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Complete List of Authors:	Makovec Knight, Jennifer; Monash University, Sports Concussion Research Group Nguyen, Jack; Monash University, Sports Concussion Research Group Mitra, Biswadev; Monash University School of Public Health and Preventive Medicine, Department of Epidemiology and Preventive Medicine Willmott, Catherine; Monash University,

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Soft-shell Headgear, Concussion and Injury Prevention in Youth Team Collision Sports: A Systematic Review

Jennifer Makovec Knight[a], Jack V.K Nguyen[a], Biswadev Mitra[b, c, d], Catherine Willmott[a, e]

a. Turner Institute for Brain and Mental Health, School of Psychological Sciences, Monash University, Melbourne, Australia.

b. Emergency & Trauma Centre, The Alfred Hospital, Melbourne, Australia.

c. Department of Epidemiology & Preventive Medicine, Monash University, Melbourne, Australia.

d. National Trauma Research Institute, The Alfred Hospital, Melbourne, Australia.

e. Monash-Epworth Rehabilitation Research Centre, Epworth Hospital, Melbourne, Australia.

Corresponding Author: Professor Biswadev Mitra

Corresponding Authors Email: biswadev.mitra@monash.edu

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J. Makovec Knight: 0000-0001-9879-0538

J.V.K. Nguyen: 0000-0002-6698-1935

B. Mitra: 0000-0002-0508-2450

C. Willmott: 0000-0001-8517-9035

Abstract

Objectives: The aim of this systematic review was to assess the association between soft-shell headgear (HG) use and sports related concussion (SRC). Secondary objectives were to assess the association between HG and superficial head injury and investigate potential increases in injury risk among HG users. **Design:** Five databases were searched using a systematic review strategy with inclusion criteria: youth <18 years, English-language, *in-vivo* studies published after 1980 that evaluated the intervention of HG. **Primary and Secondary Outcome Measures:** We extracted data on incidence rates of SRC, superficial head injury or other injuries. **Results:** There were 4355 unique manuscripts that met search criteria of which eight studies were eligible for icnlusion. The majority (n=5) reported no association between HG use and SRC in soccer and rugby. Three of four reporting superficial head injury found no association with HG use. Of the five studies reporting on injury rates to all body regions, four were conducted in rugby. Two of these found increased injury risk for rugby HG users. The one soccer study did not report this association. **Conclusions:** HG use was not associated with reduced rates of SRC or superficial head injury in youth soccer and rugby. The possibility of increased injury risk to all body regions for rugby HG users was raised. The need for research specific to youth and female athletes was highlighted. **Registration:** A review protocol was registered with PROSPERO, ID- CRD42018115310

Strengths and Limitations of the Study

- This systematic review provides the first comprehensive examination of the evidence for the use of soft-shell padded headgear as sports related concussion prevention in youth athletes.
- A literature search revealed only five studies that specifically pertained to youth, rendering the findings less rigorous due to the potential for the adult participants to have diluted the differences in outcomes.
- This review provides an up to date evidence base for community decision making on club headgear mandates and a picture of where data is currently lacking on the topic.

Introduction

The Centre for Disease Control and prevention (CDC) estimates that traumatic brain injury (TBI) affects 2.87 million people in the United States of America (USA) annually.[1] Collision sports are recognized as a significant contributor, with exponential increases in hospital admissions for children and adolescents sustaining TBI since the early 2000s.[2] The majority of these are classified as sports related concussion (SRC), with one study indicating that SRC emergency department visits have increased by more than 85% in 8- to 13-year-olds and by more than 200% in 14- to 19-year-olds. [3] Increased public awareness around SRC and higher numbers of youth participation in collision sport are likely contributing to these increases.[4]

In most cases of youth SRC, symptoms resolve within four weeks,[5] though some players have protracted recovery with cognitive, behavioural and emotional difficulties that interfere with school attendance, academic endeavors, sporting performance, social life and family relationships for months and sometimes years.[6] Helmets, rule changes and game development have been variably implemented as brain injury prevention initiatives in collision sports such as football, rugby and soccer.[7] Helmet sub-types include those with a hard-outer shell used in the National Football League in the USA, and soft-shell padded headgear (HG), that either fully covers the head (e.g. rugby scrum cap) or resembles a headband (e.g. soccer headgear) with an opening at the top. HG is most commonly used in rugby, with inconsistent uptake in Australian football and soccer,[8] albeit with varying policy guidelines across community clubs. Within the sporting community it is a widely held belief that such HG protects against injury[8] and SRC,[9] leading some youth Australian football, soccer and rugby clubs to mandate its use.[9 10]

Previous reviews have evaluated HG effectiveness across a diverse range of HG models and sports (e.g. skiing, American football, hockey etc). Findings indicate evidence for hard-shell helmets in the prevention of severe TBI,[11] though findings for SRC prevention with HG are equivocal at best.[7] As such, debate continues with regard to HG for SRC prevention,[7 11] and whether there is any evidence to support the notion of potential risk (i.e. risk compensation behaviour). The risk compensation hypothesis posits that players may be at greater risk of sustaining injuries due to increased tackling using the head and increases in aggressive play because they assume greater safety when wearing HG.[12 13] To date, no reviews have focused exclusively on youth populations, important because youth may be more vulnerable to risk compensation,[14] because the cognitive processes associated with risk taking in the developing brain are immature in comparison to that in adults.[15]

The primary objective of this study was to assess the *in-vivo* evidence for the intervention of HG for SRC in youth collision sports. Secondary objectives were to assess HG for prevention for superficial head injury (injuries superficial to the skull) and investigate potential indicators of risk compensation behavior by assessing the association between HG and rates of injury to all body regions.

Methods

The review was conducted in accordance the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[16] See supplementary file for search strategy.

Data Sources

The search was conducted in April 2020 and was restricted to studies published after 1980. Studies that evaluated the use of HG in relation to SRC and other injuries in youth team sports were identified using the following databases: Ovid MEDLINE, Cochrane Library, Scopus, PsycINFO, and SPORTDiscus.

Study Selection

Inclusion criteria were English language studies with cohorts of youth team athletes reporting on the use of HG and the primary (SRC) and secondary outcomes (head injury superficial to the skull and/or injuries to other body regions). Studies were excluded if they were laboratory based, conducted in adult only cohorts, conducted in individual and/or non-contact sports or only included participants wearing hard-shell helmets. Authors Archbold, et al. [17] were contacted for additional unpublished data on the rates of SRC sustained by HG users and non-users.

Study Selection

Two review authors (JMK and JN) independently screened manuscripts on title and abstract, selecting agreed citations in full text using the predetermined eligibility criteria. The reviewers then independently screened the selected manuscripts in full text. Disagreements were adjudicated by a senior member of the team.

Data Extraction

Data on study design, sporting code, sample size, cohort characteristics, methods, outcomes and covariates predicted to alter injury risk, and main findings were extracted from each study. Description of study participants, injury definitions and the denominators used to compute injury incidence were extracted in as much detail as each study provided. Incidence rates (IR), incidence rate ratios (IRR) and risk ratios (RR) were extracted (if reported) from each study. Due to the expected heterogeneity in reported statistical methods and study design, a meta-analysis was not planned.

Quality and Level of Evidence Assessment

Two reviewers (JMK and JN) independently assessed the quality of non-randomised studies using the nine-item Newcastle Ottawa Scale (NOS) for Cohort Studies.[18] The NOS assesses three domains and assigns up to a maximum of nine points for: 1) selection of cohorts (four points); 2) comparability of cohorts (two points); and 3) outcomes (three points). On this scale, scores between 7-9 were considered good quality, and scores 1-6 were considered low quality. The quality of randomised control trials (RCTs) were assessed using the 11-item Physiotherapy Evidence Database (PEDro) scale.[19] On this scale, scores between 9–11 were considered excellent quality; 6–8, good quality; 4–5, fair quality; and <4, poor quality.[20] Reviewers also assessed levels of evidence using the Oxford Centre for Evidence-Based Medicine (OCEBM) guidelines.[21] The OCEBM levels range from level one, representing systematic reviews, level two representing randomized trials, level three denoting non-randomized controlled cohort/follow-up, level four denoting case series, to level five, denoting mechanistic reasoning. All included studies were assigned a number indicating the level of evidence and quality.

Results

Of the 4,355 citations that remained after duplicates were removed, 73 were screened in full text for eligibility and of these, 65 were excluded (Figure 1). The most common reasons for exclusion were if studies were laboratory-based or utilised hard-shell helmets. Studies were also excluded based on outcome measures and alternate populations. After screening, eight studies were included for qualitative analysis and none were excluded based on quality analysis.

Figure 1. The figure depicts a PRISMA flowchart showing systematic exclusion of articles at each stage of the review.

Study characteristics

All studies were published between 2001 and 2019 and study designs included prospective cohort injury surveillance (n=4), randomised control trial (RCT) (n=2), pilot RCT (n=1), and cross sectional (n=1). There were six rugby and two soccer cohorts, with a total of 12,064 participants. Three studies included female athletes, who represented 2,038 (17%) of the total included participants. Of the eight included studies, five were exclusive to youth, and others comprised mixed adult/youth cohorts who ranged in age from 13 to 45 years. Studies examined the effect of HG upon rates of SRC (n=6), injuries to other body regions (n=5), head injury superficial to the skull (n=4), and frequency of impacts sustained to the head (n=1). Three studies examined a combination of these outcomes, as they associated the use of soft-shell HG with SRC, superficial head injury and injuries to other body regions. Injury data was typically collected for games and training sessions, with the exception of three studies that included injuries sustained in games only.[22-24] Study characteristics are summarised in Table 1.

Table 1. Methodological Details of Studies**.**

Headgear Use and SRC

Outcomes for SRC, superficial head injury, head impacts, and injuries to other body regions stratified by HG use vs. no-HG use (No-HG) are listed in Table 2. There were seven studies included that analyzed SRC. Of these, five (one in soccer and four in rugby) found no differences in rates of SRC with or without HG.[17 24-27] Reduced risk of SRC among HG users was reported in two studies: lower rates of SRC in rugby HG users (IR = 7.39 95%CI: 5.55-9.65) compared with non-users (IR 12.62; 95%CI: 8.38-18.27)[23] and lower adjusted risk of SRC for HG users in soccer (RR: 0.38; p<0.001).[28]

Headgear use and superficial head injury

There were four included studies that investigated the association of HG use and superficial head injury. Two assessed rugby cohorts and found no difference in rates of sustaining superficial head injury between HG users and non-users,[17 24] while another rugby study concluded that HG tended to be effective in reducing superficial head injury, but the association (adjusted RR 0.59; 95%CI: 0.19-1.85) was not statistically significant.[25] In soccer HG users, 52 superficial head injuries were reported, compared to 216 reported by the non-users (adjusted RR = 1.86, $p<0.05$).[28] Among these four studies reporting superficial head injuries as an outcome measure, only one reported frequency and type of head impacts using game video analysis. That study found no statistically significant association with HG use (HG =15 impacts, No-HG =7 impacts).[24]

Headgear and injuries to all body regions

There were five included studies that reported on injuries to all body regions. Four of these conducted the analyses with SRC and all body injuries combined as a composite outcome variable.[17 22 25 26] Reporting this composite outcome were two studies conducted in rugby with no differences observed in injury rates among HG users versus non-users.[17 25] In contrast, Chalmers, et al.[22] and McIntosh, et al.[26] reported increases in injury rates to all body regions in rugby players wearing standard HG, adjusted IRR: 1.23 (95% CI 1.00-1.50) and adjusted IRR: 1.16 (95% CI: 1.04-1.29), respectively. The McIntosh, et al.[26] study also investigated injury rates to all body regions for players who wore "modified HG". The use of this HG was not associated with increased injury risk, adjusted IRR: 1.05 (95% CI: 0.78-1.41), although the group accounted for only 11% of exposures to SRC due to poor compliance. The remaining RCT study by McGuine et al.[27] reported the outcome of injury to other body regions (excluding SRC) and found no difference in rates for soccer HG users and non-users with adjusted RR = 0.91 (95%CI 0.64-1.29).

Table 2. Outcome data for concussion, head injury and injuries to other body regions stratified by headgear vs no-headgear.

Quality and Levels of Evidence Results

Interrater agreement for quality analysis between the two reviewers (JMK and JN) assessing the eight included manuscripts was 94.44%. The results for quality assessment and levels of evidence for cohort studies can be seen in Table 3.

Selection bias was considered low in all studies. Only one study was not awarded full points in this domain, as Delaney.et al.[28] did not ascertain the exact number of exposures to SRC reliably due to using self-report, as opposed to direct observation or secure record. For comparability of cohorts, all studies controlled for age, sex and injury history, with only one study not controlling for additional factors. Delaney, et al.[28] did not account for factors such as player position and player experience that may, in addition to HG use, modify injury rates.[29]

For the final domain, three studies did not assess outcomes using an independent observer. The findings of Delaney, et al.[28] were deemed to have the highest risk of bias due to a cross-sectional survey design with the survey accessible online to players (aged 12-17 years) who could re-access it multiple times to update SRC symptoms. In addition, the injury definition used did not relate to time lost from participation in sport and/or medical-attention received for injury, the most common definition[30] used in all other studies. Two other studies were considered to be subject to the inherent biases associated with self-report data collection, due to a prospective design where researchers completed weekly, post-game follow up interviews with players over the phone.[22 25] These self-reported methods contrasted those used where direct SRC and injury observation was completed by trained data collectors, athletic trainers, and medical professionals.

Table 3. Results for NOS scale risk of bias assessment and Level of Evidence (OCEBM).

Both RCTs[26 27] were assessed as good quality, the *OCEBM* levels of evidence were scored as two (table 4). On the PEDro scale, they both recieved scores of eight with only three criteria not met (5-7). These criteria related to the blinding of participants, therapists and assessors. It was deemed unfeasible to expect blinding in these studies due to the fact that the intervention (HG use) was directly observable.

Table 4. Randomized Study quality (PEDro Scale) & Level of Evidence (OCEBM)

Discussion

The findings from this review do not support the use of the current, commercially available HG to prevent SRC in youth soccer or rugby. The majority of *in-vivo* evidence is consistent with laboratory research showing that HG does not mitigate the forces associated with head impacts.[31-34] Though some protection may be offered against superficial head injury, as purported by Delaney et al.[28] and prior studies where HG has been shown to protect against soft tissue injuries sustained to areas of the head covered by padding.[35] Importantly, there may also be potential for increased risk of sustaining all types of injuries. Two studies reported 23% [22] and 16% [26] increases in injury risk for rugby players who wore commercially available HG, raising the possibility that risk compensation is a phenomena possible in rugby, but not soccer, as increased injuries were not observed among soccer HG users in a RCT. Soccer is unique in that SRC and other types of injury are sustained when players purposefully use their head to progress the ball,[8] when players knock heads[36] or when falling over during a tackle.[37] In contrast, the majority of SRC and other injuries in rugby are sustained during player to player collisions during full body tackling.[37 38] These fundamental differences may render rugby HG users more vulnerable to risk compensation behaviours because injury mechanisms overtly differ and their style of play allows for the head to be used as a tackle weapon.

The studies included in the review span almost two decades raising the possibility that changes in HG technology might influence outcomes. No chronological trends were apparent in the analysis and industry experts are of the opinion that the commercially available HG has not advanced considerably since the 1990s.[34] Confounding a summative interpretation was the heterogeneity found in definitions of injury. One study referred to superficial head injury as the ear and scalp only,[25] while others included the face[17 28] or excluded the face from the definition.[26] Some studies defined an injury as occurring only if a player was observed to miss time from play,[17 23 26] or received attention from a medic or athletic trainer,[23 24 27] while others used retrospective player self-report.[22 25 28] Retrospective self-reported methods are not consistent with standards which suggest prospective recording by health professionals is superior to retrospective interview.[30] The differences in methodology were prominent in the heterogeneity of reported outcomes with far higher proportion of SRC recorded when self-reported compared to studies that used direct observation.[27 28]

A key finding of this review is that standardized definitions are vital to ensure the translation of findings to clinicians and the community. It is recommended that injury definitions are guided by the most recently published consensus statements, and that definitions rely on a number of factors to describe severity. It is recommended that a SRC be defined as a “traumatic brain injury induced by biomechanical forces” with physical, behavioural, cognitive and somatic clinical features documented with each SRC event.[5] A superficial head injury should be defined as any injury to the head that is superficial to the skull (including contusions, abrasions and lacerations).[28] To capture the full spectrum of SRC and other injuries and facilitate comparison with past results, it is recommended that researchers record all injuries using a combination of “broad” definitions (e.g. injury recorded if it causes a player pain or discomfort) and “narrow definitions” (e.g., injury recorded if player misses a game).[39] As an example, an injury anywhere on the body should be initially documented by body region (e.g., lower leg, arm, head) and pathology (bruise, open wound, fracture) if it causes a player pain. Additional information on whether that injury resulted in time lost from play, missed games, required medical attention or resulted in hospital transfer should be collected as surrogates for severity.[40] Data collection conducted by a medical professional diagnosing and classifying SRC and other injuries would be optimal, however, we acknowledge this is not possible in most youth community sports. As an alternative, live observation by trained data collectors that are athletic trainers or work in health-related fields has shown promise.[30] Video analysis may also have a role in augmenting findings from studies in the field by allowing researchers to examine the number of head impacts sustained by each player and code the behaviours of HG wearers.

Under-representation of female athletes in the included studies was frequently observed. Compared with male athletes, females have been reported to have higher rates of SRC[41-45] report more SRC symptoms,[46 47] demonstrate worse cognitive impairment following SRC,[45 46] and may take longer to recover.[47 48] In addition, it has been suggested that females are at higher risk of the effects of sub-concussive impacts due to differences in neck strength and body composition.[49] Given the exponential increase in female participation in these sports,[50-52] further evaluation of injury risk and prevention in this cohort is crucial to future research.

Ultimately, injury surveillance systems specific to youth have not yet been developed, as they largely exist at the elite level and require significant financial and operational resources to conduct.[30] Nonetheless, identifying constraints is an important step for researchers conducting future studies to address this important issue. Existing constraints are the potential ethical dilemmas regarding HG being implemented in an RCT because of the lack of evidence that supports its protective benefit versus potential harm. Other barriers include poor compliance. For instance, only 11% of exposure hours were attributable to those in the modified HG arm of the McIntosh, et al.[26] RCT due to very low compliance. A HG RCT conducted in Australian football that was screened for inclusion also revealed that SRC and injury outcomes could not be assessed due to very low compliance in HG use.[53] Low compliance was less problematic in the included soccer RCT with 99.5% of those allocated to the HG arm consistently wearing it,[27] raising the question of what encourages compliance in these types studies. As seen in McGuine's (2019) study, players chose their preferred HG model from a range of provided options that met specific testing standards. This potentially contributed to higher compliance because the players had greater involvement and autonomy. It may also be that soccer HG is less intrusive because it covers less of the head and may not induce as much discomfort via increased heat and perspiration.

A limitation of this review was that only five studies were identified that specifically pertained to youth cohorts, with all other studies comprising mixed youth and adult cohorts. This rendered the findings less rigorous due to the potential for the adult participants to have diluted the differences in outcomes due to their higher level of experience, training and increased maturity in risk-taking decision-making.[15] This review however, provides a picture of where data is currently lacking on the topic, and should provide motivation for future research in the area.

Conclusion

Extending upon the most recent CISG consensus,[5] this review indicates a lack of scientifically rigorous research that clearly outlines the benefit or harm of wearing HG in youth collision sports. Future research should include a representative population and focus on including female participants across a range of sporting codes that use HG. Standardisation of the definitions and measurement of outcome variables are indicated for comparability across studies.

Contributors: CW was the chief investigator. CW, BM, and JMK were involved in the planning, design and registration of the study protocol. JMK conducted the systematic search with assistance from a librarian with expertise in the area. JMK and JVKN screened studies

for eligibility. JMK extracted data from studies and wrote the first draft of the manuscript. All authors made revisions and approved the final manuscript. Patients and/or the pubic were not involved in the conduct of this systematic review.

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53. Braham R, Finch CF. Do community football players wear allocated protective equipment? Descriptive results from a randomised controlled trial. *Journal of science and medicine in sport* 2004;7(2):216-20.

Table 1. Methodological Details of Studies

Study	Study Design	Year	Sport/ Country	Level, Sex & Age: M(SD)	Outcomes	Operational Definition of Outcomes	Data Collection Method	Covariates in Analysis
McIntosh and McCrory [44]	Pilot RCT	2001	Rugby/ Australia	School competition, males U15's.	Concussion and head impacts.	Concussion verified by a medical practitioner and classified as a traumatic event that resulted in the player missing a game or training time.	Club personnel completed standardized reporting forms and researchers reviewed video footage.	Headgear Use
Marshall, et al.[36]	Prospective cohort injury surveillance	2005	Rugby/ New Zealand	Community and school competition, 240 males and 87 females U17 to U22 and 23 and over.	Concussion, head injury and injury for all body regions combined.	Any event that resulted in an injury requiring medical attention or causing a player to miss at least one game or practice.	Researchers completed weekly follow up interviews with players over the phone.	Protective equipment, level of competition, playing position, playing out of usual position, injury history, frequency of in-season injury, body somatype, fitness level, health status, anger, anxiety, negative affect, task orientation in

								sport, and perceived importance of injury to team performance.
Delaney, et al.[14]	Cross sectional study	2007	Soccer/ Canada	Community competition, U13 to U18, 180 males and 98 females.	Concussion and head injury.	Concussion symptoms listed were consistent with the Concussion in Sports Group (CISG) statement[39]. Head injury defined as abrasions lacerations or contusions.	Players completed retrospective online survey	Headgear and mouthguard use, sex, age, concussion history, level of experience, and considering oneself as a "header".
McIntosh, et al.[42]	Cluster randomized control trial	2009	Rugby/ Australia	Community and school competition, U13, U15, U18 and U20 males	Concussion, head injury and injury for all body regions combined.	Concussion in accordance with CISG[38]. Injury required on field treatment, a player being removed from the game, or a player missing the next game.	Trained data collectors recorded data on standardized reporting form	Standard headgear, modified headgear, no headgear & competition level.
Hollis, et	Prospective	2009	Rugby/	Community	Concussion	Any event where a	Trained data	Headgear and mouthguard use, age,

al.[25]	cohort injury surveillance		Australia	competition males 19-45 yrs. and school competition males aged 15-18 yrs. 22.7(5.5)		player left the field due to dizziness, confusion, loss of coordination, and/or loss of consciousness; and stoppage of play was required, or they received medical attention because of a blow to the head.	collectors, coaches, club doctors and physical therapists recorded data on standardized reporting forms.	height, weight, impulsivity, time spent training, experience, player position, concussion history, competition level.
Chalmers, et al.[10]	Prospective cohort injury surveillance	2011	Rugby/ New Zealand	Community competition, males aged 13 & above	Injury for all body regions combined.	Any event that resulted in an injury requiring medical attention or causing a player to miss at least one scheduled game or team practice.	Researchers completed weekly follow up interviews with players over the phone.	Protective equipment. age, ethnicity, experience, lifestyle factors, injury history, player position, training, time of season, foul play, warm ups, weather conditions, ground conditions.
Archbold,	Prospective	2017	Rugby/	School	Concussion,	Any injury that prevents	Trained data	Headgear, mouthguard and

et al.[1]	cohort injury surveillance		Ireland	competition, Males, 16.8 (0.8)	head injury and injuries for all body regions combined.	a player from taking full part in all training and match play or activities planned for that day for a period of greater than 24 hrs from midnight at the end of the day the injury was sustained.	collectors recorded data using online database.	shoulder pad use, age, weight, height, playing position, injury history, strength profile and experience.
McGuine, et al.[40]	Cluster randomized control trial	2019	Soccer/ USA	School competition, 1853 females and 913 males, 15.6(1.2)	Concussion and injuries for all body regions combined, excluding concussion.	Concussion recorded in accordance with NATA position statement.[7] Other injury determined by onset, mechanism, characteristics and physical examination.	Athletic trainers recorded in an online database.	Headgear use, school, sex, age, year cohort, SCAT3 baseline symptom severity and concussion history.

Table 2.

Study	N	No-HG exposures	HG exposures	No-HG concussion	HG concussion	No-HG superficial head injury	HG superficial head injury	No-HG all body regions combined	HG all body regions combined	Findings
McIntosh and McCrory [44]	294	357 player exposures	1179 player exposures	n=2 sustained SRC	n=7 sustained SRC	n=7 sustained head impacts	n=15 sustained head impacts	*Data not recorded*	*Data not recorded*	No significant difference in SRC rates with HG use and no difference in the locations or frequency of head impacts with HG use.
Marshall, et al. [36]	304	4,656 player weeks	752 player weeks	*Not reported*	RR = 1.13 95% CI [0.40-3.16]	*Not reported*	RR = 0.59, 95% CI [0.19- 1.85]	*Not reported*	RR = 0.96, 95% CI [0.75-1.23]	No significant difference in SRC, head injury to the ear and scalp or injury rates for all body regions combined with HG use.

Delaney, et al. [14]	278	n=216* players	n=52 players	n=114 sustained SRC RR= 2.65	n=14 sustained SRC RR = 0.38	n=216 sustained head injury RR= 1.86	n=52 sustained head injury RR= 0.54	*Data not recorded*	*Data not recorded*	HG use significantly reduced rates of SRC and head injury.
Hollis, et al. [25]	3,207	n=2,173 players	n=1,034 players	IR = 12.62 95% CI [8.38-18.27]	IR = 7.39 95% CI [5.55-9.65]	*Data not recorded*	*Data not recorded*	*Data not recorded*	*Data not recorded*	HG use significantly reduced rates of SRC.
McIntosh, et al. [42]	3,686	1,493 exposure hrs (44%)	Standard HG 1,128 exposure hrs (46%)	90 SRCs sustained	85 SRCs sustained with standard HG IRR=1.13 95% CI [0.86-1.49]	106 head injuries sustained	100 head injuries sustained with standard HG IRR= 1.14 95% CI [0.84-1.54]	799 injuries sustained	828 injuries sustained with standard HG IRR= 1.16 95% CI [1.04-1.29]	No significant difference in SRC or head injury rates with standard HG use. Standard HG use associated with 16% increase in injury for all body regions combined.

			Modified HG 1,474 exposure hrs (11%)	See above row for control group	19 SRCs sustained with Modified HG IRR= 1.06 95% CI [0.70-1.60]	See above row for control group	22 head injuries sustained with modified HG IRR= 1.03 95% CI [0.67-1.58]	See above row for control group	175 injuries sustained with modified HG IRR= 1.05 95% CI [0.78-1.41]	No significant difference in SRC, head injury or injuries for all body regions combined with modified HG use.
Chalmers, et al. [10]	704	4,223 player games	1,807 player games	*Data not recorded*	*Data not recorded*	*Data not recorded*	*Data not recorded*	IRR:1.00	IRR: 1.23 95% CI [1.00-1.50]	HG use associated with a 23% increase in injury for all body regions combined.
Archbold, et al. [1]	825	n=553 players	n=258 players	n=42 sustained SRC	n=31 sustained SRC. Log rank=0.02; df =1; *p*=0.88	*Not reported*	log rank=0.327; df=1 *p*= 0.57	549 injuries Exp (b)= 1	258 injuries Exp (b)= 1.07 95% CI [0.84-1.37]	No significant difference in SRC, head/face injury, or all injuries rates with HG use.

McGuine, et al. [40]	2,766	n=1,539 players	n=1, 498 players	n=68 sustained SRC 4.4%.	n=62 sustained SRC 4.1% RR= 0.98 95% CI [0.62-1.56]	*Data not recorded*	*Data not recorded*	8.6% players sustained other body region injuries.	8% players sustained other body region injuries. RR = 0.91 95% CI [0.64-1.29]	No significant difference in SRC or injuries to other body regions with HG use.

All extracted statistics are adjusted, Head Injury refers to superficial to the skull (i.e., abrasion, lacerations, contusions etc.) or specified as No. of impacts; HG = Headgear group, No-HG = No headgear group; IRR = Incidence Rate Ratio; IR = Incidence Rate; RR = Relative Risk or Risk Ratio; Exp (b) Results from Cox proportional Hazard model, *10 athletes could not reliably be classified as wearing or not wearing HG.

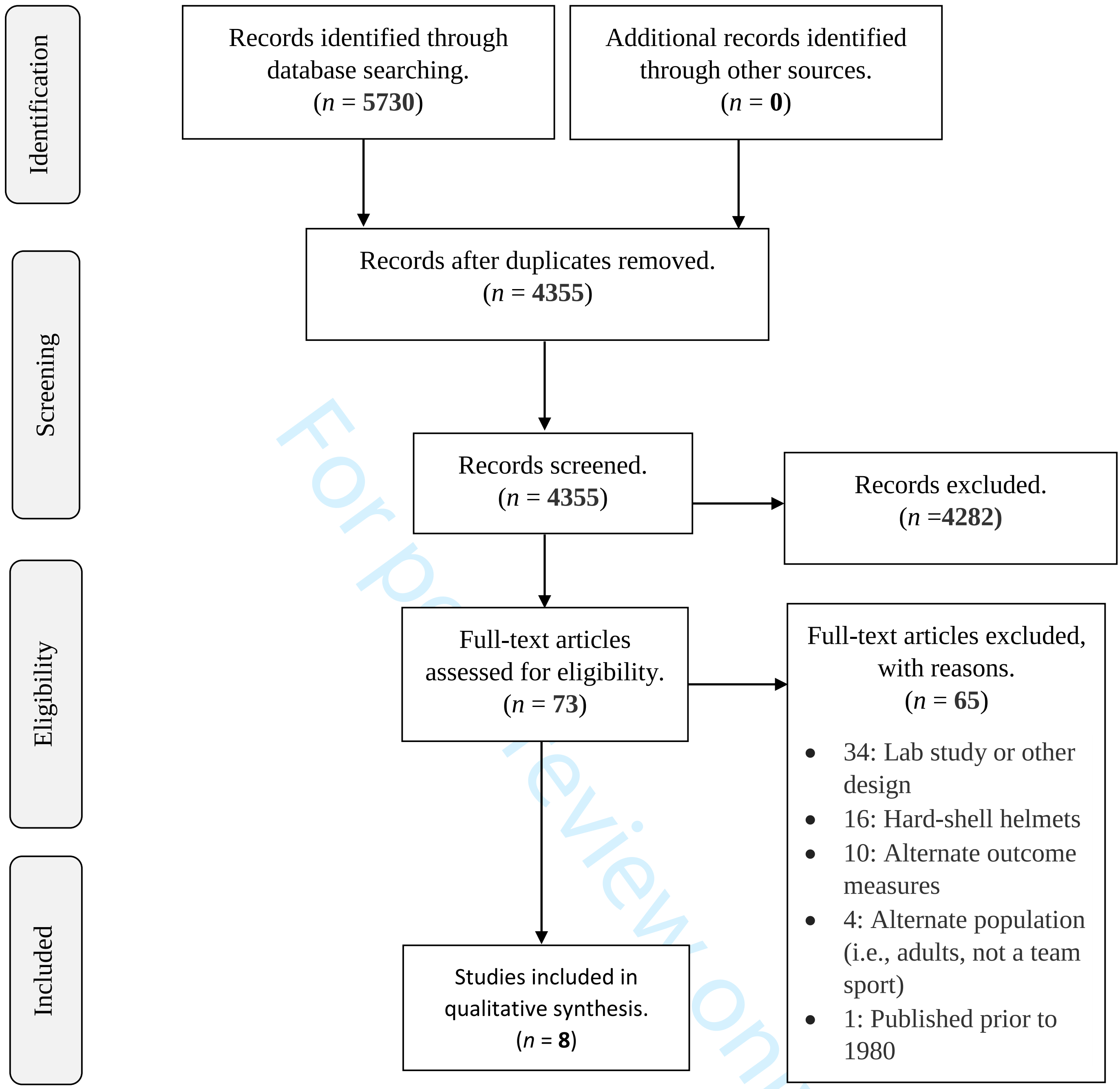
Table 3. *Results for NOS scale risk of bias assessment and Level of Evidence (OCEBM)*

Study	Selection				Comparability		Outcome			NOS Score	OCEBM
	a	b	c	d	e	f	g	h	i		
McIntosh and McCrory [44]	*	*	*	*	*	*	*	*	*	9	3
Marshall, et al. [36]	*	*	*	*	*	*		*	*	8	3
Delaney, et al.[14]	*	*		*	*			*	*	6	3
Hollis, et al. [25]	*	*	*	*	*	*	*	*	*	9	3
Chalmers, et al. [10]	*	*	*	*	*	*		*	*	8	3
Archbold, et al. [1]	*	*	*	*	*	*	*	*	*	9	3

a = Representativeness of the exposed cohort, b = Selection of the non- exposed cohort, c= Ascertainment of exposure, d = Outcome of interest was not present at start of study, e = Study controls for age, sex, injury history f = Study controls for additional factors, g = Assessment of outcome, h = Follow up long enough, I = Adequacy of follow up of cohorts. * = criteria met

Study	1	2	3	4	5	6	7	8	9	10	11	Score	OCEBM
McIntosh et al. (2009)	*	*	*	*				*	*	*	*	8	2
McGuine et al. (2019)	*	*	*	*				*	*	*	*	8	2

Table 4. *Randomized Study quality (PEDro Scale) & Level of Evidence (OCEBM)*


Identification
Screening
Eligibility
Included
Records identified through database searching. (n = 5730)
Additional records identified through other sources. (n = 0)
Records after duplicates removed. (n = 4355)
Records screened. (n = 4355)
Records excluded. (n =4282)
Full-text articles assessed for eligibility. (n = 73)
Full-text articles excluded, with reasons. (n = 65)
34: Lab study or other design
16: Hard-shell helmets
10: Alternate outcome measures
4: Alternate population (i.e., adults, not a team sport)
1: Published prior to 1980
Studies included in qualitative synthesis. (n = 8)

Supplementary Material

Search Strategy for OvidMedline:

"Head Protective Devices" OR "headgear" OR "helmet*" OR "protective gear" OR "protective equipment" OR : head protect*" AND "sport" OR "football" OR "soccer" OR "rugby" OR "athlete*".

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary file
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6 & 7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9 & 10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	13 & 14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11 & 12
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Soft-shell Headgear, Concussion and Injury Prevention in Youth Team Collision Sports: A Systematic Review

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Soft-shell Headgear, Concussion and Injury Prevention in Youth Team Collision Sports: A Systematic Review

Jennifer Makovec Knight[a], Jack V.K Nguyen[a], Biswadev Mitra[b, c, d], Catherine Willmott[a, e]

a. Turner Institute for Brain and Mental Health, School of Psychological Sciences, Monash University, Melbourne, Australia.

b. Emergency & Trauma Centre, The Alfred Hospital, Melbourne, Australia.

c. Department of Epidemiology & Preventive Medicine, Monash University, Melbourne, Australia.

d. National Trauma Research Institute, The Alfred Hospital, Melbourne, Australia.

e. Monash-Epworth Rehabilitation Research Centre, Epworth Hospital, Melbourne, Australia.

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Corresponding Author: Professor Biswadev Mitra

Corresponding Authors Email: biswadev.mitra@monash.edu

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J. Makovec Knight: 0000-0001-9879-0538

J.V.K. Nguyen: 0000-0002-6698-1935

B. Mitra: 0000-0002-0508-2450

C. Willmott: 0000-0001-8517-9035

Abstract

Objectives: To assess the association between soft-shell headgear (HG) use and sports related concussion (SRC). Secondary objectives were to assess the association between HG and superficial head injury and investigate potential increase in injury risk among HG users. **Design:** A systematic search in Ovid MEDLINE, Cochrane Library, Scopus, PsycINFO, and SPORTDiscus was conducted in April 2020. Inclusion criteria were youth <18, English language, *in-vivo* studies published after 1980 that evaluated SRC and other injury incidence in HG users compared to non-users. **Outcome Measures:** Incidence rates of SRC, superficial head injury or other injuries. **Results:** Eight studies were eligible. The majority (n=5) reported no difference in the rate of SRC among HG users versus non-users. One rugby study identified significantly lower risk of SRC for non-HG users (RR: 0.63; 95%CI: 0.41-0.98) compared to HG users, whereas a cross-sectional survey of soccer players indicated higher risk of SRC for non-HG users (RR: 2.65; %CI: 1.23-3.12) compared to HG users. Three of the four studies investigating superficial head injury found no significant differences with HG use, though the soccer survey reported reduced risk among HG users (RR= 1.86; 95%CI:0.09- 0.11). Increased incidence of injuries to all body regions for rugby HG users was reported in two studies with adjusted RRs of 1.16 (95%CI: 1.04-1.29) and 1.23 (95%CI: 1.00-1.50). **Conclusions:** HG use was not associated with reduced rates of SRC or superficial head injury in youth soccer and rugby. The possibility of increased injury risk to all body regions for rugby HG users was raised. The need for research specific to youth and female athletes was highlighted.

Strengths and Limitations of the Study

- This systematic review provides the first comprehensive examination of the limited available evidence for the use of soft-shell padded headgear for sports related concussion prevention in youth athletes.

- The review included only five studies that specifically pertained to youth cohorts. Many studies combined adult and youth participants, potentially confounding findings regarding risk taking behavior with headgear which may differ across age.
- The literature search revealed few articles. Included studies generally lacked robust evidence and did not assess the intervention of headgear as the primary outcome. As such, the conclusions should be interpreted with caution.
- This review provides an up to date evidence base for community decision making on club headgear mandates and an indication of where data is currently lacking on the topic, specifically in youth and female athletes.

Introduction

Traumatic brain injury (TBI) is a leading cause of disability and death, contributing to a growing worldwide disease burden.[1] Global estimates indicate that TBI affects 60 million individuals per year.[2] Collision sports are recognized as a significant contributor, with exponential increases in hospital admissions for children and adolescents sustaining TBI since the early 2000s.[3] The majority of these are classified as mild traumatic brain injury, or sports related concussion (SRC), with one study indicating that SRC emergency department visits have increased by more than 85% in 8- to 13-year-olds and by more than 200% in 14- to 19-year-olds. [4] Increased public awareness around SRC and higher numbers of youth participation in collision sport are likely contributing to these increases.[5]

In most cases of youth SRC, symptoms resolve within four weeks,[6] though some players have protracted recovery with cognitive, behavioural and emotional difficulties that interfere with school attendance, academic endeavors, sporting performance, social life and family relationships for months and sometimes years.[7] Playing technique (e.g. teaching skills that reduce exposure to head impacts), rule changes (e.g. limiting tackling and contact) and the use of protective equipment (e.g. hard shell helmets, padded headgear and mouthguards) are variably implemented as brain injury prevention initiatives in collision sports such as football, rugby and soccer.[8] Helmet sub-types include those with a hard-outer shell used in the National Football League in the USA, and soft-shell padded headgear (HG), that either fully covers the head (e.g. rugby scrum cap) or resembles a headband (e.g. soccer headgear) with an opening at the top. HG is most commonly used in rugby, with inconsistent uptake in Australian football and soccer,[9] albeit with varying policy guidelines across community clubs. Within the sporting community it is a widely held belief that such HG protects against injury[9] and SRC,[10] leading some youth Australian football, soccer and rugby clubs to mandate its use.[10 11]

Previous reviews have evaluated HG effectiveness across a diverse range of HG models and sports (e.g. skiing, American football, hockey etc). Findings indicate evidence for hard-shell helmets in the prevention of severe TBI,[12] though findings for SRC prevention with HG are equivocal at best.[8] A systematic review by Emery and colleagues (2018) found inconsistent evidence for the use of HG in rugby, and more consistent evidence that HG may play a role in soccer SRC prevention.[13] The evidence however, was scarce and largely drawn from cross-sectional, rather than randomised control trial methods. The most commonly accepted opinion is that HG provides limited or no protection against SRC,[14] although, this may be due to a lack of evidence, rather than a lack of effect.[15] As such, debate continues with regard to HG for SRC prevention,[8 12] and whether there is any evidence to support the notion of potential risk (i.e. risk compensation behaviour). The risk compensation hypothesis posits that players may be at greater risk of sustaining injuries due to increased tackling using the head and increases in aggressive play because they assume greater safety when wearing HG.[16 17] Importantly, to date, no reviews have focused exclusively on youth populations. Youth may be more vulnerable to risk compensation than adults,[18] as the cognitive processes associated with risk taking in the developing brain are immature.[19]

The primary objective of this study was to assess the *in-vivo* evidence for the intervention of HG for SRC in youth collision sports. Secondary objectives were to assess HG for prevention for superficial head injury (injuries superficial to the skull) and investigate potential indicators of risk compensation behavior by assessing the association between HG and rates of injury to all body regions.

Methods

The review was conducted in accordance the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[20] See supplementary file for search strategy. A review protocol was registered with PROSPERO, ID- CRD42018115310.

Patient and Public Involvement

Over many years the study investigators have worked clinically in treating patients with SRC, ranging from initial presentation to the Emergency Department, through to specialist treatment clinics providing interventions for those with prolonged symptoms. Whether children should wear HG to play team sports was a frequent question posed by parents, players and sporting club staff.

Data Sources

A systematic search was conducted in April 2020 using databases; Ovid MEDLINE, Cochrane Library, Scopus, PsycINFO, and SPORTDiscus.

Study Selection

Studies were included when the population of interest were athletes under aged 18 years who participated in a collision team sports study assessing the intervention of HG in comparison to no-HG upon the primary (SRC) and secondary outcomes (head injury superficial to the skull and/or injuries to other body regions). Included studies were limited to those using quantitative methods to report SRC, head injury and other injury rates (e.g., cross sectional survey, prospective cohort injury surveillance, randomized control trials). Studies were excluded when they did not report data on incidence of SRC, head injury superficial to the skull and/or injuries to other body regions in HG and no-HG groups, were not published in English language, or were published prior to 1980, laboratory based, conducted in adult only cohorts, conducted in individual and/or non-contact sports or only included participants wearing hard-shell helmets. Authors Archbold, et al. [21] were contacted and agreed to provide additional unpublished data on the rates of SRC sustained by HG users and non-users.

Two review authors (JMK and JN) independently screened manuscripts on title and abstract, selecting agreed citations in full text using the predetermined eligibility criteria. The reviewers then independently screened the selected manuscripts in full text. Disagreements were adjudicated by a senior member of the team.

Data Extraction

Data on study design, sporting code, sample size, cohort characteristics, methods, outcomes and covariates predicted to alter injury risk, and main findings were extracted from each study. Description of study participants, injury definitions and the denominators used to compute injury incidence were extracted in as much detail as each study provided. Incidence rate ratios (IRR), relative risk and risk ratios with 95% confidence intervals (CI) were extracted (if reported) from each study. Where these were not available, relative risk and 95%

CI were calculated using the incidence data available. Due to the expected heterogeneity in reported statistical methods and study design, a meta-analysis was not planned.

Quality and Level of Evidence Assessment

Two reviewers (JMK and JN) independently assessed the quality of non-randomised studies using the nine-item Newcastle Ottawa Scale (NOS) for Cohort Studies.[22] The NOS assesses three domains and assigns up to a maximum of nine points for: 1) selection of cohorts (four points); 2) comparability of cohorts (two points); and 3) outcomes (three points). On this scale, scores between 7-9 were considered good quality, and scores 1-6 were considered low quality. The quality of randomised control trials (RCTs) were assessed using the 11-item Physiotherapy Evidence Database (PEDro) scale.[23] On this scale, scores between 9–11 were considered excellent quality; 6–8, good quality; 4–5, fair quality; and <4, poor quality.[24] Reviewers also assessed levels of evidence using the Oxford Centre for Evidence-Based Medicine (OCEBM) guidelines.[25] The OCEBM levels range from level one, representing systematic reviews, level two representing randomized trials, level three denoting non-randomized controlled cohort/follow-up, level four denoting case series, to level five, denoting mechanistic reasoning. All included studies were assigned a number indicating the level of evidence and quality.

Results

Of the 4,355 citations that remained after duplicates were removed, 73 were screened in full text for eligibility and of these, 65 were excluded (Figure 1). The most common reasons for exclusion were if studies were laboratory-based or utilised hard-shell helmets. Studies were also excluded based on outcome measures and alternate populations. After screening, eight studies were included for qualitative analysis and none were excluded based on quality analysis.

Study characteristics

All studies were published between 2001 and 2019 and study designs included prospective cohort injury surveillance (n=4), randomised control trial (RCT) (n=2), pilot RCT (n=1), and cross sectional (n=1). There were six rugby and two soccer cohorts, with a total of 12,064 participants. Three studies included female athletes, who represented 2,038 (17%) of the total included participants. Of the eight included studies, five were exclusive to youth, and others comprised mixed adult/youth cohorts who ranged in age from 13 to 45 years. Studies examined the effect of HG upon rates of SRC (n=6), injuries to other body regions (n=5), head injury superficial to the skull (n=4), and frequency of impacts sustained to the head (n=1). Three studies examined a combination of these outcomes, as they associated the use of soft-shell HG with SRC, superficial head injury and injuries to other body regions. Injury data was typically collected for games and training sessions, with the exception of three studies that included injuries sustained in games only. Study characteristics are summarised in Table 1.

Table 1. *Methodological details of studies*

Study	Study Design	Sport/ Country	Randomisation of HG use, compliance & wearing rates	Exposure quantification	Level, Sex & Age: M(SD)	Outcomes	Operational Definition of Outcomes	Data Collection Method	Variables adjusted for in analysis
McIntosh and McCrory, 2001	Pilot RCT	Rugby/ Australia	Random number approach to select 9 HG teams, & 7 non-HG teams. Compliance data NA.	Player game hours	School competition, males U15's.	Concussion and head impacts.	Concussion verified by a medical practitioner and classified as a traumatic event that resulted in the player missing a game or training time.	Club personnel completed standardized reporting forms and researchers reviewed video footage.	NA
Marshall, et al, 2005	Prospective cohort injury surveillance	Rugby/ New Zealand	Players were asked weekly whether they used protective gear. HG was worn for 14% of player weeks.	Player weeks	Community and school competition, 240 males and 87 females U17 to U22 and 23 and over.	Concussion, head injury and injury for all body regions combined.	Any event that resulted in an injury requiring medical attention or causing a player to miss at least one game or practice.	Researchers completed weekly follow up interviews with players over the phone.	Protective equipment, level of competition, playing position, playing out of usual position, injury history, frequency of in-season injury, body somatype, fitness level, health status, anger, anxiety, negative affect, task orientation in sport, and perceived importance of injury to team performance.
Delaney, et al, 2007	Cross sectional study	Soccer/ Canada	Players were retrospectively asked if they wore HG and how often	No. of players	Community competition, U13 to U18, 180 males and 98	Concussion and head injury.	Concussion symptoms listed were consistent with the	Players completed retrospective online survey	Headgear and mouthguard use, sex, age, concussion history, level of experience, and considering oneself as a

			18.7% of players reportedly used HG (73.1% female). All HG users wore HG for games, while 69.2% wore HG for practices.		females.		Concussion in Sports Group (CISG) statement[26]. Head injury defined as abrasions lacerations or contusions.		"header".
McIntosh, et al, 2009	Cluster randomized control trial	Rugby/ Australia	HG assigned to rugby teams within a club/ school and level yearly. 45.7 % standard HG and 10.8% modified HG compliance.	Player game hours	Community and school competition, U13, U15, U18 and U20 males	Concussion, head injury and injury for all body regions combined.	Concussion in accordance with CISG[27]. Injury required on field treatment, a player being removed from the game, or a player missing the next game.	Trained data collectors recorded data on standardized reporting form	Standard headgear, modified headgear, no headgear & competition level.
Hollis, et al, 2009	Prospective cohort injury surveillance	Rugby/ Australia	Reports on baseline questionnaire outlined 671 players "always" 145 "often", 227 "sometimes , 207 "rarely" and 985 "never" used HG.	Player game hours	Community competition males 19-45 yrs. and school competition males aged 15-18 yrs. 22.7(5.5)	Concussion	Any event where a player left the field due to dizziness, confusion, loss of coordination , and/or loss of consciousness; and stoppage of	Trained data collectors, coaches, club doctors and physical therapists recorded data on standardized reporting forms.	Headgear and mouthguard use, age, height, weight, impulsivity, time spent training, experience, player position, concussion history, competition level.

							play was required, or they received medical attention because of a blow to the head.		
Chalmers, et al, 2011	Prospective cohort injury surveillance	Rugby/ New Zealand	Not reported	Player game hours	Community competition, males aged 13 & above	Injury for all body regions combined.	Any event that resulted in an injury requiring medical attention or causing a player to miss at least one scheduled game or team practice.	Researchers completed weekly follow up interviews with players over the phone.	Protective equipment. age, ethnicity, experience, lifestyle factors, injury history, player position, training, time of season, foul play, warm ups, weather conditions, ground conditions.
Archbold et al, 2017	Prospective cohort injury surveillance	Rugby/ Ireland	46.8% of players reported using HG in a baseline demographic questionnaire prior to the season.	Player game hours	School competition, Males, 16.8 (0.8)	Concussion, head injury and injuries for all body regions combined.	Any injury that prevents a player from taking full part in all training and match play or activities planned for that day for a period of greater than 24 hrs from midnight at	Trained data collectors recorded data using online database.	Headgear, mouthguard and shoulder pad use, age, weight, height, playing position, injury history, strength profile and experience.

							the end of the day the injury was sustained.		
McGuine, et al, 2019	Cluster randomized control trial	Soccer/ USA	Stratified Randomisation using school enrolment size as stratification variable. If a team participated in both years assignment remained the same	Player game hours	School competition, 1853 females and 913 males, 15.6(1.2)	Concussion and injuries for all body regions combined, excluding concussion.	Concussion recorded in accordance with NATA position statement.[28] Other injury determined by onset, mechanism, characteristics and physical examination.	Athletic trainers recorded in an online database.	Headgear use, school, sex, age, year cohort, SCAT3 baseline symptom severity and concussion history.

Quality and Levels of Evidence Results

Interrater agreement for quality analysis between the two reviewers (JMK and JN) assessing the eight included manuscripts was 94.44%. The results for quality assessment and levels of evidence for cohort studies can be seen in Table 2. Selection bias was considered low in all studies. Only one study was not awarded full points in this domain, as Delaney.et al.[29] did not ascertain the exact number of exposures to SRC reliably due to using self-report, as opposed to direct observation or secure record. For comparability of cohorts, all studies controlled for age, sex and injury history, with only one study not controlling for additional factors. Delaney, et al.[29] did not account for factors such as player position and player experience that may, in addition to HG use, modify injury rates.[30]

For the final domain, three studies did not assess SRC and injury outcomes using an independent observer. The findings of Delaney, et al.[29] were deemed to have the highest risk of bias due to a cross-sectional survey design with the survey accessible online to players (aged 12-17 years) who could re-access it multiple times to update SRC symptoms. In addition, the injury definition used did not relate to time lost from participation in sport and/or medical-attention received for injury, the most common definition[31] used in all other studies. Two other studies were considered to be subject to the inherent biases associated with self-report data collection, due to a prospective design where researchers completed weekly, post-game follow up interviews with players over the phone.[32 33] These self-reported methods contrasted those used where direct SRC and injury observation was completed by trained data collectors, athletic trainers, and medical professionals.

Table 2. *Results for NOS scale risk of bias assessment and Level of Evidence (OCEBM*

Study	Selection				Comparability		Outcome			NOS	OCEBM
	a	b	c	d	e	f	g	h	i	Score	
McIntosh and McCrory. 2001	*	*	*	*	*	*	*	*	*	9	3
Marshall, et al. 2005	*	*	*	*	*	*		*	*	8	3
Delaney, et al. 2007	*	*		*	*			*	*	6	3
Hollis, et al. 2009	*	*	*	*	*	*	*	*	*	9	3
Chalmers, et al. 2011	*	*	*	*	*	*		*	*	8	3
Archbold, et al. 2017	*	*	*	*	*	*	*	*	*	9	3

a = Representativeness of the exposed cohort, b = Selection of the non- exposed cohort, c= Ascertainment of exposure, d = Outcome of interest was not present at start of study, e = Study controls for age, sex, injury history f = Study controls for additional factors, g = Assessment of outcome, h = Follow up long enough, I = Adequacy of follow up of cohorts. * = criteria met

Both RCTs[34 35] were assessed as good quality, the *OCEBM* levels of evidence were scored as two (table 3). On the PEDro scale, they both recieved scores of eight with only three criteria not met (5-7). These criteria related to the blinding of participants, therapists and assessors. It was deemed unfeasible to expect blinding in these studies due to the fact that the intervention (HG use) was directly observable.

Table 3. Randomized Study quality (PEDro Scale) & Level of Evidence (OCEBM)

Study	1	2	3	4	5	6	7	8	9	10	11	Score	OCEBM
McIntosh et al. (2009)	*	*	*	*				*	*	*	*	8	2
McGuine et al. (2019)	*	*	*	*				*	*	*	*	8	2

Overall, methodology across studies tended to lack scientific rigour in one or more aspects, and incidence of injury was made difficult to interpret due to different methods of reporting injuries (e.g., per player, per player weeks, per player hours). The most common convention was for authors to report injuries per player 1000 player games. The two studies who did not conform to this, were subject to retrospective self-report bias. For instance, Marshall et al., (2005) obtained injury data from players at weekly intervals and therefore reported by 'player week', and Delaney et al., (2007) reported injuries "per player", likely because players reported SRC at a single survey time point. These studies likely reported injuries in this way because they did not capture players true exposure to injury, and therefore could not report per hour.

Few studies prospectively recorded HG wearing rates throughout the season. Indeed, many studies relied on a questionnaire administered at a single time point asking players whether they used HG. In the Hollis et al., (2009) study the authors used a Likert scale (e.g., never, rarely, sometimes) to ascertain HG useage rates, and reported that players who 'always' wore HG were significant less likely to sustain SRC than those who 'rarely' wore HG. Firstly, this is not an accurate reflection of HG use, as players may have decided to use or not use HG depending on how they felt on match day, and secondly, the rates of SRC among those who 'always' wore HG, compared to those who 'never' wore HG, were in fact very similar (see table 4 for details).

The RCTs (of which there were only 2) were the only studies that reliably recorded HG use. Without accurate data on whether players consistently wore HG, the results are prone to bias and confounding as player propensity to risk taking may have been inconsistent across games. In addition, HG uptake was generally low across observational studies, and compliance poor in RCTs, rendering many studies statistically underpowered to assess for difference in outcomes amongst HG users and non-users. As data reporting methodologies differ across studies, the data presented should be interpreted with caution, especially when comparing results that were obtained across varying contexts with inconsistent definitions of SRC and injury.

Headgear Use and SRC

Outcomes for SRC, superficial head injury, head impacts, and injuries to other body regions stratified by HG use vs. no-HG use (No-HG) are listed in Table 4. There were seven studies included that analyzed SRC. Of these, five (one in soccer and four in rugby) found no differences in rates of SRC with or without HG (See table 4).[21 33-36] Contrasting findings were seen in two other studies; a prospective cohort study in rugby showed that non-HG users were at significantly lower risk of SRC (RR: 0.63; 95%CI: 0.41-0.98) than HG users, and a cross-sectional survey of soccer players outlined higher risk of SRC for non-HG users (RR: 2.65; 95%CI: 1.23-3.12) compared to HG users.

Headgear use and superficial head injury

There were four included studies that investigated the association of HG use and superficial head injury. Two assessed rugby cohorts and found no statistically significant difference in rates of sustaining superficial head injury between HG users and non-users,[21 36] In the soccer survey study, non-HG users were reported to have higher adjusted risk of superficial head injury (RR= 1.86; 96%CI: 0.09- 0.11) compared to HG users.[29] Among the four studies reporting superficial head injury, one reported frequency and type of head impacts using game video analysis. That study found no statistically significant association among HG users (RR: 1.54; 95% CI: 0.63-3.75) compared to non-HG users.[36]

Headgear and injuries to all body regions

There were five included studies that reported on injuries to all body regions. Four of these conducted the analyses with SRC and all body injuries combined as a composite outcome variable.[21 32 33 35] Reporting this composite outcome were two studies conducted in rugby with no differences observed in injury rates among HG users versus non-users.[21 33] In contrast, Chalmers, et al.[32] and McIntosh, et al.[35] reported increases in injury rates to all body regions in rugby players wearing standard HG, adjusted RR: 1.23 (95% CI 1.00-1.50) and adjusted RR: 1.16 (95% CI: 1.04-1.29), respectively. The McIntosh, et al.[35] study also investigated injury rates to all body regions for players who wore "modified HG". The use of this HG was not associated with increased injury risk, adjusted IRR: 1.05 (95% CI: 0.78-1.41), although the group accounted for only 11% of exposures to SRC due to poor compliance. The remaining RCT study by McGuine et al.[34] reported the outcome of injury to other body regions (excluding SRC) and found no difference in rates for soccer HG users and non-users with adjusted RR = 0.91 (95%CI 0.64-1.29).

Table 4. Outcome data for concussion, head injury and injuries to other body regions stratified by headgear vs no-headgear.

Study	N	No-HG exposures	HG exposures	No-HG SRC	HG SRC	No-HG superficial head injury	HG superficial head injury	No-HG all body regions combined	HG all body regions combined
McIntosh and McCrory., 2001	294	357 player game hours	1179 player game hours	n=2 *Relative Risk= 0.94 95% CI [0.19-4.52]	n= 7	n=7 *Relative risk = 1.54 90% CI [0.63-3.75]	n= 15	-	-
Marshall, et al. 2005	304	4,656 player weeks	752 player weeks	*Not reported*	Rate ratio= 1.13 95% CI [0.40-3.16]	*Not reported*	Rate ratio= 0.59, 95% CI [0.19- 1.85]	*Not reported*	Rate ratio= 0.96, 95% CI [0.75-1.23]
Delaney, et al. 2007	278	n= 216 players	n= 52 players	n=114 Relative Risk= 2.65 95%CI [1.23-3.12]	n= 14	n=151 Relative Risk= 1.86 96%CI [1.49-3.45]	n= 15	-	-
Hollis, et al. 2009	3,207	n= 985 players	n= 671 players	7.48 per 1000 player hours. *Relative Risk= 0.68 95%CI [0.24- 1.93]	7.39 per 1000 player hours.	-	-	-	-
McIntosh, et al. 2009	3,686	1,493 player game hours	Standard HG 1,128 player game hours	n= 90	n= 85 with standard HG. Incidence Rate ratio= 1.13 95% CI [0.86-1.49]	n= 106	n= 100 with standard HG. Incidence Rate ratio= 1.14 95% CI [0.84-1.54]	n= 799	n= 828 with standard HG. Incidence Rate ratio= 1.16 95% CI [1.04-1.29]

			Modified HG 1,474 player game hours	See above row for control group	n= 19 with Modified HG. Incidence Rate ratio= 1.06 95% CI [0.70-1.60]	See above row for control group	n= 22 with modified HG. Incidence Rate ratio= 1.03 95% CI [0.67-1.58]	See above row for control group	n= 175 with modified HG. Incidence Rate ratio= 1.05 95% CI [0.78-1.41]
Chalmers, et al. 2011	704	4,223 player game hours	1,807 player game hours	-	-	-	-	n= 4,419 injuries. Incidence Rate ratio:1.00	n= 1,844 injuries. Incidence Rate ratio: 1.26 95% CI [1.00-1.50]
Archbold, et al. 2017	811	n= 553 players	n= 258 players	n= 42 *Relative Risk= 0.63 95%CI [0.41-0.98]	n=31	log rank=0.327; df=1; p=0.567)	*Not reported*	n=549 *Relative Risk= 0.99 95%CI [0.99-1.00]	n= 258
McGuine, et al. 2019	3,050	n= 1,545 players	n= 1,505 players	n= 68	n= 62 Risk ratio= 0.98 95% CI [0.62-1.56]	-	-	*Not reported*	Risk ratio= 0.91 95% CI [0.64-1.29]

Discussion

The Association of Headgear with Sports Related Concussion, Superficial Head Injury and other Injuries.

The findings from this review do not support the use of the current, commercially available HG to prevent SRC in youth soccer or rugby. The majority of *in-vivo* evidence is consistent with laboratory research showing that HG does not mitigate the forces associated with head impacts.[37-39] Though some protection may be offered against superficial head injury, as purported by Delaney et al.[29] and prior studies where HG has been shown to protect against soft tissue injuries sustained to areas of the head covered by padding.[40] Importantly, there may also be potential for increased risk of sustaining all types of injuries. Two studies reported 23% [32] and 16% [35] increases in all types of injury risk for rugby players who wore commercially available HG, and indeed, results from one prospective cohort injury surveillance study indicated higher risk of SRC among players who wore HG.[21] Raised by these findings, is the possibility that risk compensation is a phenomena occurring in rugby, but not soccer, as increased injuries were not observed among soccer HG users in a RCT. Soccer is unique in that SRC and other types of injury are sustained when players purposefully use their head to progress the ball,[9] when players knock heads[41] or when falling over during a tackle.[42] In contrast, the majority of SRC and other injuries in rugby are sustained in player to player collisions during full body tackling.[42 43] These fundamental differences may render rugby HG users more vulnerable to risk compensation behaviours because injury mechanisms overtly differ and their style of play allows for the head to be used as a tackle weapon.

Given that perceptions about HG and associated behavioural changes may differ across the lifespan, it is unclear whether injury risk associated with HG use differs between adult and youth populations. A commonly held belief reported by youth rugby players is that

HG makes them feel safer in contact situations and allows them to play 'harder'.[16 44] A study on HG perceptions among adult and youth rugby players indicated that these beliefs differed with age, as youth tended towards greater acceptance and beliefs in the utility of HG.[45]Adult HG users may be protected against risk compensation as they are less prone to misguided beliefs about HG.

The studies included in the review span almost two decades raising the possibility that changes in HG technology might influence outcomes. No chronological trends were apparent in the analysis and industry experts are of the opinion that the commercially available HG has not advanced considerably since the 1990s.[39] Confounding a summative interpretation was the heterogeneity found in definitions of injury. One study referred to superficial head injury as the ear and scalp only,[33] while others included the face[21 29] or excluded the face from the definition.[35] Some studies defined an injury as occurring only if a player was observed to miss time from play,[21 35 46] or received attention from a medic or athletic trainer,[34 36 46] while others used retrospective player self-report.[29 32 33] Retrospective self-reported methods are not consistent with standards which suggest prospective recording by health professionals is superior to retrospective interview.[31] The differences in methodology were prominent in the heterogeneity of outcomes with far higher proportion of SRC recorded when self-reported compared to studies that used direct observation.[29 34]

Directions for Future Research.

A key finding of this review is that standardized definitions and reliable recording of HG use are vital to ensure the translation of findings to clinicians and the community. It is recommended that injury definitions are guided by the most recently published consensus statements, and that definitions rely on a number of factors to describe severity. It is recommended that a SRC be defined as a "traumatic brain injury induced by biomechanical forces" with physical, behavioural, cognitive and somatic clinical features documented with each SRC event.[6] A superficial head injury should be defined as any injury to the head that is superficial to the skull (including contusions, abrasions and lacerations).[29] To capture the full spectrum of SRC and other injuries and facilitate comparison with past results, it is recommended that researchers record all injuries using a combination of "broad" definitions (e.g. injury recorded if it causes a player pain or discomfort) and "narrow definitions" (e.g., injury recorded if player misses a game).[47] As an example, an injury anywhere on the body should be initially documented by body region (e.g., lower leg, arm, head) and pathology (bruise, open wound, fracture) if it causes a player pain. Additional information on whether that injury resulted in time lost from play, missed games, required medical attention or resulted in hospital transfer should be collected as surrogates for severity.[48] Data collection conducted by a medical professional diagnosing SRC and reliably classifying players as HG-users and non-HG users would be optimal, however, we acknowledge this is not possible in most youth community sports. As an alternative, live observation by trained data collectors that are athletic trainers or work in health-related fields has shown promise.[31] Video analysis may also have a role in augmenting findings. This could allow researchers to examine the number of head impacts sustained by each player, observe whether the player was wearing HG at the time of impact, and code the behaviours of HG wearers.

Under-representation of female athletes in the included studies was frequently observed. Compared with male athletes, females have been reported to have higher rates of SRC[49-53] report more SRC symptoms,[54 55] demonstrate worse cognitive impairment following SRC,[53 54] and may take longer to recover.[55 56] In addition, it has been suggested that females are at higher risk of the effects of sub-concussive impacts due to differences in neck strength and body composition.[57] Given the exponential increase in female participation in these sports,[58-60] further evaluation of injury risk and prevention in this cohort is crucial to future research.

Ultimately, injury surveillance systems specific to youth have not yet been developed, as they largely exist at the elite level and require significant financial and operational resources to conduct.[31] Nonetheless, identifying constraints is an important step for researchers conducting future studies to address this important issue. Existing constraints are the potential ethical dilemmas regarding HG being implemented in an RCT because of the lack of evidence that supports its protective benefit versus potential harm. Other barriers include difficulty truly randomizing HG (i.e., allocation often occurs based on entire teams and is stratified by gender) and poor compliance. For instance, only 11% of exposure hours were attributable to those in the modified HG arm of the McIntosh, et al.[35] RCT due to very low compliance. A HG RCT conducted in Australian football that was screened for inclusion also revealed that SRC and injury outcomes could not be assessed due to very low compliance in HG use.[61] Low compliance was less problematic in the included soccer RCT with 99.5% of those allocated to the HG arm consistently wearing it,[34] raising the question of what encourages compliance in these types studies. As seen in McGuine's (2019) study, players chose their preferred HG model from a range of provided options that met specific testing standards. This potentially contributed to higher compliance because the players had greater involvement and autonomy. It may also be that soccer HG is less intrusive because it covers less of the head and may not induce as much discomfort via increased heat and perspiration.

Strengths and Limitations.

The primary strength of this review is that it provides a picture of where data is currently lacking, highlights significant evidence gaps particularly in youth and female athletes, and outlines a framework for researchers to further explore this important topic. The review included only five studies that specifically pertained to youth cohorts. Many studies combined adult and youth participants, potentially confounding findings in outcomes due to the higher level of experience, training and increased maturity in risk-taking decision-making among adults.[19] Without robust data it was difficult to draw definitive conclusions about the role of HG in sports injury prevention. An important methodological issue was that reporting of results across studies was inconsistent. Reporting of homogenous outcomes and 95% confidence intervals was not possible in all cases as data was not available, although attempts were made to re-analyse available data to provide consistency.

Conclusion

Extending upon the most recent CISG consensus,[6] this review indicates a lack of scientifically rigorous research that clearly outlines the benefit or harm of wearing HG in youth collision sports. Future research should include a representative population and focus on including female participants across a range of sporting codes that use HG. Standardisation of the definitions and measurement of outcome variables are indicated for comparability across studies.

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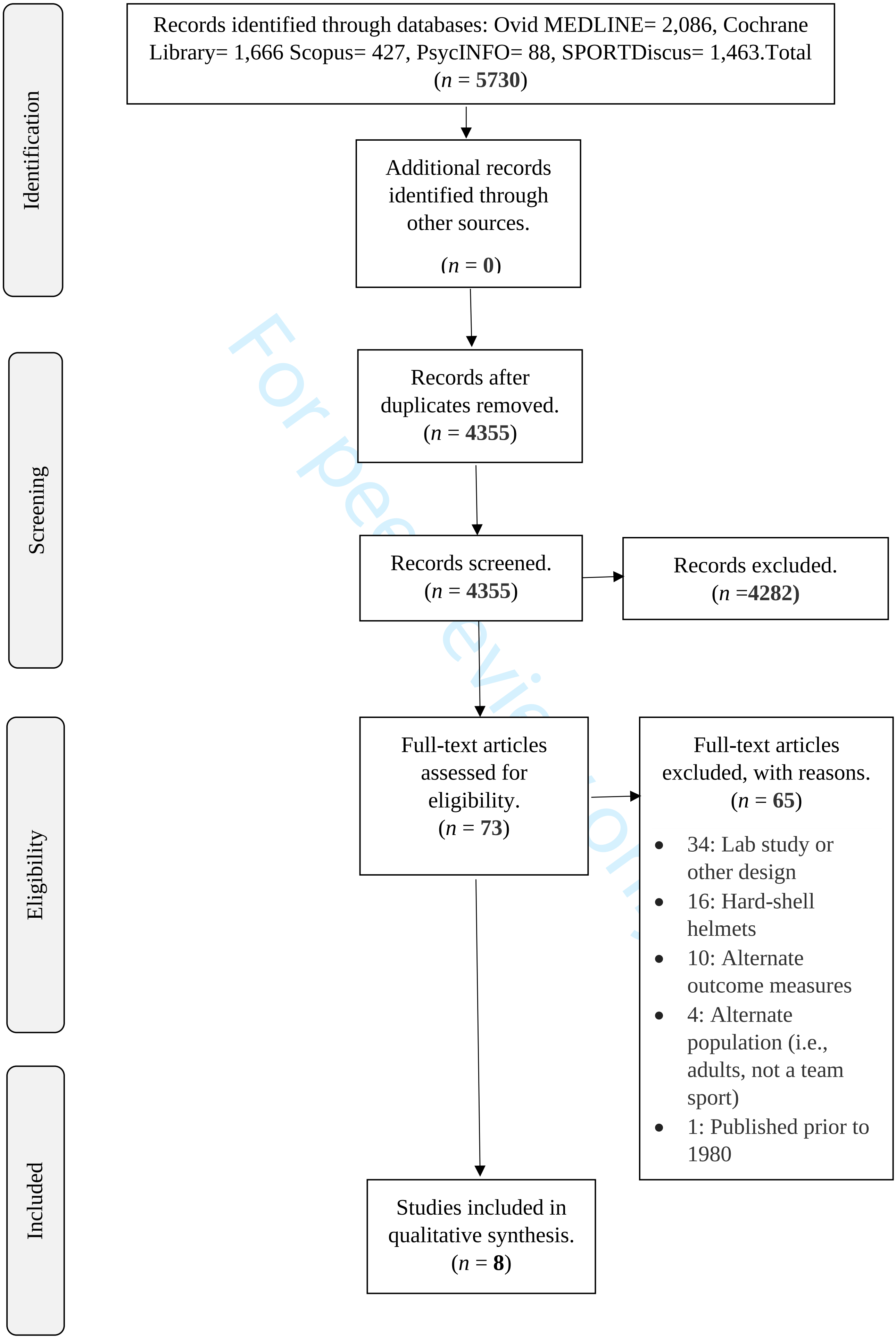
Figure 1. The figure depicts a PRISMA flowchart showing systematic exclusion of articles at each stage of the review.


Identification
Screening
Eligibility
Included
Records identified through databases: Ovid MEDLINE= 2,086, Cochrane Library= 1,666 Scopus= 427, PsycINFO= 88, SPORTDiscus= 1,463.Total (n = 5730)
Additional records identified through other sources. (n = 0)
Records after duplicates removed. (n = 4355)
Records screened. (n = 4355)
Records excluded. (n =4282)
Full-text articles assessed for eligibility. (n = 73)
Full-text articles excluded, with reasons. (n = 65)
34: Lab study or other design
16: Hard-shell helmets
10: Alternate outcome measures
4: Alternate population (i.e., adults, not a team sport)
1: Published prior to 1980
Studies included in qualitative synthesis. (n = 8)

Supplementary Material

Search Strategy for OvidMedline:

"Head Protective Devices" OR "headgear" OR "helmet*" OR "protective gear" OR "protective equipment" OR : head protect*" AND "sport" OR "football" OR "soccer" OR "rugby" OR "athlete*".

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary file
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6 & 7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9 & 10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	13 & 14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11 & 12
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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