

Does Padded Headgear Prevent Head Injury in Rugby Union Football?

ANDREW S. MCINTOSH¹, PAUL MCCRORY², CAROLINE F. FINCH³, JOHN P. BEST⁴, DAVID J. CHALMERS⁵, and RORY WOLFE⁶

¹*School of Risk and Safety Sciences, The University of New South Wales, Sydney, AUSTRALIA;* ²*Centre for Health, Exercise and Sports Medicine, University of Melbourne, Victoria, AUSTRALIA;* ³*The University of Ballarat, Victoria, AUSTRALIA;* ⁴*Orthosports Group, Sydney, AUSTRALIA;* ⁵*Injury Prevention Research Unit, Department of Preventive and Social Medicine, University of Otago, Dunedin, NEW ZEALAND;* and ⁶*Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, AUSTRALIA*

ABSTRACT

MCINTOSH, A. S., P. MCCRORY, C. F. FINCH, J. P. BEST, D. J. CHALMERS, and R. WOLFE. Does Padded Headgear Prevent Head Injury in Rugby Union Football? *Med. Sci. Sports Exerc.*, Vol. 41, No. 2, pp. 306–313, 2009. **Background:** Concussion is a serious problem in many contact sports, including rugby union football. The study's primary aim was to measure the efficacy of padded headgear in reducing the rates of head injury or concussion. **Methods:** A cluster randomized controlled trial with three arms was conducted with rugby union football teams as the unit of randomization. Teams consisted of males participating in under 13-, 15-, 18-, and 20-yr age group competitions. The interventions were "standard" and "modified" padded headgear. Headgear wearing and injury were measured for each study team at each game over two seasons. **Results:** Eighty-two teams participated in year 1 and 87 in year 2. A total of 1493 participants (10,040 player hours) were in the control group, 1128 participants (8170 player hours) were assigned to the standard headgear group, and 1474 participants (10,650 player hours) were assigned to the modified headgear group. The compliance rates were low in all groups, but 46% of participants wore standard headgear. An intention-to-treat analysis showed no differences in the rates of head injury or concussion between controls and headgear arms. Incidence rate ratios for standard headgear wearers referenced to controls were 0.95 and 1.02 for game and missed game injuries. Analyses of injury rates based on observed wearing patterns also showed no significant differences. Incidence rate ratios for standard headgear wearers referenced to nonwearers were 1.11 and 1.10 for game and missed game injuries. **Conclusions:** Padded headgear does not reduce the rate of head injury or concussion. The low compliance rates are a limitation. Although individuals may choose to wear padded headgear, the routine or mandatory use of protective headgear cannot be recommended. **Key Words:** FOOTBALL, HEAD INJURY, CONCUSSION, HELMETS, SPORTS INJURY PREVENTION, RANDOMIZED CONTROLLED TRIAL

Over the last decade, brain injury in sport, including concussion, and its prevention have been a focus of research, policy, and public interest. Sports-related head injury is of special interest due to the large participant numbers and their age, coupled with the view that sport provides social and health benefits (22). There is a lack of class 1 evidence regarding the efficacy of currently avail-

able headgear in reducing head injury in sport (6,18,22). From a biomechanical perspective, well-designed headgear has the potential to prevent injury by decreasing the impact force and distributing it over a larger area of the head. This has been demonstrated for pedal and motor cycle helmets (31,19). After many years of research and development, some improvement in the performance of helmets in American football has been achieved (7,32).

Rugby union football is a popular international sport. Head injury has been reported to account for between one sixth and one third of all rugby injuries by body region (2,3,5,8,12,26,28–30). The majority are soft tissue injuries (2,3,5,8,12,26,28–30). Although catastrophic brain injury in rugby is rare (5,8), concussion is common and accounts for up to 15% of all rugby injuries. In rugby, the use of headgear is not mandatory, and the only sanctioned padded headgear (or scrum cap) consists of soft polyethylene (PE)

Address for correspondence: Andrew S. McIntosh, Ph.D., M.Biomed.E., B.A.Sc., School of Risk and Safety Sciences, The University of New South Wales, Sydney 2052, Australia; E-mail: a.mcintosh@unsw.edu.au.

Submitted for publication July 2007.

Accepted for publication June 2008.

0195-9131/09/4102-0306/0

MEDICINE & SCIENCE IN SPORTS & EXERCISE®

Copyright © 2009 by the American College of Sports Medicine

DOI: 10.1249/MSS.0b013e3181864bee

foam padding with no hard outer shell (15), unlike helmets in American football, baseball, or ice hockey. Laboratory tests on International Rugby Board (IRB)-approved padded headgear (“standard”) have shown that the impact energy attenuation performance is unlikely to reduce the risk of concussion (20,23,24). Laboratory tests have also shown that increases in the thickness and density of headgear foam can improve the impact performance (24). Field studies of standard padded headgear have demonstrated that its effectiveness may be limited (17,21,25,26).

In contrast to the potential benefits of headgear, there are concerns that sport participants wearing headgear may play more recklessly based on the misguided belief that they are protected from injury. This phenomenon has been suggested in a variety of sports and is known as *risk compensation* (13) and may result in a paradoxical increase in injury rates (11,25). This is a particular issue in younger athletes (13).

Using a randomized controlled trial (RCT) design, this study examines the efficacy of padded headgear in preventing head injuries in rugby union football in a male youth population. A cluster design was chosen due to the structure of team sport and the difficulties of delivering different interventions to participants within individual teams.

METHODS

Study design and intervention. A clustered randomized controlled trial (RCT) design was used to accommodate the team nature of many sports and the team-based delivery of interventions in sport, in this case rugby. There were two intervention arms and one control arm. The primary objective of the study was to examine the efficacy of padded headgear in rugby union football in young males aged 12–21 yr. The study was designed to detect a 25% reduction in the rate of head injury or concussion for headgear wearers over the two rugby seasons. The following null hypotheses were tested in this study: in comparison to no headgear, neither standard nor modified headgear altered the rate of (a) head injury or (b) concussion. A secondary, but related, objective was to examine risk compensation as it applied to headgear use. Risk-compensating behaviors might reveal themselves by headgear wearers becoming more aggressive in body contact situations, which might increase their injury risk. The following null hypothesis was tested: the overall rates of injury were the same for each study arm.

Interventions were IRB Law 4 compliant “standard” headgear and “modified” headgear (15,24). The modified headgear was formed using a 16-mm-thick, 60-kg·m⁻³ PE foam compared with a 10-mm-thick, 45 kg·m⁻³ PE foam in standard headgear. Laboratory testing of the modified headgear demonstrated that it offered superior impact energy attenuation performance compared with the standard model. Although the performance did not necessarily extend to

providing sufficient protection against the concussive impacts that the authors had observed in previous research in professional Australian football, rugby league, and rugby union, it was possible that it offered protection in younger cohorts (23,24). The controls were not supplied with headgear but were allowed to wear headgear if they chose to do so due to ethical considerations. Players in the intervention groups were provided with headgear free of charge and with encouragement to wear headgear.

Incidence rates and nature of injury data from Bird et al. (3) were used to calculate a head injury rate estimate for games of 16.35 per 1000 player-game hours. For 80% power (two-sided alpha level of 5%) to detect a 25% decrease in injury rate in the standard headgear group from a rate of 16.35 injuries per 1000 playing hours in the no-headgear group, we required 368 injuries, and on the assumption of two seasons each of 15 games on average of 1 h game time per game, we required 429 players in each group. With 15 players per team, this was a requirement of 29 teams per group. A third group of participants randomized to modified headgear was included with an equal number of teams as the other two study groups. No adjustment was made for the clustering of players by team in these *a priori* calculations because no information on likely intracluster correlation size was available for rugby union teams, and our *a priori* hypothesis was that the cluster effect would be negligible.

Participants and randomization. All players in rugby teams in one club and three school-based competitions that had agreed in principle to participate in the study were considered eligible for inclusion. The rugby teams were in the following levels: schoolboy under 13 yr (U13), schoolboy under 15 yr (U15), schoolboy under 18 yr (U18), and club colts rugby under 20 yr (U20). All participants were male. Clubs and schools were invited to participate by letter and followed-up by phone calls and meetings. Once agreement was reached on involvement, individual teams were contacted through their coaches. Recruitment of teams and players occurred before randomization of teams into each study arm. Players or parents/guardians provided informed written consent, and the study was approved by the UNSW Human Research Ethics Committee.

Sampling units were groups of rugby teams within a club/school and level, for example, A and B teams, C and D teams, first and second grades, and third and fourth grades. This decision was made in recognition that players often migrated within these team groups. A new randomization occurred in each year of the study and was conducted after stratification for age group and was balanced so as to have an equal number of teams in each study arm in each age group.

Outcome measures. The primary outcome measures were the rates of head injury and concussion in each group. The secondary outcome measures were injury rates for all body regions combined. Outcome measures were calculated on an individual player basis. Head injury was limited to the cranium and excluded the face. Head injury included

superficial and intracranial injury. Facial injuries were coded separately and are not reported here. Concussion cases comprised a subset of head injuries and were defined according to the Vienna consensus statement on concussion (1). The key points of this definition are that (i) concussion is caused by a direct impact to the head or impulsive loading, and (ii) symptoms have a rapid onset and are short lived. The following signs and symptoms are recognized as being typical of concussion and were recorded in this study: headache, loss of consciousness or impaired conscious state, confusion, dizziness, amnesia, nausea/vomiting, and convulsive convulsion/impact seizure.

Two operational injury definitions were used: 1) game injury—any injury requiring on-field treatment or resulting in the player being removed from the field during a rugby game, and 2) missed game injury—an injury occurring in a rugby game resulting in the player missing a game the next week (usually at least 7 d absence from competition). The set of missed game injuries overlapped largely with the set of game injuries. The two definitions of injury represent two common measures of injury in sport (9,14). The operational definition of “game injury” may exclude some superficial head injuries.

Primary data collectors (PDC) were trained and paid to record injury, compliance (i.e., headgear wearing), and exposure at each game in the study using standard methods. The recording forms and methods had been piloted in rugby and applied to two studies of Australian football and found to be a reliable method of data collection in the field (4,10). Random weekly checks of the PDC and their data recording were made. Weekly reviews of each player’s participation in a game were undertaken to identify which players missed games. When a player was absent due to injury, more accurate medical data pertinent to the injury were obtained from treating medical staff. For noninjury cases, the reasons for absence were recorded, e.g. sick or relegated to lower grade. For seasons interrupted by holidays and byes and the last game of the season, player availability was ascertained through communication with team staff to identify missed game injuries.

Statistical methods. Incidence rates were calculated as the number of injuries per 1000 h of player-game time. To compare injury rates between groups, that is, intention-to-treat analysis, we obtained incidence rate ratios (IRR) from Poisson regression models. Robust standard errors were calculated to allow for randomization by team (27). Multivariate analyses used the same method but with additional covariates included, that is, the potential confounders. Intracluster correlations were calculated to assess whether our *a priori* hypothesis, that is, that the cluster effect would be negligible, had led to a reduction in power. We calculated intracluster correlations in our observed study data by comparing standard errors from our analysis method with standard errors from an analysis that ignored the clustering. This comparison showed negligible inflation of standard errors due to clustering. All analyses

were undertaken using Stata software version 7 (Statacorp, College Station, TX), and the term “statistically significant” was used for a *P* value <0.05.

RESULTS

Eighty-two teams participated in year 1 and 87 teams in year 2 of the study (Fig. 1). The median recorded player-game exposures per participant was nine, and this varied depending on level and participation in finals. A total of 3686 players participated in at least one game in one season during the study, with 409 of those participating in both seasons. The total player-game exposures recorded with measured study arm, game time, headgear use, and injuries was 30,316.

Table 1 presents the allocation characteristics of a subset of participants in each study arm stratified by level of play (*n* = 1409). These measures were not collected from all participants due to budgetary constraints and training session time restrictions. Age, body mass, and stature were similar across each study arm, demonstrating baseline equivalence.

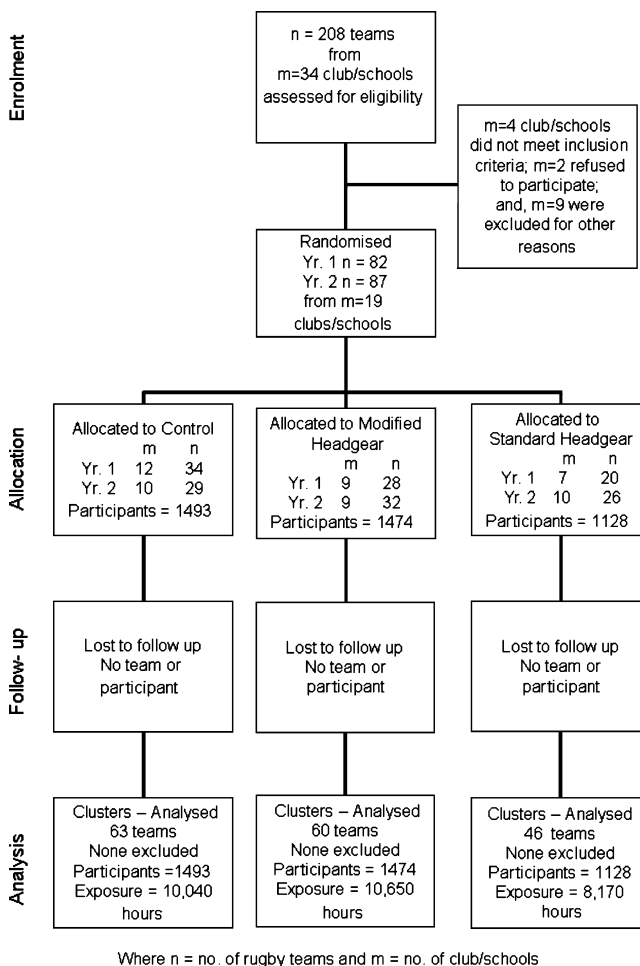


FIGURE 1—Flow chart of cluster and participants. The 409 players who participated in both seasons have been counted in each year.

TABLE 1. Allocation characteristics for a subset of participants stratified according to level and study arm.

	Study Arm		
	Control	Standard Headgear	Modified Headgear
Age (yr), mean ± SD [count (missing)]			
U13	13.0 ± 0.4 [93(17)]	12.9 ± 0.4 [91(11)]	13.0 ± 0.5 [114(42)]
U15	15.0 ± 0.3 [62(7)]	15.0 ± 0.3 [134(20)]	15.0 ± 0.3 [118(12)]
U18	17.4 ± 0.5 [92(15)]	17.5 ± 0.6 [107(65)]	17.3 ± 0.6 [143(10)]
U20	19.2 ± 1.0 [177(24)]	19.2 ± 0.9 [133(6)]	19.1 ± 0.8 [145(6)]
Total	16.9 ± 2.5 [424(63)]	16.3 ± 2.6 [465(102)]	16.6 ± 2.3 [520(70)]
Stature (cm), mean ± SD [count (missing)]			
U13	161 ± 7 [93(0)]	161 ± 10 [91(0)]	162 ± 8 [114(0)]
U15	175 ± 7 [62(0)]	174 ± 7 [134(1)]	175 ± 7 [118(0)]
U18	178 ± 7 [92(0)]	180 ± 6 [107(0)]	179 ± 7 [143(0)]
U20	181 ± 7 [177(1)]	182 ± 7 [133(2)]	179 ± 8 [145(1)]
Total	175 ± 11 [424(1)]	175 ± 11 [465(3)]	175 ± 10 [520(1)]
Body mass (kg), mean ± SD [count (missing)]			
U13	54 ± 9 [93(26)]	55 ± 12 [91(0)]	56 ± 11 [114(0)]
U15	69 ± 9 [62(1)]	70 ± 11 [134(0)]	71 ± 12 [118(26)]
U18	77 ± 11 [92(0)]	78 ± 11 [107(0)]	82 ± 12 [143(0)]
U20	88 ± 14 [177(0)]	89 ± 16 [133(0)]	89 ± 17 [145(1)]
Total	77 ± 17 [424(27)]	74 ± 17 [465(0)]	76 ± 18 [520(27)]

2002 and 2003 data have been combined. Data are from a sample of convenience. Table displays mean ± SD of age, stature, and body mass. In addition, the size of the cohort surveyed (count) and the number of players missing (missing) when that measure was made are presented.

Table 2 presents the distribution of player-game exposures by study arm versus the measured headgear-wearing patterns (compliance). Player-game exposures were fairly equally distributed across the study arms. Table 2 shows that in 44% of exposures no headgear was worn and in 46% standard headgear was worn and modified in only 11%. Table 2 also shows that modified headgear was worn in only 25% of games played by those randomized to the modified headgear arm. The high wearing rate of standard headgear was expected based on the observed pre-2002 headgear-wearing patterns. There was a bias toward more exposures in the U20 level as they played at least twice the number of games per season as the school age players. Forty-one percent (41%) of all exposures were in the U20 compared with 25% in the U18 and 17% each in U15 and U13.

A total of 1841 injuries were experienced by 1159 players in the study; in two cases, game time data were missing and were excluded from subsequent analyses. Six hundred and four injuries resulted in a player missing at least one game the following weekend. Injuries to the head (excluding the face) accounted for 13% of all game injuries and 8% of all missed game injuries. Concussion accounted for 11% of all game injuries and 8% of missed game injuries. Only

TABLE 2. Player-game exposures by study arm and compliance.

	Study Arm			Total
	Control	Standard Headgear	Modified Headgear	
Compliance				
None	5072 (48.9%)	3577 (40.1%)	4538 (41.2%)	13,187 (43.5%)
Standard	5191 (50.0%)	4986 (55.9%)	3684 (33.4%)	13,861 (45.7%)
Modified	110 (1.1%)	355 (4.0%)	2803 (25.4%)	3268 (10.8%)
Total	10,373 (34%)	8918 (29%)	11,025 (36%)	30,316 (100%)

Each cell contains the hours of exposure and, in parentheses, the percent within the study arm or total. Compliance denotes observed use of headgear.

8% (16/199) of the total concussion cases missed at least two games due to concussion, and these were distributed evenly across the study arms.

Seventy-five percent of participants concussed during a game left the field of play and did not return in that game. The remaining 25% of concussed players received on-field attention and completed the game. Only 20% of the concussed players lost consciousness, and no player lost consciousness for longer than 5 min. Almost 50% of concussed players suffered from headaches or dizziness and 22% had limited posttraumatic amnesia. Six percent of the concussion cases were sent to hospital from the game but none were admitted.

Table 3 presents the injury rates for head injury, concussion, and all body regions for each study arm and all body regions combined. The overall injury rate was 63.7 injuries per 1000 h of player-game exposure. The overall missed game injury rate was 20.9 injuries per 1000 h.

Table 4 presents the results of the univariate analyses of injury rates for all body regions, head injury, and concussion on an intention-to-treat basis and compliance (as worn). No significant differences in injury rates were observed for the head (excluding face), concussion, and all body regions across the three arms of the study.

The analyses reported in Tables 3 and 4 were repeated after adjusting for level of play (Table 5). There was a

TABLE 3. Head, concussion and all body region injury rates.

Intervention	Game Injuries			Missed Game Injuries		
	Injury Count	Rate	95% CI	Injury Count	Rate	95% CI
All body regions						
Combined	1839	63.7	60.9–66.7	602	20.9	19.3–22.6
Intention-to-treat analysis						
Control	709	70.6	65.6–76.0	215	21.4	18.7–24.5
Modified	688	64.6	60.0–69.6	233	21.9	19.2–24.9
Standard	442	54.1	49.3–59.4	154	18.8	16.1–22.1
Compliance analysis						
Wore none	799	61.5	57.4–65.9	272	20.9	18.6–23.6
Modified	175	60.6	52.2–70.2	47	16.3	12.2–21.6
Standard	828	66.9	62.5–71.6	271	21.9	19.4–24.7
Head injury						
Combined	234	8.1	7.1–9.2	49	1.7	1.3–2.3
Intention-to-treat analysis						
Control	82	8.2	6.6–10.1	19	1.89	1.2–3.0
Modified	96	9.0	7.4–11.0	15	1.41	0.9–2.3
Standard	56	6.9	5.3–8.9	15	1.84	1.1–3.1
Compliance analysis						
Wore none	106	8.6	7.1–10.4	23	1.86	1.2–2.8
Modified	22	7.6	5.0–11.6	2	0.69	0.2–2.8
Standard	100	7.7	6.3–9.4	22	1.69	1.1–2.6
Concussion						
Combined	199	6.9	6.0–7.9	47	1.63	1.2–2.2
Intention-to-treat analysis						
Control	67	6.7	5.2–8.5	18	1.79	1.1–2.8
Modified	80	7.5	6.0–9.4	14	1.31	0.8–2.2
Standard	52	6.4	4.9–8.4	15	1.8	1.1–3.1
Compliance analysis						
Wore none	90	7.3	5.9–8.9	21	1.6	1.1–2.5
Modified	19	6.6	4.2–10.3	2	0.7	0.2–2.8
Standard	85	6.5	5.3–8.1	22	1.8	1.2–2.7

Incidence rates presented as injuries per 1000 h of player-game exposure with 95% CI. Rates for head injury exclude facial injury. Injury counts for compliance data reflect the association with known use of the intervention and are slightly lower in total than for equivalent intention-to-treat data.

TABLE 4. Univariate analyses of game and missed game injuries.

Intervention	Game Injuries			Missed Game Injuries		
	IRR	<i>P</i> value*	95% CI	IRR	<i>P</i> value*	95% CI
All body regions						
Intention-to-treat analysis						
Comparison among three groups		0.16			0.33	
Control	Reference			Reference		
Modified	0.92	0.62	0.64–1.30	1.02	0.87	0.78–1.34
Standard	0.77	0.15	0.54–1.10	0.88	0.35	0.68–1.15
Compliance analysis						
Comparison among three groups		0.17			0.32	
None	Reference			Reference		
Modified	0.98	0.92	0.73–1.33	0.78	0.2	0.53–1.14
Standard	1.09	0.06	1.00–1.19	1.05	0.62	0.87–1.25
Head injury						
Intention-to-treat analysis						
Comparison among three groups		0.48			0.81	
Control	Reference			Reference		
Modified	1.10	0.66	0.71–1.72	0.74	0.54	0.29–1.89
Standard	0.84	0.49	0.51–1.38	0.97	0.94	0.42–2.24
Compliance analysis						
Comparison among three groups		0.72			0.41	
None	Reference			Reference		
Modified	0.99	0.96	0.65–1.51	0.41	0.20	0.10–1.60
Standard	1.11	0.50	0.82–1.51	1.10	0.72	0.65–1.84
Concussion						
Intention-to-treat analysis						
Comparison among three groups		0.78			0.76	
Control	Reference			Reference		
Modified	1.13	0.65	0.67–1.90	0.73	0.50	0.30–1.80
Standard	0.95	0.87	0.54–1.69	1.02	0.95	0.45–2.32
Compliance analysis						
Comparison among three groups		0.74			0.45	
None	Reference			Reference		
Modified	1.01	0.98	0.67–1.69	0.43	0.24	0.10–1.76
Standard	1.11	0.45	0.69–1.21	1.10	0.71	0.66–1.83

Intention-to-treat and compliance analyses presented by all regions, head injury, and concussion. Head injury excludes facial injury. Incidence rate ratios (IRR) are reported relative to the control group for intention-to-treat analyses and no headgear worn for compliance analyses.

* *P* value for comparison against reference.

significant difference between the incidence rates of game injuries to all body regions based on compliance and after adjustment for level of play ($P = 0.03$). Standard headgear wearers had a 16% higher incidence of game injury than nonwearers ($P = 0.01$). No other significant differences were found in the overall rates of injury. The low number of cases that missed at least two matches prevented any meaningful analysis of headgear and head injuries that resulted in extended absences from the game.

DISCUSSION

This study is the first reported RCT of headgear as an injury control method in rugby union football and one of the few studies of this design of a sports injury intervention. The results show that the padded headgear trialed in this study does not reduce the rate of head injury and concussion, even after adjustment for level of play. Concussion as a proportion of all injuries was 11%, which is similar to the findings of Targett (30) and Davidson (8). There is potential for bias in the analyses presented due to uncontrolled confounding, for example, player position, previous head injury, behavioral factors, and poor compliance. In particular, the poor compliance is a major limitation. It is also acknowledged that a missed game injury is only a surrogate

measure of injury severity, as medical or team injury management protocols postconcussion were not standardized. Using the definition of a missed game injury, headgear did not reduce the severity of head injury or concussion significantly.

Participants were drawn from youth rugby primarily because the incidence of concussion is greatest in youth rugby and there is a corresponding need to develop effective interventions. Teams were randomized into each arm of the study. There were slightly fewer teams in the standard headgear arm than planned. This was influenced by recruiting teams in pairs within a level. It was not ethically possible to require players either to cease wearing headgear or to force them to wear a particular type. For example, whereas 36% of the player-game exposures were for players randomized to the modified headgear arm of the study, only 11% of the total game exposures were for players observed by the primary data recorders wearing the modified headgear. Players provided informal feedback that the modified headgear was too stiff and therefore uncomfortable. The observed headgear-wearing patterns highlight the difficulties facing researchers undertaking RCT of sports interventions, in particular when there is a preexisting but mixed pattern of use. In addition, the requirement to wear novel equipment or variants may require incentives to be offered

TABLE 5. Analyses of game and missed game injuries after adjustment for level of play.

Intervention	Game Injuries			Missed Game Injuries		
	IRR	P value*	95% CI	IRR	P value*	95% CI
All body regions						
Intention-to-treat analysis						
Comparison among three groups		0.10			0.19	
Control	Reference			Reference		
Modified	0.88	0.47	0.63–1.24	1.01	0.95	0.80–1.27
Standard	0.75	0.10	0.54–1.06	0.88	0.24	0.70–1.09
Compliance						
Comparison among three groups		0.03			0.81	
None	Reference			Reference		
Modified	1.05	0.75	0.78–1.41	0.85	0.34	0.60–1.19
Standard	1.16	0.01	1.04–1.29	1.09	0.34	0.91–1.31
Head injury						
Intention-to-treat analysis						
Comparison among three groups		0.48			0.81	
Control	Reference			Reference		
Modified	1.09	0.70	0.69–1.72	0.75	0.55	0.29–1.92
Standard	0.83	0.49	0.49–1.41	0.98	0.97	0.42–2.28
Compliance analysis						
Comparison among three groups		0.66			0.49	
None	Reference			Reference		
Modified	1.03	0.91	0.67–1.58	0.46	0.27	0.12–1.83
Standard	1.14	0.41	0.84–1.54	1.14	0.62	0.68–1.91
Concussion						
Intention-to-treat analysis						
Comparison among three groups		0.78			0.76	
Control	Reference			Reference		
Modified	1.12	0.69	0.65–1.91	0.74	0.50	0.30–1.79
Standard	0.94	0.85	0.52–1.72	1.03	0.94	0.46–2.34
Compliance analysis						
Comparison among three groups		0.67			0.51	
None	Reference			Reference		
Modified	1.06	0.80	0.70–1.60	0.48	0.31	0.12–2.01
Standard	1.13	0.37	0.86–1.49	1.14	0.62	0.69–1.88

Intention-to-treat and compliance analyses presented by all regions, head injury, and concussion. Head injury excludes facial injury. Incidence rate ratios (IRR) are reported relative to the control arm for intention-to-treat analyses and no headgear worn for compliance analyses.

* P value for comparison against reference.

to the participants or the team. Sports clothing, tickets to popular games, or interaction with prominent players or coaches might be effective incentives.

Laboratory testing previously showed that currently available standard headgear had limited potential to attenuate impacts to the head and reduce the head's acceleration to tolerable limits (20). In this context, the results of this study are not surprising. Other field studies have not observed a reduction in the rate of concussion or head injury as a result of wearing padded headgear; however, these studies were restricted to limited populations (17,21,25). Jones et al. (17) suggested that current headgear may prevent some types of superficial head injury based on their case control study. The results of this study did not confirm those observations; however, the differences may be due to the levels of play studied, the differing study designs, and the definition of game injury. Superficial head injuries that did not require on-field treatment or removal from the field were not included.

As reported, head injury and concussion rates based on headgear-wearing compliance were not significantly different. However, there was a trend toward a lower rate of head injuries and concussion causing a missed game for wearers of the modified headgear, with a 63% and 57% reduction, respectively, compared with wearing the standard

headgear. No such trend was observed for all injury regions combined. This observation is consistent with the laboratory testing of impact energy attenuation and indicates that further laboratory-based research and development might produce an effective product. Although laboratory tests on the modified headgear used in this study demonstrated greater energy attenuation properties than standard headgear, either the modifications were not sufficient to reduce game head injuries and concussion or the study required a longer period to observe significant differences in head injury and concussion (24). Rephrased, the results of the study confirmed that the biomechanical laboratory tests are a valid predictor of headgear efficacy. This in itself is a valuable finding because it strengthens the role of laboratory testing for helmets as these produce immediate results at far less cost and inconvenience than volunteer studies.

There was limited evidence that wearing headgear was associated with increased injury rates based on a 16% increased overall game injury rate for those wearing standard headgear after adjustment for level of play. Differences in injury rates to the head were not significant, but wearers of the standard headgear did have a 14% higher incidence of game and missed game injuries than nonwearers. It is unclear whether this truly reflects an aspect of risk compensation (13). Further analyses are planned on a more extensive data

set, including playing history, injury history, and attitudes, from a subset of participants.

The study identified that the IRB regulations on return to play after concussion were not followed in this cohort (16). Although this topic was not specifically studied, the reasons for this observation may be that 1) the study design adopted a broad definition of concussion that is consistent with the current opinion and might have been more inclusive than the IRB considered in their law, and 2) there is no specific method for the IRB's law to be policed in community rugby.

This study showed that standard padded headgear did not reduce the rate of head injury or concussion or increase the overall rate of injury. These findings need to be considered in the context of the low compliance in the RCT study. Although individuals may choose to wear padded headgear, its routine or mandatory use to prevent injury in rugby football cannot be recommended. Further laboratory-based research and development of headgear is required.

Funding/support and role of sponsor: This project was funded by the International Rugby Board (IRB). No investigator's salary was funded by the sponsor. RW was paid to undertake the statistical analyses from the research grant. The investigators, not the IRB, were responsible for decisions regarding the design and conduct of the study as well as collection, management, analysis, and inter-

pretation of the data. The authors prepared this manuscript and it was sent to the IRB for approval. All authors and researchers are independent of the IRB, and the project was conducted independently. Caroline Finch was supported by the National Health and Medical Research Council Principal Research Fellowship. Paul McCrory was supported by the National Health and Medical Research Council. The decision to publish was controlled by the authors and not the trial sponsor.

Conflict of Interest: There is no conflict of interest. No author has a financial interest in the manufacture of headgear or was paid by the sponsor.

Contributors: AM was the principal investigator and guarantor. He contributed to the study design, the development of the intervention, the data analysis, and the interpretation, drafting, and writing of the article. PM, CF, JB, and DC contributed to the study design and data interpretation as well as the drafting and writing of the article. RW contributed to the data interpretation as well as the drafting and writing of the article. RW conducted the statistical analyses. In addition, PM and JB provided sports medicine input, and CF and DC contributed to the design of the statistical analyses. Ms. M. Romiti, Ms. D. Twomey, Mr. C. French, and Mr. T. Savage were research assistants on this project. They worked in a full-time or casual capacity and assisted with recruitment of participants, data collection, and data entry. Mr. John Searl from the Australian Rugby Union liaised with the ARU and the rugby clubs. Many other people contributed to the execution of the project, for example, PDC, club/school personnel, team staff, and medical personnel. We gratefully acknowledge their contributions.

The study was approved by the UNSW Human Research Ethics Committee (Approval HREC 99085).

The results of the present study do not constitute endorsement by ACSM.

REFERENCES

- Aubry M, Cantu R, Dvorak J, et al. Summary and agreement statement of the first International Conference on Concussion in Sport, Vienna 2001. *Br J Sports Med.* 2002;36(1):6-7.
- Bathgate A, Best JP, Craig G, Jamieson M, Wiley JP. A prospective study of injuries to elite Australian rugby union players. *Br J Sports Med.* 2002;36(4):265-9.
- Bird YN, Waller AE, Marshall SW, Alsop JC, Chalmers DJ, Gerrard DF. The New Zealand Rugby Injury and Performance Project: V. Epidemiology of a season of rugby injury. *Br J Sports Med.* 1998;32(4):319-25.
- Braham RA, Finch CF. The reliability of team-based primary data collectors for the collection of exposure and protective equipment use data in community sport. *Br J Sports Med.* 2004;38(4):e15.
- Brooks JHM, Fuller CW, Kemp SPT, Reddin DB. Epidemiology of injuries in English professional rugby union: Part 1. Match injuries. *Br J Sports Med.* 2005;39(10):757-66.
- Cantu RC, Muller FO. Catastrophic football injuries in the U.S.A.: 1977-1990. *Clin J Sport Med.* 1992;2(3):180-5.
- Collins M, Lovell MR, Iverson GL, Ide T, Maroon J. Examining concussion rates and return to play in high school football players wearing newer helmet technology: a three-year prospective cohort study. *Neurosurgery.* 2006;58(2):275-86.
- Davidson RM. Schoolboy rugby injuries, 1969-1986. *Med J Aust.* 1987;147(3):119-20.
- Finch CF. An overview of some definitional issues for sports injury surveillance. *Sports Med.* 1997;24(3):157-63.
- Finch CF, Braham R, McIntosh AS, McCrory P, Wolfe R. Should football players wear custom fitted mouthguards? Results from a group randomised controlled trial. *Inj Prev.* 2005;11(4):242-6.
- Garraway WM, Lee AJ, Hutton SJ, Russell EBAW, Macleod DAD. Impact of professionalism on injuries in rugby union. *Br J Sports Med.* 2000;34(5):348-51.
- Garraway WM, Macleod DAD. Epidemiology of rugby football injuries. *Lancet.* 1995;345(8963):1485-7.
- Hagel B, Meeuwisse W. Risk compensation: a "side effect" of sport injury prevention? *Clin J Sport Med.* 2004;14(4):193-7.
- Hägglund M, Waldén M, Bahr R, Ekstrand J. Methods for epidemiological study of injuries to professional football players: developing the UEFA model. *Br J Sports Med.* 2005;39(6):340-6.
- International Rugby Board. *The Laws of the Game, Rugby Union.* (Law 4 Players' Clothing) Dublin (Ireland): International Rugby Board; 2007. p. 40. Available from: http://www.irb.com/mm/Document/LawsRegs/0/LAW4_4518.pdf
- International Rugby Board. *Regulations Relating to the Game.* (Regulation 10. Medical) Dublin (Ireland): International Rugby Board; 2007. p. 117. Available from: http://www.irb.com/mm/document/lawsregs/0/irbregulationsrelatingtothegamea4feb08_4575.pdf
- Jones SJ, Lyons RA, Evans R, et al. Effectiveness of rugby headgear in preventing soft tissue injuries to the head: a case-control and video cohort study. *Br J Sports Med.* 2004;38(2):159-62.
- Levy ML, Ozgur BM, Berry C, Aryan HE, Apuzzo MLJ. Birth and evolution of the football helmet. *Neurosurgery.* 2004;55(3):656-62.
- Liu B, Ivers R, Norton R, Blows S, Lo SK. Helmets for preventing injury in motorcycle riders. *Cochrane Database Syst Rev.* 2003;(4):CD004333.pub2. doi:10.1002/14651858.CD004333.pub2. First published online: 20 October 2003 in Issue 4, 2003. p. 133.
- McIntosh AS, McCrory P. Impact energy attenuation performance of football headgear. *Br J Sports Med.* 2000;34(5):337-41.
- McIntosh AS, McCrory P. Effectiveness of headgear in a pilot study of under 15 rugby union football. *Br J Sports Med.* 2001;35(3):167-9.
- McIntosh AS, McCrory P. Preventing head and neck injury. *Br J Sports Med.* 2005;39(6):314-8.
- McIntosh AS, McCrory P, Comerford J. The dynamics of concussive head impacts in rugby and Australian rules football. *Med Sci Sports Exerc.* 2000;32(12):1980-4.

24. McIntosh AS, McCrory P, Finch CF. Performance enhanced headgear: a scientific approach to the development of protective headgear. *Br J Sports Med.* 2004;38(1):46–9.
25. Marshall SW, Loomis DP, Waller AE, et al. Evaluation of protective equipment for prevention of injuries in rugby union. *Int J Epidemiol.* 2005;34(1):113–8.
26. Marshall SW, Waller AE, Dick RW, Pugh CB, Loomis DP, Chalmers DJ. An ecologic study of protective equipment and injury in two contact sports. *Int J Epidemiol.* 2002;31(3):587–92.
27. Murray DM. *Design and Analysis of Group-Randomized Trials.* New York: Oxford University Press; 1998. p. 99.
28. Seward H, Orchard J, Hazard H, Collinson D. Football injuries in Australia at the elite level. *Med J Aust.* 1993;159(5):298–301.
29. Sparks JP. Half a million hours of rugby football. The injuries. *Br J Sports Med.* 1981;15(1):30–2.
30. Targett SG. Injuries in professional rugby union. *Clin J Sport Med.* 1998;8(4):280–5.
31. Thompson DC, Rivara FP, Thompson R. Helmets for preventing head and facial injuries in bicyclists. *Cochrane Database Syst Rev.* 1999;(4): CD001855. doi:10.1002/14651858.CD001855. This version first published online: 25 October 1999 in Issue 4, 1999. p. 129.
32. Viano DC, Pellman EJ, Withnall C, Shewchenko N. Concussion in professional football: performance of newer helmets in reconstructed game impacts-Part 13. *Neurosurgery.* 2006;59(3): 591–606.