Does soccer headgear reduce the incidence of sport-related concussion? A cluster, randomised controlled trial of adolescent athletes

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ABSTRACT

Background There have been no large randomised controlled trials to determine whether soccer headgear reduces the incidence or severity of sport-related concussion (SRC) in US high school athletes.
Objective We aimed to determine whether headgear reduces the incidence or severity (days out from soccer) of SRCs in soccer players.
Methods 2766 participants (67% female, age 15.6±1.2) (who undertook 3050 participant years) participated in this cluster randomised trial. Athletes in the headgear (HG) group wore headgear during the season, while those in the no headgear (NoHG) group did not. Staff recorded SRC and non-SRC injuries and soccer exposures. Multivariate Cox proportional hazards models were used to examine time-to-SRC between groups, while severity was compared with a Wilcoxon rank-sum test.
Results 130 participants (5.3% female, 2.2% male) sustained an SRC. The incidence of SRC was not different between the HG and NoHG groups for males (HR: 2.00 (0.63–6.43) p=0.242) and females (HR: 0.86 (0.54–1.36) p=0.520). Days lost from SRC were not different (p=0.583) between the HG group (13.5 (11.0–018.8) days) and the NoHG group (13.0 (9.0–18.8) days).
Conclusions Soccer headgear did not reduce the incidence or severity of SRC in high school soccer players.
Trial registration number NCT02850926.

INTRODUCTION

Sport-related concussion (SRC) injuries in adolescent athletes can cause significant short-term disablement, and if left untreated pose significant health risks to these athletes.[1–3] SRCs are a particular concern in soccer and comprise 8%–13% of all sport injuries in high school.[4–6]

The high numbers of SRCs sustained by soccer players beg the question of whether protective headgear can reduce these injuries.[7 8] Laboratory studies have produced conflicting data as to whether headgear would reduce the impact of a blow sufficiently to reduce the likelihood of an SRC.[9–12] Concussion consensus statements indicate that protective headgear has not been appropriately tested to see whether they reduce the risk of sustaining SRC in soccer.[13–15] Currently, the National Federation of State High School Associations (www.nfhs.org/WorkArea/DownloadAsset.aspx?id=6760; revised and approved January 2012) and the US Soccer Federation (https://www.ussoccer.com/stories/2014/03/17/11/21/u-s-soccer-on-head-injuries-and-padded-headgear) permit players to wear headgear that meets the American Society for Testing Materials International testing standards (www.astm.org/Standards/F2439.htm).

The primary aim of this study was to determine if the number of SRC injuries in soccer players wearing HG is lower than soccer players who did not wear headgear (NoHG). A secondary aim was to determine if the median number of days of soccer participation lost post-SRC injury is different between soccer players in the HG group compared with players in the NoHG group.

METHODS

This was a randomised controlled trial that used stratified cluster (school) randomisation.

Team randomisation

High school soccer teams were contacted for participation during the 2016/2017 and/or 2017/2018 school years. Prior to randomisation schools agreed to take part in the study. Schools were then randomly assigned to be in the HG (headgear group) or the NoHG (control) group based on a stratified randomisation. School enrolment size (small: <400 students; medium: 400–800; or large: >800) was the stratification variable. If a team participated in both years of the study, their group assignment remained the same for both years.

Participants

Potential participants included all interscholastic soccer players (age 14–18, grades 9–12) and were recruited prior to the start of the soccer season. Injury and exposures were recorded for each participant for a single season. If the player wanted to enrol during the second year of the study, they signed an additional consent and completed an updated baseline form.

Headgear

Participants in the HG group were allowed to individually choose which headgear model to wear for the season. Each of the headgear models met the ASTM testing standards in tests conducted by the manufacturer and were approved for use by the National Federation of State High School Associations.

Data collection

Participants completed a self-report questionnaire prior to the season to collect information regarding their sex, date of birth, grade in school, history of SRCs and the Sport Concussion Assessment Tool 3rd edition (SCAT3) Concussion Symptom and Symptom Severity Scale. Licensed athletic trainers (ATs) working with each team were responsible for inseason data collection and reported the type of headgear worn for each practice and competition as well as the onset of all SRC and non-SRC injuries electronically through REDCap. ATs and the coaching staffs recorded the number of soccer practice and competition athletic exposures (AEs) for each participant for the entire season.

ATs determined the onset, mechanism, injury characteristics and diagnosis of all SRC and non-SRC injuries by taking a history of the injured participant and performing the appropriate physical examination no later than 72 hours post injury. ATs recorded the incidence of any suspected SRC using the definition provided by the National Athletic Trainers' Association Position Statement: Management of Sport Concussion[16] of an SRC as a 'trauma induced alteration in mental status that may or may not involve loss of consciousness'. When appropriate, injured participants were referred to their primary care physician for further evaluation and treatment.

Participants recovering from an SRC were allowed to return to full unrestricted participation in accordance with consensus-based guidelines.[16] ATs (who were not blinded to group) monitored all participants who sustained an SRC, from the date of the onset of the injury, and recorded all missed exposures. Injured participants had to be cleared by a licensed medical provider (AT or physician) before being allowed to return to soccer. This clinician either was or may have been aware of the player's helmet use/non-use status.

Participant compliance and dropout

Enrolled participants (n=94 males and n=17 females) who decided to drop out prior to the start of the regular season were not included in the analyses. For participants who remained in the study, protocol compliance was monitored by the school AT. If a participant in the HG group did not wear their headgear for an Soccer Athletic Exposure (SAE), their participation was recorded as taking place without headgear. If a NoHG participant wanted to start wearing headgear on their own, they were allowed to do so and the AT recorded the type of headgear worn for each practice and game during the season. Participants were clearly aware of whether they were in the headgear or no headgear group.

Statistical analysis

The two groups of players (HG and NoHG) were summarised using means (SD), medians (IQR) and frequencies (%) of baseline characteristics, when appropriate. SRC rates were summarised as both the percentage of soccer players injured as well as injuries per 1000 AEs.

Our primary analysis examined whether randomised group was associated with time-to-first SRC using a Cox proportional hazards model controlling for school as a cluster effect, and additionally controlling for sex, age, year cohort, SCAT3 symptom severity group and concussion history as fixed effects. This was an a priori set of confounders selected based on previously published research regarding sports-related concussions (sex, age, SCAT3 symptom severity at baseline and concussion history) and to control for possible secular changes in soccer rules or equipment (cohort year).

Strata (school size) was considered as a covariate to account for in all models, but having school identification as a random effect and school size as a fixed effect caused models to not converge. Strata was therefore not included as a covariate. Models accounting for the correlation among individuals in both years (n=284, 10.3% of the total enrolment) were assessed but did not differ statistically from results treating them as independent; thus for model parsimony only school identification was adjusted for as a random effect. Risk ratios were estimated by mixed-effects Poisson regression models with the number of athlete exposures as an offset, similar covariates as above and school as a random effect. Secondarily, we repeated the primary analysis for other baseline characteristics variables to see whether they were associated with time-to-first SRC. Differences in severity of SRCs between groups were tested using a Wilcoxon rank-sum test. Finally the incidence of acute-onset, contact-related, non-SRC injuries was compared between the HG and NoHG groups.

All analyses were initially run following the intent-to-treat principle with all participants other than those who had dropped out before the start of the season. An exploratory secondary set of analyses for males and females as well as headgear model was conducted 'as treated' to account for participants who were non-compliant at the time of their SRC rather than their group assignment. All analyses were done using R V.3.3 and were conducted at the 0.05 significance level.[17]

Sample size calculation

This sample size was calculated based on the reported national rates of SRC as reported by the High School RIO of 5.66/10 000 AEs. It was expected that an average of 35 participants per school
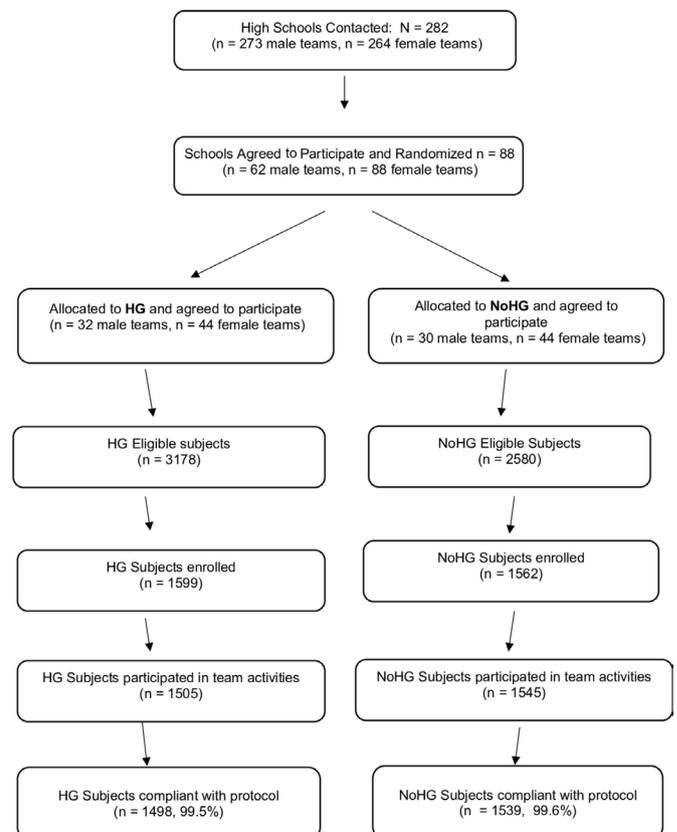
Figure 1 Subject randomisation flow chart. HG, headgear group; NoHG, no headgear group.

Table 1   Participant demographics

Characteristics	NoHG (n=1545)	HG (n=1505)
Age, years*	15.7 (1.2)	15.6 (1.2)
Sex†		
Female	999 (64.7)	1031 (68.5)
Male	546 (35.3)	474 (31.5)
Grade†		
9th	443 (28.7)	487 (32.4)
10th	424 (27.4)	421 (28.0)
11th	398 (25.8)	358 (23.8)
12th	280 (18.1)	238 (15.8)
Previous SRC (within 12 months), yes†	124 (8.0)	147 (9.8)
Previous SRC (ever), yes†	266 (17.2)	295 (19.6)
Total SCAT3 symptom score‡	0.0 (0.0–2.0)	0.0 (0.0–3.0)
Total SCAT3 symptom score groups†		
0	929 (60.1)	879 (58.4)
1–5	428 (27.7)	415 (27.6)
>5	188 (12.2)	211 (14.0)
SCAT3 symptom severity score‡	0.0 (0.0–3.0)	0.0 (0.0–4.0)
SCAT3 symptom severity score groups†		
0	929 (60.1)	879 (58.4)
1–7	445 (28.8)	407 (27.0)
>7	171 (11.1)	219 (14.6)

*Reported as mean (SD).
†Sex, grade, previous SRC, SCAT3 symptom and severity reported as frequency and (%).
‡Total SCAT3 symptom and severity scores reported as median (IQR: 25th–75th).
HG, headgear group; NoHG, no headgear group; SRC, sport-related concussion.

Table 2   Headgear models worn for the study

Manufacturer, model	Females (n)	Males (n)	Total (n)
Full90 Sports, Premier (*Full90, San Diego, California*)	230	155	385
Forcefield, Ultra Forcefield Sweatband (*ForceField Protective Headgear, Great Neck, New York*) http://www.forcefieldheadbands.com	364	136	500
LDR Headgear, Soccer Headband (*Leader Headgear, Fond du Lac, Wisconsin*) www.leaderheadgear.com	2	1	3
Storelli ExoShield (*Brooklyn, New York*) www.storelli.com/exoshield-soccer-headguard.html	363	159	522
Unequal Technologies Halo 10 mm (*Unequal Technologies, Glen Mills, Pennsylvania*) www.unequal.com	72	23	95

When evaluated by their AT, participants reported a median total SCAT3 symptom score of 9.0 (5.0, 14.0) and total SCAT3 severity score of 20 (13.0, 41.0). Injured participants reported a median of 6.0 (4.0, 10.0) days until they were asymptomatic. Twelve (9.2%) participants (n=11 females, n=1 male) were medically disqualified from soccer participation for the rest of the season. The remaining participants spent 5.5 (5.0, 7.0) days in a return-to-play protocol and missed a total of 13.0 (10.0, 19.0) days from soccer.

Compliance summary and missing outcome data
Of the 1545 athletes assigned to the control arm, only 6 (0.39%) used headgear for the majority of AEs or had an SRC while wearing headgear, while 7 (0.47%) of the 1505 athletes assigned to wear headgear did not wear headgear for the majority of AEs or had an SRC while not wearing headgear. This is an athlete compliance rate of 99.6%. At the AE level there were only a total of 711 (0.47%) non-compliant AEs out of the 151 157 AEs for the entire study.

The primary outcome of SRC occurrence for each athlete during the duration of the study had 0 missing data points. Each individual exposure for each athlete had non-missing data for SRC status (yes/no). There was no need to impute missing outcome data.

Primary results
The univariable results did not differ appreciably from multivariable results, and so only results adjusted for all the covariables are presented. There was no difference (HR (95% CI): 0.98 (0.64 to 1.51), p=0.935) in the rate of SRCs between the HG group (n=68, 4.4%) and the NoHG group (n=62, 4.1%) (table 4) after adjusting for age, sex, year, concussion in the last 12 months and symptom severity. Seven participants in the HG group sustained SRCs while not wearing headgear.

A second set of analyses (as treated) did not reveal a difference (HR: 0.78 (0.48 to 1.25) p=0.303) in the rate of SRCs between the participants who did not wear headgear (n=75, 4.9%) and the players who wore headgear (n=55, 3.7%). Females in the HG group had an SRC rate of 4.2% (n=43), and females in the NoHG group had a rate of 6.5% (n=65). These rates represent a non-significant HR of 0.70 (0.43–1.15) (p=0.154).

Additional as-treated analyses were carried out for the whole cohort and separately for both males and females and showed a great deal of variability in the rate of SRCs sustained while wearing different headgear models. Overall, the SRC incidence ranged from 2.5% (HR: 0.54 (0.20–1.43), p=0.213) for players wearing the *Storelli ExoShield* to 5.4% (HR: 1.09 (0.62–1.91), p=0.765) for players wearing the *Ultra Forcefield Sweatband*.

would participate in 60 AEs per athlete per season. We assumed a 1% within-cluster (school) correlation. Based on these assumptions, we would expect an approximate rate of 3.4% SRC in the control group. We hypothesised a 50% reduction in the rate of SRC in the HG group (1.7%). To achieve 80% power to detect this difference in SRC rates with a test of proportions controlling for a clustered random effect and a two-sided 5% significance level, we would need to enrol a minimum of N=2800 participants. We planned to enrol four additional schools in each group to ensure sufficient sample size to detect the hypothesised difference.

RESULTS
Participant allocation
Participant allocation is shown in figure 1. A total of 2766 unique participants (66% female, age 16.0±1.1, grades 9–12) participated in a total of 3050 player seasons and 151 157 soccer exposures (34% competitions) during the study. Baseline participant characteristics are found in table 1. The HG group had a greater percentage of females and higher percentage with greater SCAT3 severity total scores. Each of these variables, in addition to age, cohort year and SRC within the last year, was controlled for in the analyses of SRC rates between groups. The headgear models worn by participants in the HG group are shown in table 2.

SRC characteristics
A total of 130 SRCs (females: n=108, 5.3%, 1.10/1000 exposures; males: n=22, 2.2%, 0.42/1000 exposures) were sustained by the participants during the study. None of the participants sustained more than one SRC. The onset characteristics of the SRCs are shown in table 3.

Table 3 Sport-related concussion onset characteristics

Variables	n (%)
Session	
Competition	103 (79.2)
Practice	27 (20.8)
Position	
Mid-field	49 (37.7)
Defence	37 (28.5)
Forward	25 (19.2)
Goalie	19 (14.6)
Mechanism	
Contact with player (other than slide tackle)	72 (55.4)
Contact with ball	46 (35.4)
Stepped/fell on or kicked	6 (4.6)
Slide tackle	4 (3.3)
Other	2 (1.6)
Activity	
Defending	34 (26.2)
Chasing loose ball	17 (13.1)
Goal tending	17 (13.1)
Heading ball with contact	13 (10.0)
Blocking shot or pass	12 (9.2)
General play	10 (7.7)
Heading ball without contact	8 (6.2)
Ball handling—dribbling	7 (5.4)
Other	15 (12.1)
Head contact with	
Other player	53 (40.7)
Head	18 (13.8)
Upper extremity	22 (16.9)
Lower extremity	13 (10.0)
Ball	46 (35.4)
Surface	27 (20.8)
Other	4 (3.0)
Head location of blow	
Side	41 (31.5)
Back	29 (22.3)
Front	29 (22.3)
Face	23 (17.7)
Top	8 (6.2)
Player see the blow coming?	
No	73 (56.2)
Yes	46 (35.4)
Unknown	11 (8.5)
Foul called on play (competition only)	
No	80 (77.7)
Yes	11 (10.7)
Unknown	5 (4.9)
Not available	7 (6.8)

As-treated analyses for each sex and headgear model are found in online supplementary table 1.

Secondary results

SRC severity

No difference (p=0.831) was observed in the number of days participants reported concussion symptoms between the two groups (median (IQR): HG: 6.5 (4.0–10.8), NoHG: 6.0 (4.0–10.0)) and no difference (p=0.075) in the number of days

participants spent in a return-to-play protocol between the two groups (HG: 6.0 (5.0–7.0), NoHG: 6.5 (4.0–10.8)). The total days out from soccer due to SRC did not significantly differ (p=0.583) between the HG group (13.5 (11.0, 18.8)) and the NoHG group (13.0 (9.0, 18.8)).

Non-SRC acute-onset injuries

A total of 253 (8.2%) participants sustained a total of 276 non-SRC acute-onset injuries causing them to miss a median of 6.0 (2.0, 13.0) days from soccer. The majority of acute non-SRC injuries were to the ankle and knee, and were predominantly ligament sprains, contusions or muscle strains (table 5). No difference was detected (RR: 0.91 (0.64–1.29), p=0.584) in the risk of non-SRC acute-onset injuries between the HG group (8.0%) and the NoHG group (8.6%). No difference was observed in the number of days out from soccer as the result of their non-SRC acute-onset injuries between the HG group (6.0 (2.0, 14.0)) and the NoHG group (5.0 (2.0, 11.5)) (p=0.498).

DISCUSSION

This is the first large-scale study to examine whether adolescent soccer players wearing protective headgear sustained fewer SRCs than players without headgear. Notably, our results show that the incidence of SRCs was similar in both the HG and NoHG groups. These results are also noteworthy since licensed medical professionals recorded the onset, duration and resolution of each of the SRCs sustained by participants in this study. These results differ from a retrospective study by Delaney et al[18], who reported that a single brand of soccer headgear was effective in reducing the self-reported incidence of concussions in a convenience sample of players aged 5–17. This may be due in part to the prospective design of our study, the use of multiple headgear models, the large sample size and the fact that we had ATs reporting the actual occurrence of the injuries. Our study is the first to report that there was no difference in the severity of SRCs for players wearing or not wearing headgear.

Post-hoc, we examined data separately for males and females. It is important to note that SRCs occurred at twice the rate among females than males. Further among males, there was no difference in SRCs between the two groups. Among females there was no difference in SRCs between groups, but some may infer that there was trend efficacy in females. This 'trend' should be interpreted with caution since we were underpowered to show the same trends as the female participants in this subgroup analysis. We do feel, however, that the reported data could be used in future research endeavours to calculate appropriate sample size estimates for future randomised controlled trials in female soccer players.

Most previous studies on soccer headgear efficacy were carried out in laboratory settings. While several studies reported[9 10] that various protective headbands attenuated the peak force, to a limited degree, of a soccer ball, other studies by Withnall et al[11 12] reported that the impact of a soccer ball will not be decreased to a sufficient degree to prevent an SRC. These studies each used the impact of a soccer ball to the head as the possible injury-causing mechanism, which may not reflect what actually occurs on the soccer field. We found that only 35% of the SRCs were sustained by head contact with a soccer ball, while head-to-player contact resulted in the most SRCs.

An ancillary finding of our study is that players wearing certain soccer headgear models experienced various rates of

Table 4 Cluster adjusted risk ratios and Cox proportional hazard ratios comparing the incidence of SRC between the HG and NoHG groups

| | n | SRC | % SRC | Multivariate risk ratio | | Multivariate HR | |
				95% CI	P value	95% CI	P value
Intent to treat							
Overall	3050	130	4.3				
All no headgear	1545	68	4.4	Reference	–	Reference	–
All headgear	1505	62	4.1	0.98 (0.62 to 1.56)	0.946	0.98 (0.64 to 1.51)	0.935
Males—no headgear	546	8	1.5	Reference	–	Reference	–
Males—headgear	474	14	3.0	1.83 (0.60 to 5.53)	0.286	2.00 (0.63 to 6.43)	0.242
Females—no headgear	999	60	6.0	Reference	–	Reference	–
Females—headgear	1031	48	4.7	0.90 (0.55 to 1.48)	0.683	0.86 (0.54 to 1.36)	0.520
As treated							
All no headgear	1546	75	4.9	Reference	–	Reference	–
All headgear	1504	55	3.7	0.63 (0.37 to 1.08)	0.091	0.78 (0.48 to 1.25)	0.303
Males—no headgear	548	10	1.8	Reference	–	Reference	–
Males—headgear	472	12	2.5	0.93 (0.27 to 3.20)	0.909	1.33 (0.43 to 4.11)	0.623
Females—no headgear	998	65	6.5	Reference	–	Reference	–
Females—headgear	1032	43	4.2	0.64 (0.38–1.08)	0. 094	0.70 (0.43 to 1.15)	0.154

Multivariable analysis consisted of Poisson regression and Cox proportional hazards survival analysis controlling for age, sex, year, concussion in the last year and symptom severity group as covariates and school cluster effect.
As treated designation is based on majority headgear use (yes/no) for those without an SRC, and whether they were wearing headgear when SRC occurred for those with SRC.
HG, headgear group; NoHG, no headgear group; SRC, sport-related concussion.

SRCs. Each of the models used for this study met the same ASTM testing standard in tests conducted and self-reported by the individual manufacturers. Independent biomechanics lab testing has sought to duplicate injury-causing mechanisms such as player-to-player contact rather than just head-to-ball contact.[19] The authors concluded that various headgear models had different force attenuation capabilities and characteristics and that we anticipate would offer differing levels of protection from an SRC.

Our results show that players wearing *Forcefield*, which had a lower lab-based impact attenuation, had an SRC incidence of 5.4%, whereas players using Storelli had an SRC incidence of 2.5%. Once again, these are not 'different' in the context of our study since our study was not powered to examine differences between headgear types.

The risk compensation theory suggests that players wearing headgear may play more aggressively due to the feeling that the added head protection limits risk of injury. Our data do not support this theory as both the incidence and severity of acute contact-related injuries—those injuries to other body parts, not the head—did not differ between the participants in both groups.

Limitations

This study has several potential limitations. First is the risk for selection bias with regard to both the teams that agreed to allow data collection as well as the individual players who enrolled in the study, where players with a history of SRCs would be more likely to enrol and/or remain in the study as part of the HG group. However, the proportion of players with a history of SRCs was similar for both the HG and NoHG groups. Second, participants were not instrumented with accelerometers and we had no video of the concussive injuries. Therefore, we cannot comment on whether players' headgear reduced impact forces. Finally, it would have been beneficial to have used a single headgear model in the HG group. However, the parameters of the study required that each approved headgear model was made available for use by study participants.

Table 5 Non-SRC acute-onset injury characteristics

Variables	n (%)
Body area	
Ankle	95 (34.4)
Knee	49 (17.8)
Foot	26 (9.4)
Lower leg	26 (9.4)
Upper leg	23 (8.3)
Head (non-SRC)	14 (5.1)
Other	66 (23.9)
Injury type	
Ligament sprain	129 (46.7)
Contusion	80 (29.0)
Muscle tendon strain	41 (14.9)
Fracture (acute)	18 (6.9)
Dislocation	4 (1.4)
Other	4 (1.4)

SRC, sport-related concussion.

What are the findings?

► Protective headgear did not reduce the rates of concussion in high school soccer players.

How might it impact on clinical practice in the future?

► This study extends the conclusion from the 2017 Concussion in Sport Group consensus statement that found there is limited evidence supporting the use of protective equipment to reduce the risk of sport-related concussion in many sports including soccer.

Future directions

This study highlights the need for additional headgear efficacy research, with particular focus on female players. Future protocols should include validated accelerometer instrumentation in conjunction with headgear use to better understand the role that headgear plays with regard to possible reduction in the impact forces that may cause SRCs in soccer players. Future researchers should also consider using the headgear models that showed higher levels of impact resistance in independent lab tests as well as a lower rate of SRC reported in this study.

CONCLUSION

Soccer headgear did not reduce the incidence of SRCs in the overall sample of high school soccer players.

Patient involvement

All participants (and their parents if they were under 18 years old) were required to sign a consent/assent document to participate in this trial. No identifiable patient or personal medical information is included in this manuscript.

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