Reducing musculoskeletal injury and concussion risk in schoolboy rugby players with a pre-activity movement control exercise programme: a cluster randomised controlled trial

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ABSTRACT

Background Injury risk in youth rugby has received a much attention, highlighting the importance of establishing evidence-based injury reduction strategies.

Aim To determine the efficacy of a movement control exercise programme in reducing injuries in youth rugby players, and to investigate the effect of programme dose on injury measures.

Methods In a cluster-randomised controlled trial, forty independent schools (118 teams, 3,188 players aged 14-18 years) were allocated to receive either the intervention or a reference programme, both of which were to be delivered by school coaches. The intervention comprised balance training, whole-body resistance training, plyometric training, and controlled rehearsal of landing and cutting manoeuvres. Time-loss (>24 hours) injuries arising from school rugby matches were recorded by coaches and medical staff.

Results 441 time-loss match injuries (intervention-233; control-208) were reported across 15,938 match exposure-hours (intervention-9,083; control-6,855). Intention-to-treat results indicated unclear effects of trial arm on overall match injury incidence (Rate Ratio (RR)=0.85, 90% CL: 0.61-1.17), although clear reductions were evident in the intervention arm for concussion incidence (RR=0.71, 0.48-1.05). When trial arm comparisons were limited to teams who had completed 3 or more weekly programme sessions on average, clear reductions in overall match injury incidence (RR=0.28, 0.14-0.51) and concussion incidence (RR=0.41, 0.17-0.99) were noted in the intervention group.

Conclusion A preventive movement control exercise programme can reduce match injury outcomes, including concussion, in schoolboy rugby players when compared with a standardised control exercise programme, although to realise the greatest effects players should complete the programme at least three times per week.

INTRODUCTION

The injury risk in youth rugby has received attention in the mainstream public and sports medicine literature,[1,2] and has prioritised the formulation of appropriate preventive measures.[3] Musculoskeletal injuries and concussion are prominent reasons for time-loss from sport for adolescent rugby players,[4,5] and significant youth sports injuries in general have been implicated in long-term disability and compromised quality of later life.[6,7] Conditioning the musculoskeletal system to tolerate external forces, through enhancing strength and movement control, has been advocated as means of reducing musculoskeletal injury risk, as indicated by a growing evidence base that supports using multifaceted preventive exercise programmes to reduce musculoskeletal injury risk across male sports like basketball,[8] and soccer.[9-11] Moreover, cross-sectional associations between neck strength measures with concussion risk in young athletes invite the possibility that interventions to enhance neck strength may reduce concussion risk.[12] The injury patterns in rugby differ from other team sports, owing to a greater frequency of concussion, upper body, and contact-related injuries,[13,14] and so it is uncertain if introducing a targeted exercise programme can reduce musculoskeletal injuries and/or concussion in youth rugby players.

The efficacy of preventive exercise programmes is dependent upon several factors; of which the frequency of programme use (i.e. dose) may be one such factor.[15] Dose-response relationships have typically been identified between programme use and reductions in knee ligament injury incidence in female sportspeople.[16,17] Assessing the effects of programme dose can be useful in reinforcing the outcomes of intervention research and informing subsequent implementation attempts.[18]

The aims of this study were to assess the efficacy of a pre-activity movement control exercise intervention to reduce the incidence and burden of rugby-related injuries in a schoolboy population, and to assess the influences of programme dose and compliance on injury outcomes.

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METHODS

Study Design and Recruitment

A cluster-randomised controlled trial was conducted across independent school rugby teams over 1 playing season (August-December 2015). Study design was in accordance with the CONSORT statement,[19] and the trial was registered before recruitment (Trial registration number: ISRCTN13422001). Study procedures were approved by the Research Ethics Approval Committee for Health (REACH) at the University of Bath.

Each school was treated as a cluster, within which under-15 (U15), under-16 (U16), and under-18 (U18) teams were allocated to the same trial arm. A-priori sample size calculations were undertaken,[20] incorporating injury data collected from a previous study on injuries in schoolboy rugby players.[5] To discern a 30% reduction in match injury incidence at 80% statistical power, 13 schools per trial arm were required. Seven additional schools were recruited in each trial arm to account for attrition, yielding a target sample of 40 schools. Schools deemed eligible to participate had on-site access to physiotherapists or nurses who would treat all rugby-related injuries. Two-hundred and twenty schools were identified and sequentially contacted in randomised groups of 60 through trial invitation letters; emails, and direct telephone calls to senior members of the sport and rugby programmes until 40 schools had provided written informed consent from a member of the senior management team to participate in the trial. Schools were randomly allocated to the intervention or control groups on a 1:1 basis. The randomisation process for both recruitment and allocation was completed independently of the research team. Schools were briefed that they would receive an exercise programme to be delivered by the coaches to their U15, U16, and U18 teams, but were blinded to their trial arm allocation. All U15, U16, or U18 players who participated in training or match-play at the school were eligible to participate in the trial. Coach consent (in loco parentis), player assent, and opportunity for parental opt-out (via school-parent mailing lists) were sought.

Coaches attended a pre-study workshop (typically 1 hour duration) led by the research team at each school (June-July 2015), at which they were introduced to either the intervention or control exercise programme and data collection materials, in addition to being provided with a practical demonstration of the programme. The practical demonstration of the programme entailed coaches observing a research team member leading a group of youth rugby players (U15, U16, or U18) through a session. Coaches across both trial arms received identically formatted data collection and programme materials (except for exercises). Programme materials included a filmed demonstration of the exercises (as a DVD), laminated cue cards (images and key coaching cues for each exercise), and a booklet detailing how to complete individual exercises. A further meeting was arranged at all schools during pre-season for members of the research team to collect informed assent and baseline anthropometric information (standing height, seated height, body mass) from all players involved in the trial.

The Exercise Programmes being trialled

The process of devising the intervention and control exercise programmes have been reported elsewhere.[21] Both programmes comprised 4 phases, with progressions occurring via increased difficulty and repetition volume of exercises. Phase 1 was devised for the pre-season period (typically 1-2 weeks duration). Both programmes progressed to phase 2 upon the school term commencing in September 2015, with two further planned phase progressions occurring every 4-weeks until the end of the study in December. This timing enabled players to master the exercises before being introduced to a more advanced phase. Progression of the exercises was undertaken at the team-level, with all players within the same age group teams completing the same exercises at the same time. Phase difficulty was offset by age group (i.e., phase 3 of the U15 programme was similar in difficulty to phases 2 and 1 of the U16 and U18 programmes, respectively) to maintain a sufficient stimulus for players at an appropriate level. Both programmes were intended to take place during the first 20 minutes of each pitch-based training session and match warm-up, and coaches in charge of each team acted as delivery agents. Coaches were instructed to use

the programme materials, particularly the laminated cue cards during sessions, to assess movement execution in relation to the specified cues for each exercise, and to identify movements that could be improved.

The exercise programme allocated to teams in the intervention group integrated balance/perturbation training, resistance training, plyometric training, and controlled rehearsal of sport-specific landing and cutting manoeuvres with verbal feedback and reinforcement of technique from the coach. The exercise programme allocated to the control cohort was derived from currently regarded best practice within schoolboy rugby, and featured a running-based warm-up, dynamic stretching, controlled wrestling, mobility, and speed / change of direction-related drills (without the specific feedback instructions given in the intervention programme). The content within both the intervention and control programmes were categorised into 4 separate parts (Parts A, B, C, and D) to aid the structure of sessions and compliance reporting. A sample phase from the intervention exercise programme have been supplied for supplementary reference.

Data Collection

The definitions of a reportable injury (incurring a time-loss of more than 24 hours), match exposure, and training exposure (only pitch-based activities) were adapted from the consensus statement for injury definitions and data collection procedures in rugby union.[22] Coaches recorded training exposure (length of each training session in minutes, number of players attending training session), match exposure (match date, opponent name, list of players selected to play in each fixture) and programme compliance at each session (completion of programme parts A, B, C, and D) on weekly paper-based or electronic report forms. Programme compliance indicated the proportion of programme parts that were completed at the team level across all exposures. Coaches started the injury reports by logging the date that the injury occurred, the injured player's trial ID and playing position, and the event leading directly to the injury. School medical staff recorded the injury location and a diagnosis when players visited for treatment. Logging the injury location and diagnosis

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aligned with the first two levels of the Orchard Sports Injury Classification System (Version 10).[23] Coaches recorded the return-to-play date (date of full participation in training or match-play). A member of the research team visited schools periodically (2-3 week intervals) during the study period to retrieve completed report forms and to discuss study progress, but not to promote compliance or fidelity with using the programmes.

Statistical Analyses

Statistical analyses were undertaken with IBM SPSS Statistics (Version 22.0 for Windows, IBM Corporation, Armonk, NY, USA). Trial arm comparisons across baseline player characteristics (age, anthropometric characteristics, and maturity timing) were assessed using linear and logistic regression. The odds ratio generated from the logistic regression was converted to a proportion ratio to permit analysis via magnitude-based inference.[24]

Intention-to-treat analyses compared injury measures between the trial arms for all teams that provided injury and exposure data, regardless of returning complete programme compliance or dose data. Trial arm comparisons were also undertaken on a per-protocol basis with teams that maintained a mean programme completion rate of 3 or more weekly sessions, which represented a threshold for optimal compliance based on previous findings.[25] The effects of intervention-only programme dose on injury were assessed by comparing injury measures between teams that maintained an average of 3 or more sessions per week with those who averaged completing the programmes less than 3 sessions per week. Overall match injury incidence (injuries/1000 player-hours) and burden (days lost/1000 player-hours) rates acted as dependent variables, with further stratification by injury location and event. All estimations were made using generalised linear modelling with a Poisson distribution, a log-linear link function, and offset for hours of exposure to generate rate ratios (RR) and 90% confidence limits (90% CL) for injury incidence and burden values. RR and 90% CL were assessed against pre-determined smallest worthwhile effects in injury outcome.[26] The smallest worthwhile effects favouring the intervention and favouring the control were given as RR=0.90 and RR=1.11, respectively.[27] Effects were

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deemed *clear* if the percent likelihood that the true effect favoured the intervention (RR below 0.90) was greater than 25%, and the odds ratio between favouring the intervention and favouring the control was greater than 66 (i.e. if the likelihood of effect favouring the intervention was 25% and the likelihood of effect favouring the control was less than 0.5%), otherwise effects were deemed *unclear.* Effects were qualified against probabilistic terms from the following scale: <0.5%, most unlikely; 0.5-5%, very unlikely; 5-25%, unlikely; 25-75%, possibly; 75-95%, likely; 95-99.5%, very likely; >99.5%, most likely.[28]

RESULTS

From a target population of 220 potentially eligible schools that were contacted for recruitment, 40 schools (118 teams, 3,188 players aged 14-18 years) consented to participate in the trial and were randomly allocated to the intervention or control group (Figure 1). Nine schools and 35 teams dropped out of the trial, with data collected from 31 schools, 83 teams, and 2,452 players used for analysis (intervention,17 schools, 44 teams, 1,325 players; control,14 schools, 39 teams, 1,127 players). Comparisons of baseline player anthropometric characteristics between the trial arms are outlined in Table 1. Trivial differences were detected between the trial arms for mean player age, stature, body mass, or the distribution of players by maturity timing (Table 1).

<<<<<<Figure 1 Here>>>>>>

Table 1   Summary and comparisons of player characteristics between the intervention (n=1,325 players) and control (n=1,127 players) groups

Trial Arm	Intervention	Control	Effect Size* (90% CL)	(%higher | trivial | lower)† Inference	P-value
Age (years)	16.0 ± 1.2	15.9 ± 1.1	0.06 (0.00-0.14)	(0 | 100 | 0%) Most Likely Trivial	0.19
Stature (cm)	177.4 ± 7.3	176.6 ± 7.5	0.11 (0.03-0.19)	(4 | 96 | 0%) Very Likely Trivial	0.03
Body Mass (kg)	74.7 ± 12.9	72.5 ± 13.1	0.17 (0.09-0.25)	(27 | 73 | 0%) Possibly Trivial	<0.01
Maturity Offset (%)					
>1 year post-PHV	642 (71%)	586 (70%)	1.03 (0.91-1.16)	(4 | 95 | 1%) Very Likely Trivial	0.68
≤1 year post-PHV	261 (29%)	251 (30%)			

Data presented as mean ± SD or as raw frequency (%) where specified. PHV – Peak Height Velocity. *Effect sizes for Age, Stature, and Body Mass expressed as Cohen's d; effect size for maturity offset expressed as a proportion ratio.[24] † percentage likelihood of effect being higher or lower is analogous to effect favouring intervention or control, respectively.

Exposure, injury, and compliance

The intervention cohort (n=17 schools, 44 teams) accrued 37,346 exposure-hours (match, 9,083, training, 28,263), with the control cohort (n=14 schools, 39 teams) reporting 32,375 exposure-hours (match, 6,855, training, 25,520). The intervention cohort recorded 233 match injuries (totalling 6,499 days lost) and 58 training injuries (1,028 days lost), with the control cohort recording 208 match injuries (5,907 days lost) and 54 training injuries (1,150 days lost). Overall match and training injury incidence in the intervention cohort was 26/1000 hours (23-29) and 2/1000 hours (2-3), and in the control cohort was 30/1000 hours (27-34) and 2/1000 hours (2-3), respectively.

Summary injury and exposure results between the trial arms are outlined in table 2. Of 441 reported match injuries, 168 were sustained to the head/neck (intervention, 82, control, 86), 125 to the upper limb (intervention, 65, control, 60), 113 to the lower limb (intervention, 67, control, 46), and 35 to the trunk (intervention, 19, control, 16). Of 168 head/neck injuries, 105 were reported as concussion (intervention, 51, control, 54). Match concussion incidence in the intervention group was 6/1000 hours (4-7), and in the control group was 8 (6-10).

Complete compliance data was retrieved from 63 out of 83 teams (intervention, 32 teams; control, 31 teams). In teams who had provided complete compliance information, mean programme completion rate across both trial arms was close to twice per week (intervention, 1.9 sessions/week; control, 2.0 sessions/week). Twelve out of 63 teams maintained a mean weekly programme completion rate of 3 or more sessions (intervention, 7 teams; control, 5 teams). Compliance to the exercise programmes (proportion of programme parts that were completed) were 69% and 83% across the intervention and control arms, respectively.

Table 1   Descriptive statistics for match injuries across the control and intervention cohorts

		Intervention (n=17 schools, 44 teams)	Control (n=14 schools, 39 teams)	Rate Ratio (90% CL)	P-Value
Exposure Hours	Match	9,083	6,855	--	--
	Training	28,263	25,520	--	--
Injuries	Match	233	208	--	--
	Training	58	54	--	--
Days lost to injury	Match	6,499	5,907	--	--
	Training	1,028	1,150	--	--
Overall Match	Incidence	26 (23-29)	30 (27-34)	0.85 (0.61-1.17)	0.40
	Burden	715 (701-730)	862 (844-880)	0.83 (0.58-1.18)	0.38
Overall Training	Incidence	2 (2-3)	2 (2-3)	0.97 (0.52-1.81)	0.94
	Burden	36 (34-38)	45 (43-48)	0.80 (0.40-1.60)	0.60
Match Injury by Location					
Head/Neck	Incidence	9 (7-11)	13 (10-15)	0.72 (0.51-1.01)	0.11
	Burden	260 (252-269)	285 (274-296)	0.91 (0.55-1.51)	0.77
Upper Limb	Incidence	7 (6-9)	9 (7-11)	0.82 (0.51-1.31)	0.48
	Burden	229 (221-238)	345 (333-356)	0.66 (0.40-1.10)	0.18
Trunk	Incidence	2 (1-3)	2 (1-3)	0.90 (0.47-1.71)	0.78
	Burden	36 (32-39)	43 (38-47)	0.84 (0.35-2.01)	0.74
Lower Limb	Incidence	7 (6-9)	7 (5-8)	1.10 (0.7-1.72)	0.73
	Burden	190 (182-197)	189 (181-198)	1.00 (0.52-1.93)	1.00
Match Injury by Event					
Contact	Incidence	22 (20-25)	27 (23-30)	0.85 (0.60-1.19)	0.42
	Burden	607 (594-621)	689 (673-706)	0.88 (0.60-1.29)	0.59
Non-	Incidence	2 (1-3)	2 (1-3)	0.94 (0.50-1.77)	0.88

contact	Burden	77 (72-81)	121 (114-128)	0.63 (0.25-1.64)	0.43

Incidence values presented as injuries / 1000 hours. Burden values presented as days lost/ 1000 hours.

Intention-to-treat analyses

Intention-to-treat analyses on the effect of trial arm (intervention, 17 schools, 44 teams; control, 14 schools, 39 teams) were unclear for overall match injuries (Incidence RR=0.85, 90% CL: 0.61-1.17; Burden RR=0.83, 0.58-1.18) (Figure 2). Effects were also unclear for contact-related injuries (Incidence RR=0.85, 0.60-1.19; Burden RR=0.88, 0.60-1.29). However, clear effects favouring the intervention programme were noted for head/neck injuries (Incidence RR=0.72, 0.51-1.01), upper limb injuries (Burden RR=0.66, 0.40-1.10), and concussion (Incidence RR=0.71, 0.48-1.05).

<<<<<<Figure 2 Here>>>>>>

Per-protocol analyses

Per-protocol trial arm comparisons (intervention, 4 schools, 7 teams; control, 3 schools, 5 teams) revealed that teams completing the intervention programme 3 times or more per week suffered 72% fewer overall match injuries (Incidence RR=0.28, 0.14-0.51), 72% fewer contact-related injuries (Incidence RR=0.28, 0.14-0.56), 50% fewer days lost to contact injuries (Burden RR=0.50, 0.21-1.18), 81% fewer upper limb injuries (Incidence RR=0.19, 0.07-0.50), 70% fewer lower limb injuries (Incidence RR=0.30, 0.10-0.92), and 59% fewer concussions (Incidence RR=0.41, 0.17-0.99) than teams that completed the control programme 3 or more times per week (Figure 3).

Per-protocol analyses conducted in the intervention arm indicated that teams typically completing at least 3 sessions per week with the intervention programme (4 schools, 7 teams) suffered 39% fewer match injuries (Incidence RR=0.61, 0.42-0.88), 48% fewer days

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21   lost to match injuries (Burden RR=0.52, 0.29-0.93), 42% fewer match contact injuries

22   (Incidence RR=0.58, 0.41-0.82), and 55% fewer days lost to match contact injuries (Burden

23   RR=0.45, 0.25-0.82) than teams that completed the intervention programme fewer than 3-

24   times per week (10 schools, 25 teams). Effects of intervention programme dose were

25   unclear for upper limb injuries, lower limb injuries, and concussion.

26   **<<<<<<Figure 3 Here>>>>>>**

27   **<<<<<<Figure 4 Here>>>>>>**

28   **DISCUSSION**

29   This study aimed to determine the efficacy of a movement control exercise programme for

30   preventing injury in youth rugby players, and to assess the effect of programme dose on

31   injury measures. Following intention-to-treat analyses, effects of the trial arm were unclear

32   for overall match injury. Per-protocol trial arm comparisons under conditions of high dose (>3

33   weekly programme sessions) revealed clear reductions for the intervention arm for overall

34   match injury, contact-related injury, upper and lower extremity injury and concussion

35   incidence values. Moreover, a higher intervention programme dose was shown to reduce the

36   incidence and burden of overall match injuries and contact injuries compared with lower

37   intervention programme doses (<3 weekly programme completions).

38   **Intention-to-treat analyses**

39   Intention-to-treat analyses indicated unclear effects of trial arm for overall match injury

40   (Incidence RR=0.85, Burden RR=0.83) and match contact injury (Incidence RR=0.85;

41   Burden RR=0.88). The 15% reduction in overall match injury incidence in this study is lower

42   than the 41-56% reductions noted in other studies conducted in male basketball and soccer

43   players,[8,10,11] which may be partly attributed to differences between definitions of

44   reportable injuries, programme content, or the distribution of injury types and locations

45   between the respective sports, i.e. proportion of non-contact lower limb injuries. However,

46   clear effects favouring the intervention exercise programme were noted for head/neck injury

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47 incidence (Incidence RR=0.72) and concussion incidence (Incidence RR=0.71). Sixty-two

48 percent of reported head/neck injuries in the trial were attributed to concussion, and

49 therefore the reductions in head/neck injury incidence were likely because of reductions in

50 concussion incidence. Concussion is a priority for prevention across contact and collision

51 sports due to potential concern over medium- and long-term player welfare.[29,30] Thus, the

52 substantially reduced concussion incidence across the intervention arm is a very promising

53 finding with regards to current efforts to reduce the risk of concussion.

54 Neck strength has been shown to be substantially lower in adolescent rugby players when

55 compared with adults players despite similar peripheral strength profiles.[31] Increased

56 concussion risk is associated with lower neck strength, highlighting this characteristic as a

57 potentially modifiable risk factor.[12] Enhancing neck muscle strength may prevent

58 concussion by improving the dissipation of impact forces transmitted to the brain.[32,33]

59 Therefore, it is possible that the neck resistance exercises in the intervention exercise

60 programme contributed to reduced concussion incidence via this mechanism. Neck pain is a

61 common physical complaint among young sportspeople participating in collision

62 sports,[34,35] and may be associated with increased concussion risk.[33] Given that acute

63 and cumulative rugby exposure can adversely impact neck function,[36-38] the neck

64 resistance exercises may also have contributed to preserving neck function during the

65 playing season,[39] in turn reducing concussion incidence.

66 Upper limb injuries are common in contact sports and can also result in substantial time-loss

67 in youth rugby players.[5,40] Teams in the intervention trial arm suffered substantially fewer

68 days absence due to upper limb injuries than teams in the control arm (Burden RR=0.66).

69 Little is known about the underlying risk factors and mechanisms for upper limb injuries, and

70 examples of evidence-based upper limb injury prevention are scarce.[41] Reduced

71 glenohumeral rotation and rotator cuff muscle strength imbalances may be modifiable risk

72 factors for shoulder injuries in rugby players.[42] The intervention programme may have

73 improved joint kinematics and force-handling capabilities within the upper limb as a result of

74 incorporating resistance and plyometric training of upper body regions,[43,44] thus implying

75 that reducing upper limb injury risk across youth contact sports is possible through improving

76 upper limb strength, stability, and mobility.

77 **Per-protocol analyses**

78 The lack of clear substantial effects for overall match and contact-related injuries following

79 intention-to-treat analyses should be considered in the context of dose, which may have

80 affected these outcomes. Although mean intervention programme dose in this study was

81 higher (1.9 completions per week) than has been reported in previous studies (1.3-1.4

82 completions per week),[45,46] the level of dose that teams received in the intervention trial

83 arm may have been insufficient to demonstrate a clear effect on overall match injuries.

84 Greater effects of preventive exercise programmes may be realised if regularly used at least

85 3 times per week.[25] Trial arm comparisons conducted on a per-protocol basis showed that

86 intervention trial arm teams that regularly completed the programme more than 3 times per

87 week suffered 72% fewer overall match injuries, 72% fewer contact-related injuries, 81%

88 fewer upper limb injuries, 70% fewer lower limb injuries, and 59% fewer concussions than

89 control teams with an equivalent dose. When per-protocol analyses were conducted within

90 the intervention arm, teams that regularly completed the programme over 3 times per week

91 suffered 39% fewer match injuries, 48% fewer days lost to match injuries 42% fewer contact

92 injuries and 55% fewer days lost to contact injuries than teams with less than 3 weekly

93 programme completions. Regularly performing a preventive exercise programme 3 times per

94 week over a sustained period has been shown to improve markers for neuromuscular control

95 and muscle strength in male soccer players.[47] Therefore, these physiological benefits may

96 explain the enhanced effects noted in this study with a high dose of the intervention

97 programme use compared with the control programme and a lower dose of the intervention

98 programme.

99 Evidence of a dose-response effect on overall and contact-related injuries in this study

100 presents wider applications of the dose-response effect of preventive exercise programmes,

101   and has the potential to inform subsequent implementation attempts through identifying a

102   minimum effective dose in this population. The collective findings from the intention-to-treat

103   and per-protocol analyses highlight that teams involved in contact sports can obtain benefit

104   from using preventive exercise programmes, but more importantly, regular exposure of more

105   than 3 times per week can result in substantial injury risk reduction.

106   **Limitations and future directions**

107   There were several limitations to this study that should be acknowledged. Firstly, the

108   research team members that ran the pre-trial workshops and conducted pre-season visits

109   were not blinded to the programme allocation for each school, creating potential bias

110   between the two groups in terms of the processes followed and information disseminated at

111   these workshops; this was mitigated through use of a unified workshop format. Secondly,

112   individual player compliance was not monitored during the study. Results of previous studies

113   have indicated that individual player compliance may be a more sensitive measure than

114   team compliance in determining the influence of compliance on programme efficacy,[45,46]

115   but puts considerable strain on coaches, and so wasn't feasible in this setting. Thirdly, it

116   wasn't possible to validate coach compliance reports or to monitor exercise fidelity the

117   quality of performing the exercises through unannounced visits or observations, given that

118   schools have strict policies around access to premises. Any limits of fidelity with which teams

119   used the programmes is uncertain, but may actually have mediated programme efficacy

120   along with dose and compliance.[48]

121   Further work is required to understand the mechanistic bases by which the intervention

122   exercise programme reduced injury outcomes, particularly in relation to the proposed effects

123   of the programme on neck strength and function in reducing concussion incidence, as well

124   as kinematics and force handling capacities in the upper limb. Determining efficacy is a

125   crucial step towards effecting a public health impact of injury prevention measures in rugby,

126   although results of this controlled trial alone are not sufficient to translate to reducing injuries

127   in "real world" contexts.[49,50] Further research is required to further understand the

128   contexts into which the exercise programme would be implemented, as well as identifying

129   what factors may facilitate or inhibit programme use.[18] In particular, studies should be

130   directed to identifying what factors could facilitate or inhibit teams from completing the

131   intervention programme 3 times per week.

132   **CONCLUSION**

133   Although intention-to-treat results highlighted trivial effects of the intervention exercise

134   programme on overall match injury incidence when compared with the control exercise

135   programme, a substantial reduction in overall match injury incidence was evident from per-

136   protocol trial arm comparisons under conditions of high programme dose (3 or more weekly

137   sessions). Notable beneficial effects of the preventive programme on upper and lower

138   extremity injuries and concussion incidence also have important implications for the

139   reduction of these priority injury types in youth rugby.

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149 **COMPETING INTERESTS**

150 None

151

155 **CONTRIBUTORSHIP STATEMENT**

156 GT, KS, ME & SK initiated the overall project. MH, KS, SW, CM, ME, SK & GT conceived

157 and designed the study. MH analysed the data and prepared the first draft of the manuscript.

158 All authors made substantial contributions to revision of the manuscript prior to submission.

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166   **REFERENCES**

167   1. Carter M. The unknown risks of youth rugby. *BMJ (Clinical research ed)* 2015;350:h26.

168   doi: 10.1136/bmj.h26 [published Online First: 2015/01/09]

169   2. Pollock AM, Kirkwood G. Removing contact from school rugby will not turn children into

170   couch potatoes. *British journal of sports medicine* 2016:bjsports-2016-096220.

171   3. Tucker R, Raftery M, Verhagen E. Injury risk and a tackle ban in youth Rugby Union:

172   reviewing the evidence and searching for targeted, effective interventions. A critical

173   review. *British Journal of Sports Medicine* 2016;50(15):921-5. doi: 10.1136/bjsports-

174   2016-096322

175   4. Archbold HA, Rankin AT, Webb M, et al. RISUS study: Rugby Injury Surveillance in Ulster

176   Schools. *British Journal of Sports Medicine* 2015:bjsports-2015-095491. doi:

177   10.1136/bjsports-2015-095491

178   5. Palmer-Green DS, Stokes KA, Fuller CW, et al. Match injuries in English youth academy

179   and schools rugby union: an epidemiological study. *American Journal of Sports*

180   *Medicine* 2013;41(4):749-55. doi: 10.1177/0363546512473818

181   6. Maffulli N, Longo UG, Gougoulias N, et al. Long-term health outcomes of youth sports

182   injuries. *Br J Sports Med* 2010;44(1):21-25. doi: 10.1136/bjsm.2009.069526

183   7. Maffulli N, Longo UG, Spiezia F, et al. Sports injuries in young athletes: long-term

184   outcome and prevention strategies. *The Physician and Sportsmedicine*

185   2010;38(2):29-34. doi: 10.3810/psm.2010.06.1780

186   8. Longo UG, Loppini M, Berton A, et al. The FIFA 11+ Program Is Effective in Preventing

187   Injuries in Elite Male Basketball Players A Cluster Randomized Controlled Trial. *Am J*

188   *Sports Med* 2012;40(5):996-1005. doi: 10.1177/0363546512438761

189   9. Grooms DR, Palmer T, Onate JA, et al. Soccer-specific warm-up and lower extremity

190   injury rates in collegiate male soccer players. *J Athl Train* 2013;48(6):782-89. doi:

191   10.4085/1062-6050-48.4.08

192   10. Owoeye OB, Akinbo SR, Tella BA, et al. Efficacy of the FIFA 11+ Warm-Up Programme

193   in Male Youth Football: A Cluster Randomised Controlled Trial. *J Sports Sci Med*

194   2014;13(2):321-8.

195   11. Silvers-Granelli H, Mandelbaum B, Adeniji O, et al. Efficacy of the FIFA 11+ Injury

196   Prevention Program in the Collegiate Male Soccer Player. *Am J Sports Med*

197   2015;43(11):2628-37. doi: 10.1177/0363546515602009

198   12. Collins CL, Fletcher EN, Fields SK, et al. Neck strength: a protective factor reducing risk

199   for concussion in high school sports. *The journal of primary prevention*

200   2014;35(5):309-19. doi: 10.1007/s10935-014-0355-2 [published Online First:

201   2014/06/16]

202   13. Brooks JHM, Kemp SPT. Recent Trends in Rugby Union Injuries. *Clinics in Sports*

203   *Medicine* 2008;27(1):51-73. doi: 10.1016/j.csm.2007.09.001

204   14. Junge A, Cheung K, Edwards T, et al. Injuries in youth amateur soccer and rugby

205   players - Comparison of incidence and characteristics. *Br J Sports Med*

206   2004;38(2):168-72. doi: 10.1136/bjsm.2002.003020

207   15. Sugimoto D, Myer GD, Micheli LJ, et al. ABCs of Evidence-based Anterior Cruciate

208   Ligament Injury Prevention Strategies in Female Athletes. *Curr Phys Med Rehabil*

209   *Rep* 2015;3(1):43-49. doi: 10.1007/s40141-014-0076-8

210   16. Sugimoto D, Myer GD, Barber Foss KD, et al. Dosage effects of neuromuscular training

211   intervention to reduce anterior cruciate ligament injuries in female athletes: Meta- and

212   sub-group analyses. *Sports Med* 2014;44(4):551-62. doi: 10.1007/s40279-013-0135-

213   9

214   17. Sugimoto D, Myer GD, Barber Foss KD, et al. Critical components of neuromuscular

215   training to reduce ACL injury risk in female athletes: meta-regression analysis. *Br J*

216   *Sports Med* 2016;50(20):1259-66. doi: 10.1136/bjsports-2015-095596

217   18. Finch CF. A new framework for research leading to sports injury prevention. *Journal of*

218   *Science and Medicine in Sport* 2006;9(1-2):3-9; discussion 10. doi:

219   10.1016/j.jsams.2006.02.009

220   19. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for

221   reporting parallel group randomized trials. *Ann Intern Med* 2010;152(11):726-32. doi:

222   10.7326/0003-4819-152-11-201006010-00232 [published Online First: 2010/03/26]

223   20. Hayes RJ, Bennett S. Simple Sample Size Calculation For Cluster-Randomized Trials.

224   *International Journal of Epidemiology* 1999;28(2):319-26.

225   21. Hislop MD, Stokes KA, Williams S, et al. The efficacy of a movement control exercise

226   programme to reduce injuries in youth rugby: a cluster randomised controlled trial.

227   *BMJ Open Sport Exerc Med* 2016;2(1):e000043. doi: 10.1136/bmjsem-2015-000043

228   22. Fuller CW, Molloy MG, Bagate C, et al. Consensus statement on injury definitions and

229   data collection procedures for studies of injuries in rugby union. *Clinical Journal of*

230   *Sport Medicine* 2007;17(3):177-81. doi: 10.1097/JSM.0b013e31803220b3

231   23. Rae K, Orchard J. The Orchard Sports Injury Classification System (OSICS) version 10.

232   *Clinical Journal of Sport Medicine* 2007;17(3):201-04. doi:

233   10.1097/JSM.0b013e318059b536

234   24. Hopkins WG. Generalized Linear Mixed Models in SPSS.docx. *SportSci* 2016 March

235   2016; 20(ii-iii). sportsci.org/2016/inbrief.htm#SPSS (accessed 14/12/2016).

236   25. Herman K, Barton C, Malliaras P, et al. The Effectiveness Of Neuromuscular Warm-Up

237   Strategies, That Require No Additional Equipment, For Preventing Lower Limb

238   Injuries During Sports Participation: A Systematic Review. *Bmc Med* 2012;10(1):75.

239   doi: 10.1186/1741-7015-10-75

240   26. Hopkins WG. A Spreadsheet for Deriving a Confidence Inteval, Mechanistic Inference

241   and Confidence Inference from a P-Value. *SportSci* 2007; 11.

242   sportsci.org/2007/wghinf.htm.

243   27. Hopkins WG. Linear Models and Effect Magnitudes for Research, Clinical and Practical

244   Applications. *SportSci* 2010; 14. sportsci.org/2010/wghlinmod.htm.

245   28. Batterham AM, Hopkins WG. Making Meaningful Inferences About Magnitudes.

246   *International Journal of Sports Physiology and Performance* 2006;1(1):50-57.

247   29. Batten J, White AJ, Anderson E, et al. From management to prevention: the new cure for

248   sports concussion. *British Journal of Sports Medicine* 2016:bjsports-2015-095949.

249   doi: 10.1136/bjsports-2015-095949

250   30. Benson BW, McIntosh AS, Maddocks D, et al. What are the most effective risk-reduction

251   strategies in sport concussion? *British Journal of Sports Medicine* 2013;47(5):321-26.

252   31. Hamilton DF, Gatherer D, Robson J, et al. Comparative cervical profiles of adult and

253   under-18 front-row rugby players: implications for playing policy. *BMJ Open*

254   2014;4(5):e004975. doi: 10.1136/bmjopen-2014-004975

255   32. Patel DR, Shivdasani V, Baker RJ. Management of sport-related concussion in young

256   athletes. *Sports Medicine* 2005;35(8):671-84.

257   33. Schneider KJ, Meeuwisse WH, Kang J, et al. Preseason reports of neck pain, dizziness,

258   and headache as risk factors for concussion in male youth ice hockey players.

259   *Clinical Journal of Sport Medicine* 2013;23(4):267-72. doi:

260   10.1097/JSM.0b013e318281f09f

261   34. Schneider KJ, Emery CA, Kang J, et al. Examining Sport Concussion Assessment Tool

262   ratings for male and female youth hockey players with and without a history of

263   concussion. *British Journal of Sports Medicine* 2010;44(15):1112-17. doi:

264   10.1136/bjsm.2009.071266

265   35. Shehata N, Wiley JP, Richea S, et al. Sport concussion assessment tool: Baseline

266   values for varsity collision sport athletes. *British Journal of Sports Medicine*

267   2009;43(10):730-34. doi: 10.1136/bjsm.2009.059832

268   36. Lark SD, McCarthy P. The effects of a rugby playing season on cervical range of motion.

269   *Journal of Sports Sciences* 2010;28(6):649-55.

270   37. Lark SD, McCarthy PW. Cervical range of motion and proprioception in rugby players

271   versus non-rugby players. *Journal of Sports Sciences* 2007;25(8):887-94.

272   38. Lark SD, McCarthy PW. The effects of a single game of rugby on active cervical range of

273   motion. *Journal of Sports Sciences* 2009;27(5):491-97. doi:

274   10.1080/02640410802632136

275   39. Maconi F, Venturelli M, Limonta E, et al. Effects of a 12-week neck muscles training on

276   muscle function and perceived level of muscle soreness in amateur rugby players.

277   *Sport Sciences for Health* 2016:1-10.

278   40. Bleakley C, Tully M, O'Connor S. Epidemiology of Adolescent Rugby Injuries: A

279   Systematic Review. *Journal of Athletic Training* 2011;46(5):555-65.

280   41. Steffen K, Andersen TE, Krosshaug T, et al. ECSS Position Statement 2009: Prevention

281   of acute sports injuries. *European Journal of Sport Science* 2010;10(4):223-36. doi:

282   10.1080/17461390903585173

283   42. Ogaki R, Takemura M, Iwai K, et al. Risk Factors for Shoulder Injury in Collegiate Rugby

284   Union Players. *International Journal of Sport and Health Science* 2014;12:31-37.

285   43. Andersson SH, Bahr R, Clarsen B, et al. Preventing overuse shoulder injuries among

286   throwing athletes: a cluster-randomised controlled trial in 660 elite handball players.

287   *British Journal of Sports Medicine* 2016:bjsports-2016-096226.

288   44. Niederbracht Y, Shim AL, Sloniger MA, et al. Effects of a shoulder injury prevention

289   strength training program on eccentric external rotator muscle strength and

290   glenohumeral joint imbalance in female overhead activity athletes. *Journal of*

291   *Strength and Conditioning Research* 2008;22(1):140-5. doi:

292   10.1519/JSC.0b013e31815f5634 [published Online First: 2008/02/26]

293   45. Soligard T, Nilstad A, Steffen K, et al. Compliance with a comprehensive warm-up

294   programme to prevent injuries in youth football. *British Journal of Sports Medicine*

295   2010;44(11):787-93. doi: 10.1136/bjsm.2009.070672

296   46. Hägglund M, Atroshi I, Wagner P, et al. Superior compliance with a neuromuscular

297   training programme is associated with fewer ACL injuries and fewer acute knee

298   injuries in female adolescent football players: Secondary analysis of an RCT. *British*

299   *Journal of Sports Medicine* 2013;47(15):974-79. doi: 10.1136/bjsports-2013-092644

300   47. Impellizzeri FM, Bizzini M, Dvorak J, et al. Physiological and performance responses to

301   the FIFA 11+ (part 2): A randomised controlled trial on the training effects. *Journal of*

302   *Sports Sciences* 2013;31(13):1491-502. doi: 10.1080/02640414.2013.802926

303   48. Fortington LV, Donaldson A, Lathlean T, et al. When 'just doing it'is not enough:

304   assessing the fidelity of player performance of an injury prevention exercise program.

305   *journal of Science and Medicine in Sport* 2015;18(3):272-77.

306   49. Hanson D, Allegrante JP, Sleet DA, et al. Research alone is not sufficient to prevent

307   sports injury. *British Journal of Sports Medicine* 2014;48(8):682-4. doi:

308   10.1136/bjsports-2012-091434

309   50. Twomey D, Finch C, Roediger E, et al. Preventing lower limb injuries: is the latest

310   evidence being translated into the football field? *Journal of Science and Medicine in*

311   *Sport* 2009;12(4):452-56.

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313

314 **What are the new findings?**

315 • Intention-to-treat analyses revealed that the intervention programme substantially

316 reduced upper limb injury burden (RR=0.66, 90% CL: 0.40-1.10) and concussion

317 incidence (RR=0.71, 90% CL: 0.48-1.05) compared with the control programme.

318 • Completing the intervention programme 3 times per week led to substantial

319 reductions of 72% in overall match injury incidence (RR=0.28, 90% CL: 0.14-0.51)

320 and 72% in contact-related injury incidence (RR=0.28, 90% CL: 0.28-0.56) compared

321 with the control programme.

322 **How might these impact on clinical practice in the near future?**

323 • These findings provide encouraging evidence that a pre-activity preventive exercise

324 programme can substantially reduce injury risk in youth rugby.

325 • Notable reductions in upper extremity injuries and concussion offer promising

326 implications for the prevention of these high-risk injury types in young rugby players.

327 • Findings also outline a minimum effective dose of 3 sessions a week whereby

328 programme efficacy can be optimised.

329

330 **Figure and Table Legends**

331 **Figure 1**   Flow diagram presenting the recruitment and retention of participants through

332   the study.

333 **Table 1**   Summary and comparisons of player characteristics between the

334   intervention (n=1,325 players) and control (n=1,127 players) groups

335 **Table 2**   Descriptive statistics for match injuries across the control and intervention

336   cohorts

337 **Figure 2**   Forest plot detailing the results of the intention-to treat-analyses for effects of

338   trial arm on injury measures (n=31 schools, 83 teams). Data points represent

339   RR of injury measures in the intervention arm relative to the control arm

340   (reference group, RR=1.00). Dotted vertical lines represent thresholds for

341   smallest worthwhile effects (RR=0.90 and 1.11). Data labels represent %

342   likelihood that each effect favours the intervention | is trivial | favours the

343   control, for outcome variables that demonstrate a clear effect of trial arm

344   allocation. *Likely, **Very Likely, ***Most Likely.

345 **Figure 3**   Forest plot illustrating the results of the per-protocol analyses on the effect of

346   trial arm on injury measures in teams with a mean programme completion

347   rate of more than 3 completions per week (n=7 schools, 12 teams). Data

348   points represent RR of injury measures in the intervention arm relative to the

349   control arm (reference group, RR=1.00). Dotted vertical lines represent

350   thresholds for smallest worthwhile effects (RR= 0.90 and 1.11). Data labels

351   represent % likelihood that each effect favours the intervention | is trivial |

352   favours the control, for outcome variables which demonstrate a clear effect of

353   trial arm allocation. *Likely, **Very Likely, ***Most Likely.

354

355   **Figure 4**   Forest plot illustrating the effects of intervention programme dose on injury

356   measures (n= 14 schools, 32 teams). Data points represent RR of injury

357   measures in teams completing >3 sessions per week relative to teams

358   completing <3 sessions per week (RR=1.00). Dotted vertical lines represent

359   thresholds for smallest worthwhile effect (RR= 0.90 and 1.11). Data labels

360   represent % likelihood that each effect favours >3 completions per week | is

361   trivial | favours <3 completions per week, for outcome variables which

362   demonstrate a clear effect of programme dose.*Likely, **Very Likely, ***Most

363   Likely.

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