.9 to -0.2). No other significant between-group differences in changes of performance were detected (Table 4).

Effect of adherence on performance

Cut-off values for adherence tertiles (defined by the players' total individual number of 11+ exercises) were: low adherence group of players (range; 0 to 113 11+ exercises during the season), medium adherence (range; 114 to 213 exercises), and high adherence (range; 214 to 435 exercises).

The group of players with high adherence completed the injury prevention program 2.5 times as often as players in the group with the lowest adherence. During the course of the season, players in the high-adherence group (regardless of study group assignment) participated on average 23.4 (SD 3.3, 95% CI 22.6 to 24.1) times in the 11+ warm-up, while the corresponding values for the medium-and low-adherence players were 18.0 (4.4; 17.0 to 19.0) and 9.8 (6.2; 8.4 to 11.3), respectively.

The mean number of 11+ exercises carried out throughout the study period was 271.2 exercises (SD 49.1; 95% CI 259.9 to 282.5) for players in the high-adherence group, 161.0 exercises (32.8; 153.6 to 168.4) for players in the medium, and 71.3 exercises (37.1; 62.7 to 80.0) for players in the low-adherence group. Players in the high-adherence group performed the 11+ program on average 2.2 sessions (25.5 single 11+ exercises) per week compared to the low-adherence group performing 1.5 11+ sessions per week (10.5 single 11+ exercises) [mean difference = $0.7 \, 11+$ sessions (95% CI; 0.3 to 1.0)] or 15.0 single 11+ exercises (95% CI; 12.5 to 17.5)].

Pre-season baseline performance and within-group changes from pre- to post-season testing are presented for different adherence groups in Table 5. Adjusted analyses of the between-group changes, from pre- to post-season testing for players with high, medium, and low adherence are presented in Table 4. With the exception of "triple jump on the right foot", there was no evidence of effect modification by study group analyzing the association of adherence on performance outcomes. Significant improvements in functional balance by increased reach distances of 3 to 5 cm (4-7% improvement from baseline) in the SEBT were found, favoring the high-adherence group of players. No other significant dose-response relationships between high adherence and improved performance were identified.

Adherence and injury risk

During the four-month study period, including only the players in the performance analysis who completed follow-up testing (n=226), a total of 37 players (16.4%) incurred 46 injuries, irrespective of time-loss from football play. Thirty-three (72%) of the reported injuries were lower extremity injuries. There was no difference in the risk of injury by study groups ("randomization") (Table 6). However, when examining injury rates by adherence group, the risk of sustaining an injury was significantly lower in the high-adherence group compared to the medium-adherence group (IRR=0.28, 95% CI; 0.10 to 0.79). The same was the case for lower extremity injury risk (IRR=0.32; 0.11 to 0.95). In contrast, overall injury risk did not differ between players in the high- and low-adherence groups (IRR=0.46; 0.14 to 1.49).

Discussion

We found that a 20 min neuromuscular injury prevention warm-up program can improve dynamic and functional balance performance among 13 to 18-year old female football players. These findings are important for the acceptance and adoption of the program as performance improvements should provide additional motivation to coaches to regularly deliver the program to their players. Interestingly, performance outcome and injury risk was similar for players regardless of how the 11+ program was delivered to the team. However, better functional balance and 72% reduced injury risk was found for players who highly adhered to the prescribed exercises during the season compared to those with less adherence. Improved neuromuscular control appears to be a key element of the 11+ injury prevention program, and has by previous researchers been indicated to likely benefit a football player's technical and tactical performance on the field.²⁵

Program delivery and performance

The main objective of this analysis was to evaluate different delivery methods of the FIFA 11+ program to the teams and individual change in performance outcomes. The results infer that it does only minimal influence players' performance enhancement in how the coach learned the program and taught it to the players; whether it was through the 11+ website (unsupervised control group) or through a coach-focused workshop, without (regular, coach-focused intervention group) or with additional on field supervisions (comprehensive, player-focused intervention group).

The most likely explanation for these findings is that all players, regardless of study group assignment (delivery of the intervention), benefitted from a minimum dose of structured warm-up exercises. The

overall player adherence to the 11+, based on the maximum number of 11+ sessions the teams possibly could have conducted, was 80% and thereby higher than reported in other neuromuscular injury prevention protocol in youth sports.^{5;26} On average, these players performed the 11+ warm up program twice a week, which is more often than the players in the intervention group in the original injury prevention trial of the 11+.⁶

There are contradictory findings regarding the effect that neuromuscular training programs may have in improving physical performance among team sport athletes. Football demands a wide range of technical, tactical and physiological skill attributes.²⁷ It is thereby questionable whether performance in football can be assessed strictly using objective testing.²⁵ Nevertheless, some studies have shown improvements in performance aspects relevant for football and other team sport athletes following neuromuscular training (e.g. balance, strength, sprint times, jump distance and height),^{8;10;13} while three other studies showed no effects,^{9;11;12} though similar testing procedures and populations were chosen. In three of the projects, researchers relied on coach delivery of the intervention,^{8;10;12} while others had engaged study research personnel to ensure high quantity and quality of the delivery.^{9;11;13}

A certain exercise prescription (duration, frequency, intensity) is necessary to obtain performance changes.²⁸ With a mean length of 7-11 weeks, the study duration and total number of team and player intervention sessions were comparable to previous studies, where interventions have lasted from 6 to 36 weeks and the maximum number of prevention session ranged from 18 to >36 sessions.^{8-11;13}

A slightly higher frequency of 11+ sessions seemed to counterbalance the somewhat low intensity of the 11+, measured by fewer 11+ exercises in the control teams. Nevertheless, for the understanding of the effect of the 11+ on performance changes, it appears important to also evaluate the amount of neuromuscular exercises performed by the three groups, as these differed substantially between the two intervention groups and the control group. Players in the regular, coach-focused and the comprehensive, player-focused intervention groups performed almost twice as many 11+ exercises as players in teams where the 11+ was delivered unsupervised through an educational website (control group).

Compared to coaches in the control group, coaches in the two intervention groups may have better understood the preventive value of comprehensive warm-up and the key points of performing the warm-up exercises regularly and biomechanically correct after been instructed to the 11+ program by a 2.5 hour workshop with a theoretical and practical session. In other words, an educational workshop for the coaches with and without follow-up supervisions of their delivery of the 11+ might have affected the execution of the program positively.

Adherence and performance

This is the first study to analyze the dose-effect of adherence, defined by the number of completed exercises in a neuromuscular training program, on performance and injury risk concurrently.

Over the course of the 4-month season, a dose-response relationship between the player's total number of 11+ exercises and individual performance enhancements was found for balance. Functional balance, measured by the Star Excursion Balance Test (SEBT), improved significantly for both feet and in near all directions for those players who highly adhered to the intervention. On average, these players participated in 2.2 intervention sessions a week, completed 30-40% more single 11+ exercises than the original two intervention groups, and improved with clinically relevant 3-5 cm from pre-season testing (4-7%). These findings were independent of how the 11+ program originally was delivered to the player's team. Similar proportional improvements in the SEBT have been found following eight weeks of neuromuscular training²⁹ or 12 sessions of wobble board and postural stability training.³⁰

As specifically part 2 of the 11+ program consists of varying and progressing balance, plyometric, core and strength conditioning exercises, the positive outcomes on the anterior, posterolateral and posteromedial SEBT directions were no surprise. The type of movement required in the SEBT is both multilimb and multiarticular, and reach distance is greatly influenced by the amount of knee flexion, thigh and hip strength, ankle dorsiflexion of the stance foot, as well as of general core, hip and thigh strength to stabilize the reach limb away from the center of mass.^{22,23} For football players, proper functional balance and body control is essential for technical and tactical performance to efficiently position themselves in relation to the opponent and to control and pass the ball before being challenged by the opposing player.²⁵

Impaired balance is indirectly connected to an increased risk for specifically ankle and knee sprain injuries.¹⁵⁻¹⁸ Studies by Emery et al.¹⁶ and McLeod et al.¹⁸ have demonstrated that neuromuscular training can increase the balance capabilities of female high school basketball players and high school students. Improved neuromuscular control of the trunk and core positively influence dynamic stability of the lower extremity during high-speed athletic maneuvers, as typical for football players.³¹

As the 11+ focuses on single-limb stance balance exercises in Parts 1 and 2, similar improvements as in the SEBT might be expected for players' result in the dynamic eye-closed balance test on the foam pad. During single-leg balance 11+ training, the players were also purposely pushed off balance, which provided an additional challenge to the ability to maintain a stable core and proper alignment. However, this study confirms a recent trial's²⁰ finding of a large between-subject variability compared to the SEBT, which to some degree might explain the non-significant findings for this test in this trial. No other effect of the intervention on improved jumping performance could be found for players in the high adherence group. A plausible explanation for the lack of improvements in jumping abilities is that the intensity of plyometric exercises in the 11+ program is too low. Also, the participating coaches were taught to emphasize awareness among the players about the importance of carrying-out the warm-up exercises correctly and to focus on proper technique and posture with a knee-over-toe alignment. The main aim of the 11+ program is to gradually warm up the body with avoiding high injury risk movement patterns, like a knee turning into valgus, and aiming to reduce landing forces by slightly flexed hips and knees.³ These recommendations may have negatively influenced the players' effort in more explosive jump performances as required in jumping-over-abar and single-leg triple hop for distance jumping. Similar arguments were raised by Lindblom et al.¹²

Adherence and injury risk

The present results support the work of Soligard et al.⁶ which found that the risk of overall and acute injuries was reduced by more than a third among players with high adherence compared with players with medium adherence, measured by the number of 11+ sessions. Interestingly, for the present investigation, players in the high adherence group completed 1.3 and 2.4 as many 11+ sessions compared to players in the medium and low adherence groups. Thus, the preventive effect of the 11+ increased with dosage. The risk of injuries was 72% (all injuries) and 68% (lower extremity injuries) lower among players who completed almost 70% more 11+ exercises compared with players in the medium adherence group (282% more 11+ exercises compared to the low adherence group). Somewhat surprising, no significant differences in injury rates were observed between high and low adherent players, telling us that even though calculations of injury incidences take exposure into account, a minimum exposure is necessary to be at risk of injury. The total playing exposure for players in the low adherent group was low.

Of interest, Plisky et al.¹⁷ found that young female basketball players with less than 94% composite reach during the Star Excursion Balance Test (SEBT) had a more than 6 fold increased injury risk.

Also, players with side-to-side differences greater than 4 cm in the SEBT were 2.5 times more likely to sustain a lower extremity injury.¹⁷ The SEBT has also successfully been used as a screening tool to differentiate between ACL deficient and asymptomatic patients.³² In the present study, injury risk was 3.5 times higher for players in the medium compared to high adherence group, concomitant with 2-5 cm lower reach distance per SEBT direction, and 2 times higher, though non-significant, for low- versus high-adherent players. These results suggest that the SEBT might be a helpful tool to screen athletes for functional performance and injury risk.

Methodological issues

One of the strengths of the present study is its analysis of data from a large cluster-randomized design. With a total of 226 of 340 players (66%) with complete pre- and post-season performance tests, the only comparable study in terms of player size to evaluate the effect of a neuromuscular training program on a set of performance variables is a recent study among female elite floorball players.¹⁰ Also, detailed information on team and player adherence, down to the single-exercise level, allows a sub-analysis on a dose-response effect. No other study so far has similarly defined adherence by the number of completed exercises in a neuromuscular training program and analyzed the effect on performance outcomes and injury risk. Another strength of the current findings is the strong baseline equivalence of players' performance measures.

We acknowledge several imitations. First, there was no placebo control group against which to measure the effect of the two intervention groups across. The injury prevention program, the 11+, has become standard practice after 2008,³ and the 11+ resources are readily available to anyone through the 11+ website (http://f-marc.com/11plus/). Thus, all three groups in the present trial had access to the 11+ program, through different levels of delivery and education. It is possible that participating coaches may have been exposed to the 11+ or similar neuromuscular injury prevention programs before the study. This bias could explain a dilution in effect, leading to non-significant results. Second, although the test battery used was thought to be the best suited for assessing the effect of the program, the specificity of the tests available is not 100%. Third, reach distance was not normalized for leg length fir the Star Excursion Balance Test. Thereby, we could not calculate a composite score (sum of three reach directions divided by three times limb length) as been used for the determination of injury risk by Plisky et al.¹⁷ This limitation and will not allow us to compare the present findings with other studies.^{12;17;22;29} Fourth, the varying length teams have been exposed to the 11+ intervention needs to be mentioned. Due to the logistics of recruitment and baseline testing of

teams, the duration of teams in the assigned study groups was quite varying, though the playing exposure of the teams in the project was similar. However, there was no evidence on effect modification by the intervention length assessing the association of group assignment or adherence on performance outcomes. Also, a selection bias of players who showed up for post-season testing compared to those who did not, cannot be eliminated. However, reasons for non-participations were equally distributed across the study groups, indicating that there was no differential loss of follow-ups. Caution should be given to the generalizability of the present findings, as no comparable data are available for youth males or older players being assessed in this trial setting. Fifth, related to the weather, rescheduling or cancellations, communication from the coaches to the field physiotherapists in the comprehensive, player-focused intervention group, was poor. As such, the opportunities to complete and maintain the 11+ injury prevention warm-up sessions, as intended were decreased, and the opportunity for 11+ physiotherapists to follow-up their allocated teams on the field diminished. As a result, the team 11+ physiotherapists attended a team session on average only once every two weeks (median 6 supervised sessions in total).

Perspectives

Sport-specific performance is often synonymous with winning. A recent report of Emery et al.³³ among youth elite ice hockey players found a significant association between team performance (defined as win/loss/tie record) and injury risk with a 22% lower injury rate and 36% lower extremity injury rate in teams winning more than 50% of all season games. Another study by Soligard et al.²⁵ showed that across different skill attributes, players with high levels of football skills were at greater risk of sustaining injuries than their less skilled teammates. In other words, there are direct and indirect performance effects of having players free of injury, and injury prevention warm-up routines should be established on a regular basis as soon as youth start participating in organized sports. Several neuromuscular injury prevention warm-up programs,^{1:2:4:5:34:35} including the 11+,³ have been shown to be highly successful in reducing injury risk among young team sport athletes. However, having identified effective interventions, successful dissemination and implementation of the best practice to the sports community is one of today's biggest research challenges.^{36:37} If these intervention programs were designed to not just prevent injuries, but also increase performance, combined performance and prevention training could be instituted with a higher potential for coach and athlete adherence.⁹ The present findings could further stimulate the encouraging results

following coach education experiences from Switzerland demonstrating how an injury prevention program successfully could be implemented countrywide by coaches.³⁸

Conclusions

The method of delivery of the FIFA 11+ program to coaches has only minimal influence on players' improvement in performance. However, high player adherence to the 11+ resulted in significant individual improvements in functional balance as well as in reduced injury risk.

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Competing interests statement

This project has received a grant from F-MARC, who is presented with two co-authors (MB, JD). No other relationships or activities that could appear to have influenced the submitted work.

Contributor statement

KS, CE, MR, JK, MB, JD, CF, and WM were responsible for the conception and design of the study. KS, MR, and CE coordinated the study and managed all aspects, including data collection. All authors had full access to all data. KS and JK initialized and conducted the analyses, which were planned and checked with the other co-authors. KS wrote the first draft of the paper and all authors provided substantive feedback on the paper and contributed to the final manuscript. KS, CE, and WM are the guarantors.

What are the new findings?

- High adherence to neuromuscular injury prevention exercises improves functional balance performance
- Additional on-field supervision of coaches by physiotherapists does only minimal influence improvement in player performance

How might this paper impact on clinical practice in the near future?

- Combined performance enhancement and injury prevention can most likely be instituted with a higher potential for coach and athlete adherence and should motivate coaches and other stakeholders to implement neuromuscular injury prevention warm-up training
- Improved functional balance will contribute to reduced injury risk, improved players' technical football skills and physical development in general

	Control (n=80) Mean (SD) Frequency (%)	Regular (n=68) Mean (SD) Frequency (%)	Comprehensive (n=78) Mean (SD) Frequency (%)
Anthropometrics			
Height (cm)	164.4 (5.9)	162.9 (7.6)	165.0 (6.5)
Weight (kg)	60.0 (7.9)	58.9 (10.4)	58.7 (6.6)
Age group			
U16	18 (22.5)	18 (26.5)	45 (57.7)
U18	62 (77.5)	50 (73.5)	33 (42.3)
Playing level			
Tier 1	52 (65.0)	6 (8.8)	23 (29.5)
Tier 2	14 (17.5)	0	39 (50.0)
Tier 3	14 (17.5)	62 (91.2)	16 (20.5)
Kicking leg			
Right	73 (91.3)	64 (94.1)	68 (87.2)
Left	7 (8.3)	4 (5.9)	10 (12.8)
Previous injury ¹	16 (20.0)	5 (7.4)	10 (12.8)

¹Back or lower extremity injury in the 6 weeks prior to study start

	Control (n=80) Mean (95% CI)	Regular (n=68) Mean (95% CI)	to the intervention Comprehensive (n=78) Mean (95% CI)	
Exposure (hours)		, <u> </u>		
Total	31.2	32.8	34.6	
	(28.5;33.9)	(30.0;35.6)	(32.0;37.2)	
Practice	13.5	15.8	16.9	
	(11.6;15.3)	(14.3;17.3)	(15.2;18.5)	
Match	17.7	17.0	17.8	
	(16.4;18.9)	(15.4;18.6)	(16.1;19.4)	
Injuries (#)				
All injuries	16	16	14	
Lower extremity injuries	15	16	10	
Adherence to 11+				
Weeks with intervention (#)	7.3	11.4	10.0	
	(6.9;7.7)	(10.8;11.9)	(9.7;10.4)	
Team sessions (#)	17.5	23.3	21.9	
	(15.6;19.3)	(21.4;25.3)	(20.2;23.6)	
Team sessions (%)	80.8	86.9	83.6	
	(74.6;87.0)	(81.2;92.7)	(78.2;89.0)	
Team sessions per week (#)	2.4	2.2	2.2	
	(2.2;2.7)	(2.0;2.4)	(2.1;2.4)	
Player sessions (#)	14.6	19.1	18.0	
	(12.9;16.3)	(17.4;20.8)	(16.5;19.7)	
Player sessions (%)	68.0	68.7	67.5	
	(61.6;74.4)	(63.1;74.3)	(62.6;72.3)	
Player sessions per week (#)	2.1	1.8	1.8	
	(1.8;2.3)	(1.6;1.9)	(1.7;2.0)	
Player 11+ exercises (#)	109.6	209.8	193.3	
	(95.0;124.2)	(189.3;230.3)	(173.7;212.9)	
Player 11+ exercises per	7.9	10.8	10.8	
session (#)	(7.1;8.6)	(10.6;11.1)	(10.2;11.4)	
11+ exercises groups (#, %)				
Low	42 (52.5)	8 (11.6)	23 (29.5)	
Medium	29 (36.3)	23 (33.3)	26 (33.3)	
High	9 (11.2)	37 (53.6)	29 (37.2)	

Tests	Cont	rol (n=80)	Regu	lar (n=68)	Comprehensive (n=78)	
	Pre-test	Δ	Pre-test	Δ	Pre-test	Δ
	Mean (SD)	Mean (95% CI)	Mean (SD)	Mean (95% CI)	Mean (SD)	Mean (95% CI)
Single-leg Balance (s)	, , , , ,		. <u> </u>			. ,
Left	6.52 (6.49)	-1.37 (-2.91;0.17)	5.67 (3.51)	-0.82 (-1.68;0.04)	5.51 (4.49)	0.46 (-0.48;1.41)
Right	5.60 (3.15)	-0.09 (-0.84;0.67)	5.96 (3.90)	-0.45 (-1.50;0.59)	5.68 (3.31)	0.23 (-0.89;1.35)
Star Excursion Balance Test (cm)						
Left						
Anterior	76.4 (6.6)	1.9 (0.8;3.1)	74.6 (6.5)	5.6 (4.6;6.6)	75.4 (6.3)	6.9 (5.7;8.2)
Posterolateral	80.8 (7.2)	4.6 (3.1;6.0)	80.9 (8.2)	2.1 (0.4;3.9)	81.8 (7.9)	6.1 (4.5;7.6)
Posteromedial	78.5 (8.3)	3.4 (1.5;5.3)	77.5 (9.0)	6.6 (4.4;8.7)	79.0 (9.5)	5.8 (3.9;7.6)
Right						
Anterior	75.6 (6.5)	3.2 (2.0;4.5)	75.0 (6.6)	4.9 (3.7;6.1)	74.9 (6.7)	7.6 (6.3;8.9)
Posterolateral	79.6 (7.3)	4.5 (3.1;5.9)	80.0 (7.9)	3.0 (1.3;4.8)	80.7 (8.1)	6.0 (4.2;7.8)
Posteromedial	78.5 (8.5)	4.4 (2.5;6.2)	77.6 (9.3)	7.8 (5.8;9.6)	79.4 (8.7)	5.7 (3.5;7.8)
Single-leg Triple hop (cm)						
Left	431.3 (56.9)	4.1 (-4.5;12.7)	424.3 (49.2)	0 (-9.1;9.1)	445.9 (67.4)	11.1 (1.9;20.3)
Right	443.6 (61.2)	3.4 (-6.3;13.0)	438.7 (47.7)	3.0 (-7.4;13.5)	453.1 (68.4)	15.6 (5.8;25.3)
Jumping-over-a-bar (number)	34.7 (5.4)	0.5 (-0.5;1.4)	35.5 (3.7)	0.8 (-0.1;1.6)	38.9 (3.7)	-3.1 (-4.8;-1.5)

Table 3. Crude study group performance measures including baseline (mean \pm SD) and change (Δ , mean \pm 95% CI) from pre- to post-test. Positive values denote an increase from pre- to post-tests (Δ).

Tests	Randomization			Adherence	
-	∆G Mean (95% CI)	p-value		∆G Mean (95% CI)	p-value
Single-leg Balance (s)			Single-leg Bala	nce (s)	
Left			Left		
Control			Low		
Regular	1.22 (-0.88;3.32)	0.25	Medium	-1.15 (-2.84;0.54)	0.18
Comprehensive	2.80 (1.05;4.55)	0.002	High	-0.55 (-2.39;1.29)	0.56
Right			Right		
Control			Low		
Regular	0.42 (-1.34;2.18)	0.64	Medium	-0.84 (-2.22;0.54)	0.23
Comprehensive	1.17 (-0.29;2.63)	0.12	High	0.34 (-1.18;1.83)	0.43
Star Excursion Balance Tes	st (cm)		Star Excursion	Balance Test (cm)	
Left			Left		
Anterior			Anterior		
Control			Low		
Regular	6.1 (3.2;9.0)	< 0.001	Medium	1.6 (-0.4;3.7)	0.12
Comprehensive	4.7 (2.2;7.1)	< 0.001	High	3.0 (0.6;5.3)	0.012
Posterolateral		0.0001	111811	010 (010,010)	0.012
Control			Low		
Regular	-0.3 (-5.0;4.4)	0.90	Medium	1.8 (-0.8;4.5)	0.18
Comprehensive	2.2 (-1.7;6.2)	0.27	High	4.8 (1-8;7.9)	0.002
Posteromedial	2.2 (-1.7,0.2)	0.27	Ingn	4.0 (1-0,7.2)	0.002
Control			Low		
	25(20.60)	0.28	Medium	2.3 (-0.6;5.3)	0.12
Regular	2.5(-2.0;6.9)				
Comprehensive	1.5 (-2.2;5.1)	0.43	High	3.5 (0.2;6.8)	0.037
Right			Right		
Anterior			Anterior		
Control		0.007	Low		0.74
Regular	4.3 (1.1;7.4)	0.007	Medium	0.4 (-1.8;2.6)	0.71
Comprehensive	4.1 (1.4;6.7)	0.002	High	0.8 (-1.7;3.2)	0.53
Posterolateral			_		
Control			Low		
Regular	-0.7 (-5.0;3.5)	0.74	Medium	1.6 (-1.1;4.3)	0.24
Comprehensive	1.5 (-2.1;5.1)	0.41	High	4.0 (1.0;7.0)	0.009
Posteromedial					
Control			Low		
Regular	2.5 (-1.8;6.8)	0.25	Medium	1.9 (-0.9;4.7)	0.18
Comprehensive	0.6 (-2.9;4.2)	0.74	High	4.5 (1.5;7.6)	0.004
Single-leg triple hop (cm)			Single-leg triple	e hop (cm)	
Left			Left		
Control			Low		
Regular	-14.8 (-31.1;1.4)	0.07	Medium	-2.0 (-14.9;10.9)	0.76
Comprehensive	3.1 (-10.4;6.6)	0.65	High	-3.9 (-18.3;10.4)	0.59
Right	. ,		Right		
Control			Low		
Regular	-19.6 (-39.2;-0.1)	0.049	Medium	-4.5 (-20.4;11.4)	0.58
Comprehensive	6.7 (-9.7;23.2)	0.42	High	-16.5 (-34.5;1.5)	0.07
Jumping-over-bar (number,)		Jumping-over-a	n-bar (number)	
Control			Low	. ,	
Regular	-1.0 (-6.6;4.5)	0.72	Medium	-0.6 (-2.5;1.2)	0.50
Comprehensive	-5.1 (-9.9;-0.2)	0.039	High	-0.3 (-2.5;1.9)	0.79

Table 4. Effect of the study group and adherence on performance changes. Results are adjusted for cluster, age group and playing level.

Positive values denote a result favoring the intervention groups (coach- and player focused) and higher adherence groups (medium and high) (ΔG).

Table 5. Crude adherence group performance measures including pre-test (mean \pm SD) and change (Δ , mean \pm 95% CI) from pre- to post-tests. Positive values denote an increase from pre- to post-tests (Δ).

Tests	Low adh	erence (n=73)	Medium a	dherence (n=78)	High adherence (n=75)	
	Pre-test	Δ	Pre-test	Δ	Pre-test	Δ
	Mean (SD)	Mean (95% CI)	Mean (SD)	Mean (95% CI)	Mean (SD)	Mean (95% CI)
Single-leg Balance (s)	· · · ·					, ,
Left	6.16 (5.05)	0.30 (-0.92;1.52)	5.86 (6.22)	-1.21 (-2.67;0.24)	5.57 (3.29)	-0.75 (-1.48;-0.01)
Right	5.94 (3.85)	0.49 (-0.80;1.78)	5.77 (3.41)	-0.70 (-1.29;-0.10)	5.55 (2.97)	-0.02 (-0.97;0.93)
Star Excursion Balance Test (cm)						
Left						
Anterior	77.1 (6.4)	2.8 (1.4;4.2)	75.0 (6.5)	4.9 (3.8;6.1)	74.6 (6.2)	6.5 (5.5;7.6)
Posterolateral	82.3 (7.0)	3.3 (1.9;4.7)	80.7 (7.8)	4.3 (2.8;5.9)	80.7 (8.3)	5.4 (3.5;7.3)
Posteromedial	79.8 (7.4)	3.0 (1.1;4.9)	77.3 (9.0)	5.4 (3.6;7.2)	78.1 (10.0)	7.1 (5.0;9.2)
Right						
Anterior	76.0 (6.4)	4.1 (2.6;5.7)	74.4 (7.3)	5.5 (4.3;6.6)	75.2 (5.9)	6.1 (4.9;7.4)
Posterolateral	81.6 (6.7)	3.2 (1.7;4.6)	79.3 (8.2)	4.6 (3.0;6.1)	79.7 (8.2)	6.1 (4.2;8.1)
Posteromedial	79.6 (7.0)	3.5 (1.3;5.6)	78.1 (9.2)	5.7 (4.0;7.3)	78.3 (9.9)	8.3 (6.2;10.3)
Single-leg triple hop (cm)						
Left	442.0 (66.5)	4.8 (-2.4;19.6)	430.4 (62.8)	4.6 (-8.0;8.4)	434.5 (45.8)	6.7 (-0.4;16.3)
Right	452.9 (68.4)	6.7 (-3.6;16.9)	435.2 (59.4)	10.5 (1.1;19.9)	449.2 (50.9)	5.3 (-5.1;15.7)
Jumping-over-a-bar (number)	36.6 (5.8)	-0.1 (-0.9;0.8)	36.2 (4.5)	-1.0 (-2.3;0.3)	36.7 (3.9)	-1.0 (-2.6;0.6)

Table 6. Injury incidence among players randomized to the control, regular and comprehensive intervention groups, and among players stratified into high, medium and low adherence. The control and low adherence groups served as respective reference groups. Injury incidences and incidence rate ratios (IRR) are presented with mean and 95% CI.

	Randomization				Adherence		
	Injury incidence per 1000 exposure (95% CI)	Crude IRR (95% CI)	Adjusted IRR (95% CI) ¹		Injury incidence per 1000 exposure (95% CI)	Crude IRR (95% CI)	Adjusted IRR (95% CI) ¹
All injuries							
Comprehensive	5.2 (2.4;11.5)	0.81 (0.3;1.92)	1.09 (0.50;2.37)	High	2.7 (1.1;6.6)	0.47 (0.15;1.43)	0.46 (0.14;1.49)
Regular	7.2 (4.0;12.9)	1.12 (0.56;2.23)	1.45 (0.33;6.36)	Medium	10.8 (7.6;15.4)	1.90 (0.88;4.09)	1.66 (0.76;3.65)
Control	6.4 (4.2;9.8)	-	-	Low	5.7 (2.8;11.4)	-	-
Lower extremity injuries							
Comprehensive	3.7 (1.5;9.4)	0.62 (0.23;1.63)	0.83 (0.33;2.08)	High	2.7 (1.1;6.6)	0.51 (0.16;1.63)	0.51 (0.16;1.64)
Regular	7.2 (4.0;12.9)	1.19 (0.59;2.42)	1.95 (0.44;8.71)	Medium	9.2 (6.2;13.7)	1.78 (0.79;4.02)	1.57 (0.72;3.42)
Control	6.0 (3.8;9.4)	-	-	Low	5.2 (2.4;11.1)	-	- /

¹Adjusted for cluster, age groups, level of play (tier), and previous injury (^back or lower extremity injury in the 6 weeks prior to study start)

Figure 1: Flow of clubs, teams, and players through study

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