The effectiveness of regulations and interventions on head impacts and brain injuries in youth, high-school, and collegiate football: A systematized review

By

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Thesis

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Abstract

Objective: The purpose of this study was to assess the effectiveness of regulations and interventions on head impacts in youth, high-school, and collegiate football, using a systematic search strategy to identify relevant literature.

Methods: Six databases were searched by one reviewer between 15 November 2019 and 22 February 2020 for English-language articles: PubMed, PsycINFO, Cochrane, Embase, ERIC, and Global Health. Studies that met inclusion criteria were included in the study and underwent data extraction. Studies were excluded if the sport in the study was not identified as American football, the population in the study was identified as NFL players, semi-professional, or professional players, or if the study was identified as a systematic review, or meta-analysis, or narrative review.

Results: Twenty articles met inclusion criteria and were included in data extraction and the final systematized review. Of the 20 included studies, 8 studies evaluated interventions in high-school football, 5 studies evaluated interventions in collegiate football, 6 studies evaluated interventions in youth football, and 1 study evaluated interventions in both, high-school and collegiate football. The four categories of interventions and regulations included rule changes, training, education/instruction/coaching tactical changes, and tackle football alternatives.

Conclusions: Despite a lack of understanding surrounding the relationship between head impact exposures and long-term neurocognitive deficits, interventions and regulations have been implemented to reduce head impacts and head injuries in American football. Studies evaluating the effectiveness of interventions and regulations on reducing head impact exposures or head injuries have shown mixed results. Some regulations may be more effective than others, but methodological design and risk of bias pose limitations to generalize effects.

Introduction

Approximately 5.16 million people over the age of 6 participated in tackle football in the United States in 2018.[7] However, overall participation in American tackle football is declining. Over the past 12 years, participation in tackle football has declined from approximately 8.4 million people (2006) to 5.16 million (2018).[7] Reasons for the decline in participation have been attributed to injury risks.[8] In 2009, the number of media reports discussing the concern of brain injuries in American football increased significantly, which coincided with the decline in adolescent participation in high-school tackle football.[8] Although the increase in media reports coincided with participation decline, it is important to recognize that additional factors may have contributed to the decline and therefore, can not be disregarded.[8] Additional factors that contribute to the decline in tackle football participation may be due to factors that predict parent's intention to let their kids play football, including social norms, attitudes toward football participation, behavioral control, and perceived risks of concussions.[9] Despite participation in tackle football declining, brain injuries remain a concern.

According to the Centers for Disease Control (CDC), approximately 1.6 to 3.8 million sports-related concussions occur annually.[10,11] However, this estimate may be drastically low due to the number of concussions that go unrecognized, undiagnosed, and thus unreported.[10] Amongst sports, football poses higher rates of concussions per athletic-exposure (AE) ($0.37 \cdot 1000^{-1}$ AE during the fall and $0.54 \cdot 1000^{-1}$ AE during the spring).[12,13] Common cited motivations for not reporting concussions amongst high-school football players included players not thinking the injury was serious enough, not wanting to be withheld from competition, and lacking awareness of probable concussion.[14] Motivations for not reporting, however may vary depending on level of

play and individual values.[15] Younger athletes may be motivated by peer acceptance, while collegiate athletes may have additional motivations, such as scholarships.[15]

A growing body of published, scientific literature has suggested that subconcussive impacts can lead to an increased risk of significant neurological deficits, such as chronic traumatic encephalopathy (CTE).[16,17] As newer technology, such as helmet sensors, have become available, studies have been able to quantify the number of impacts, location of impacts, and magnitude of impacts across participants in American tackle football. However, the long-term effects of repetitive head impact exposures in relation to the development of CTE is not well understood. Unlike concussions, the incidence and prevalence of CTE is unknown.[18] Some risk factors in football players that might influence the pathological severity of CTE include duration of football career, years since retiring, and age of death.[18] Concussions and subconcussive head impacts raise concerns for contact sport athletes.

To date, there have been numerous advancements in protective equipment standards, such as updated helmet standards by the National Operating Committee on Standards for Athletic Equipment (NOCSAE) and development of helmet evaluation systems by researchers at the Virginia Tech Helmet Lab.[19,20] In a recent newsletter, NOCSAE announced beginning the process to develop a youth football helmet performance standard.[21] In 2011, Rowson and Duma introduced a new metric using on-field impact exposures to asses performance of helmets, Summation of Tests for the Analysis of Risk (STAR).[22] Helmet testing typically quantifies helmet performance by measuring variables such as, linear acceleration, Gadd Severity Index (GSI), and rotational acceleration; however, these variables have limitations.[23] Using linear and rotational acceleration measures only measure the motion of the head, rather than the motion of brain tissue.[23] Variability

also exists between helmet designs and their ability to reduce head accelerations upon impact.[24] In addition, controversy exist whether helmet designs can reduce incidences of concussions.[24–26]

Helmet performance alone may not substantially reduce the risk of concussions in American football.[27] In fact, helmets may create a false sense of security for athletes, encouraging more dangerous styles of play.[28] It has been reported in one field study that youth football players intentionally used their heads in 80% of high-magnitude head impacts.[27] These findings have implications for risk- reduction strategies, suggesting that regulations and interventions could play a significant role in reducing head-impacts. However, little is known about the effectiveness of these regulations and interventions.

Concussion policy for prevention, treatment, and education exists across states, but is highly variable. States have amended their concussion laws by incorporating primary prevention, expanding the population covered by the laws, or by clarifying provisions.[29] At the collegiate level, since 1893 the National Collegiate Athletic Association (NCAA) has been implementing rules to protect college athletes form brain injuries. For example, in 2009 the NCAA implemented rules regarding the number of football full-contact practices and in 2012 moved the kickoff location to the 35-yard, while simultaneously moving the touchback spot on free kicks to the 25-yard line.[30] Leagues and conferences within the NCAA have further amended concussion policies. In 2016, Ivy League football coaches eliminated all full-contact practices during the season.[31] Governmental bodies for youth and high-school football have also made rule changes and implemented interventions for tackle football. A popular youth-football league, Pop Warner, limited contact drills to a third of all practice hours.[32]

To our knowledge, there have been no systematized reviews that specifically look at the effectiveness of football rules and interventions on head impacts and concussions. In 2017, a

previous systematic review synthesized trials examining concussion prevention via equipment, educational programs, and training programs in multiple contact sports.[33] The primary goal of this review is to synthesize findings from literature regarding the effectiveness of interventions and regulations on head impacts and head injuries in youth, high-school, and collegiate football. This information may help those making rule changes and interventions for tackle football make informed decisions for youth, high-school, and collegiate football programs.

Methods

Search Strategy

PubMed, PsycINFO, Cochrane, Embase, ERIC, and Global Health were searched between 15 November 2019 and 22 February 2020. Databases were systematically searched to identify relevant peer-reviewed, published literature using key search terms related to three categories: football, head-injuries, and interventions. Search terms under the category of head-injuries included the following terms: head, brain injuries, traumatic, brain concussion/ prevention and control, brain injury*, concussion, brain contusion, TBI, MTBI, SRC, and head impact*. A list of complete database search queries, dates, and results can be found in supplemental Appendix A. A multi-step approach was used to develop search queries by identifying key terms for each category. Terms were refined based on whether or not the term added relevant articles to the search by comparing search queries. Assistance developing the database searches was provided by a trained Biomedical and Life Sciences Librarian. The search did not consist of hand searching for literature or unpublished literature, due to timing and the scope of the question.

(*)- Signifies a wildcard symbol used in an electronic database search.

Inclusion criteria

We included studies that analyzed the effects of rules and interventions on head impacts and brain injuries in American football, and included participants at the collegiate, high-school, or youth level.

Articles were included if they met the following criteria:

1. Original research: including randomized control trials (RCTs), quasi-experimental, cohort studies, case-control, and cross-sectional
2. Participants: American football- collegiate players, high-school players, youth players
3. Control Groups: Comparison group not receiving intervention or participating in rule change
4. Main Outcomes: Head injuries, head impacts, concussions
5. Additional outcomes: magnitude of head impacts, location of head impacts, unintended consequences
6. English Language

Exclusion criteria

Studies analyzing the effectiveness of protective gear, such as helmets, neck collars, and mouthguards were not included. Systematic reviews, meta-analysis, narrative reviews and articles not published in English were excluded from this review. In addition, articles that did not analyze the effect of an intervention on head impacts or concussions were excluded. Articles that collected injury data but did not separate the data by injury descriptions were not included. Studies that analyzed interventions aimed at increasing awareness about concussions were not included. Interventions in lab settings were excluded. Lastly, articles that analyzed more than one sport were not included, unless specific football data could be extracted.

Study selection and data extraction

The flow chart of study selections is depicted in Figure 1. A total of 1,192 articles were identified through database searches after duplicates were removed. One reviewer screened all title and abstracts using abstrackr, a software for semi-automatic citation screening, to identify articles that met inclusion criteria.[34] Articles that were unclear in initial title and abstract screens were included in a full text screen. Thirty-four articles were assessed in full text screens. If articles were still unclear after a full text screen a second reviewer reviewed the article and reviewers came to a conclusion. Data was extracted from articles that met eligibility criteria by one reviewer.

The following data from each study was extracted into an excel document: title, author, participant characteristics (age, sex, height, weight, football playing experience, sample size of intervention and control conditions), study design (type of study, aim, location, date, method of recruitment, length, football level), intervention and control/comparison group characteristics (type, details, delivery), data collection methods, outcome measures, outcome definitions, relevant findings, conflicts of interest, study limitations, and funding.

Data synthesis and risk of bias

The Risk Of Bias In Non-randomized Studies-of interventions (ROBINS-I) and Cochrane Risk of Bias tool for randomized trials (RoB 2) were used to assess the bias of the studies included in the study.[35,36] One reviewer assessed each article independently using the appropriate tool for the type of study. Researcher assessed the risk of bias in the following domains: bias due to confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, outcome measurements, selection of reported results. [35,36]

Results

Search results

A total of 1,692 articles were identified through searching databases and 1,192 articles remained after duplicates were removed. Duplicates were initially removed using the 'find duplicates' function in an electronic reference database, EndNoteX9, and then hand searched for additional duplicates after screening. After an initial screen of titles and abstracts, 34 articles were included for full text screens. Full text screens yielded 20 articles that met inclusion criteria for this review, see Figure 1 for study selection flow chart. Finalized studies were published in peer-reviewed journals between 2013 and 2020.

Of the 20 included studies, 8 studies evaluated interventions in high-school football,[37–44] 5 studies evaluated interventions in collegiate football,[45–49] 6 studies evaluated interventions in youth football,[1–6] and 1 study evaluated interventions in both, high-school and collegiate football.[50] Summaries of included articles for youth, high-school, and collegiate, football are presented separately in Table 1, Table 2, and Table 3 respectively. One article that met inclusion criteria was a protocol for a proposed clinical trial analyzing a neck strengthening (TRAIN) program in high-school and collegiate football players with no results, therefore was not included in a review table.[50]

Figure 1
PRISMA flow diagram[51]

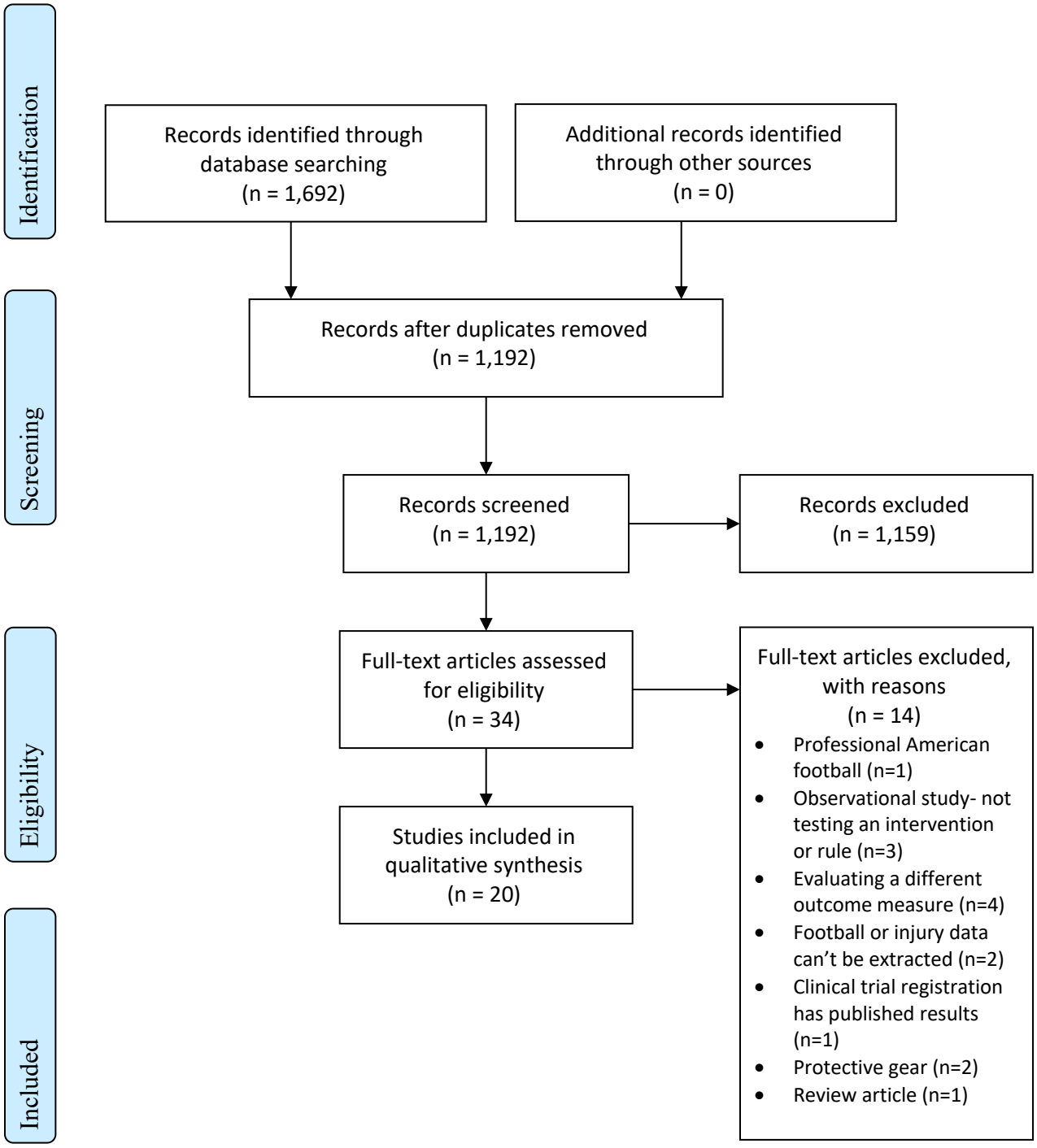


Table 1
Youth football interventions and regulations[1–6]

Citation(s)	Location	Sample	Study Design	Length of study	Intervention Type	Intervention Description	Outcome measures	Relevant findings
Kerr et al[6] (2015) Comprehensive Coach Education Reduces Head Impact Exposure in American Youth Football	US: South Carolina, Arizona	70 participants (HUF: 38, NHUF:32)	Cohort Study	1 FB season	Educational: HUF	Heads up football (HUF) leagues had an identified player safety coach that completed educational program which included training on proper equipment fitting, proper tackling technique, strategies for reducing player to player contact, concussion awareness, and sudden death information	- Head impact exposure using xPatch -Number of concussions and concussion rate	- More impacts occurred in the NHUF group (62%, 4637) vs. HUF group (38%, 2841) -6 total concussions: NHUF(6), HUF(0) however, differences between concussion rates between entire cohort of HUF and NHUF leagues not found - 8-11 year olds- mean number of impacts per practice per individual where higher in the NHUF group (9.1±3.3) compared with the HUF group (5.5±3.2 difference, 3.6; 95% CI, 2.9-4.3) - 12-15 year olds- mean number of impacts during practice per individual were higher in the NHUF (8.7±2.9) compared with HUF group (5.7±2.5; differences, 3.0; 95% CI 2.3-3.7) -At 10g and 20g threshold no difference between number of impacts per individual were found in games -10g threshold- number of impacts during practice per individual event was lower in HUF group (5.6±2.9) than in the NHUF group (8.9±3.1); difference 3.4 95% CI 2.9-3.9. This difference changed with 20g threshold but remained significant (difference 1.0 95% CI 0.7-1.3)
Toninato et al[2] (2019) Injury Rate in TackleBar Football	US: Minnesota, Wisconsin, Iowa	926 participants (intervention: 926, control: comparison to historical data)	Descriptive epidemiology study	1 FB season (2018)	Tackle football alternative: TackleBar	Nontackling alternative to tackle football where a player is considered down when a defensive player removes a foam bar from the ball carriers harness using the "wrap and rip" technique	- Number of concussions and concussion rate	-0 concussions reported; Concussion rate:0.00 per 1000 AE - Youth tackle: 0.99, 0.68 (per 1000 AE - Youth flag: 1.33 per 1000 AE
Lynall et al[3] (2019) A Comparison of Youth Flag and Tackle Football Head Impact Biomechanics	US: Not Specified	50 participants (Flag:25, Tackle:25)	Prospective Cohort Study	1 FB season	Tackle football alternative: Flag football	Nontackling alternative to tackle football where players have to remove a flag from a player instead of tackle	- Head impact exposure using Triax Smart Impact Monitors (SIM-G)	- Tackle football players experienced a significantly higher head IR during games, practices, and both combined. Impact rate (IR) tackle(overall): 3.06 (2.61, 3.58), IR flag(overall): 0.66 (0.57, 0.78), Impact rate ratio (95% CI): IRR (overall): 4.61(3.94, 5.40) - Flag reduced odds of sustaining linear acceleration head impacts among 20-29.99g (OR=0.28; 95% CI: 0.16, 0.51), 30-39.99g (OR=0.31; 95% CI: 0.17, 0.55) and >= 40g (OR=0.31; 95% CI: 0.17, 0.55) compared with tackle -Flag increased odds of sustaining rotational acceleration head impacts between 2500-7499.99 rad/sec^2 (OR=1.73 95% CI: 0.92, 5.67) compared with tackle
Peterson et al[4] (2017) Youth Football Injuries: A Prospective Cohort	US: Not Specified	3,794 participants (tackle: 3525, flag:269)	Prospective Cohort Study	1 FB season	Tackle football alternative: Flag football	Nontackling alternative to tackle football where players have to remove a flag from a player instead of tackle	- Concussion rate	- Tackle: 0.68, Flag:1.33 (concussions per 1000 exposures). Higher concussion rate in flag league than tackle, but this result is based on only 3 concussions in the flag league and is not statistically significant
Kerr et al[1] (Sep. 2015) Injury Rates in Age-Only Versus Age-and- Weight Playing Standard Conditions in American Youth Football	US: Arizona, Indiana, Massachusetts, Ohio, South Carolina, West Virginia	3167 participants (number of participants in each group not specific)	Prospective observational cohort	2 FB seasons	Rule change: team enrollment	Age- only (AO)- organized children by age (or grade in school). Age-weight (AW)- children may play with others of various ages if matched by some combination of age and weight	- Concussion rate	- The proportion of injuries that were concussions in the AO standard (12.9%) was 1.8 times that of the AW standard (7.2%; 95% CI, 1.3-2.5). -Found the concussion rate to be lower in the AW standard compared to the AO(RR, 0.6 95% CI, 0.3-1.4) However, this effect was minor relative to the imprecision of the estimate (confidence limit ratio, 4.7)

Table 1 Cont.
Youth football interventions and regulations[1–6]

Citation(s)	Location	Sample	Study Design	Length of study	Intervention Type	Intervention Description	Outcome measures	Relevant findings
Kerr et al[5] (Jul. 2015) Comprehensive Coach Education and Practice Contact Restriction Guidelines Result in Lower Injury Rates in Youth American football	US: Arizona, Indiana, Massachusetts, South Carolina	2108 participants (HUF+PW: 742, HUF only:663, NHUF: 704)	Cohort Study	1 FB season	Educational: HUF, Rule change: practice contact restriction	HUF leagues had an identified player safety coach - completed HUF training. Education -hands on training of equipment fitting, didactic and participant demonstration of proper tackling technique, strategies for reducing contact, didactic information regarding concussion, heat illness, recognition -Rule change in 2012: practice contact restrictions- No full-speed head-on blocking or tackling drills with players more than 3yds apart, amount of contact at practice reduced to max 1/3	- Number of concussions and concussion rate	- 45 total concussions: NHUF group (48.9%,22), HUF (35.6%, 16), HUF+PW (15.6%,7) -The HUF+PW practice concussion rate (0.19/1000 AEs) did not significantly differ from that of the NHUF group (0.59/1000 AEs; IRR 0.33; 95% CI, 0.11-1.02). -The HUF+PW practice concussion rate was lower than that of the HUF-only group (0.65/1000 AEs; IRR, 0.30; 95% CI, 0.09-0.96) - No statistical difference, when restricted to concussions in games

Table 2

High-school football interventions and regulations[37–44]

Citation(s)	Location	Sample	Study Design	Length of study	Intervention Type	Intervention Description	Outcome measures	Relevant findings
Swartz et al[37] (2019) A helmetless-tackling intervention in American football for decreasing head impact exposure: a randomized controlled trial	US: Not specified	180 participants initially enrolled-115 (59 WoH, 56 control) completed the study.	RCT	2 (11 week) FB seasons	Educational: The helmetless tackling and blocking intervention (HuTT; University of New Hampshire)	HuTT consisted of a 3-phase progression (Static, Dynamic, Functional) of 10 instructional drills performed without helmets and shoulder pads. Intervention sessions were 10min long - set of two drills. Pre-season (4 sessions per week) competition season (2 session per week).	- Head impact exposure using SmartImpactMonitors(SIM-G)	- Players in the WoH group experienced 26%-33% fewer game related ImpAE at two identical time points across both seasons -WoH participants had fewer ImpAE during games compared to control at weeks 4 (p= 0.0001 season 1, p=0.0005 season 2) and 7 (p=0.0001 both seasons) -WoH participants also had fewer ImpAE at week 7 during training (p=0.015) versus control in season 1
Broglio et al[38] (2016) Football Players' Head-Impact Exposure After limiting of Full-Contact Practices	US: Michigan	41 participants-(26 before rule change, 24 after rule change) 9 participated in both years.	Cross-sectional study	2 FB seasons (2013, 2014)	Rule change: Statewide restriction on full- contact practices	"After the 1st regular-season game, teams may conduct no more than 2 collision practices" the preseason rule was unchanged- "Before the first regular-season game, schools may not schedule more than 1 collision practice in a day."	- Head impact exposure using Head-Impact Telemetry system (HIT) -Number of concussions	- Average athlete sustained 592± 391 impacts during 2013, compared with 345± 236 in 2014. - Head impact exposure declined by 41.8% between seasons, with a 52.9% decline during practices and 24.8% decline during games - 8 concussions over the 2 years: 3 diagnosed in 2013 and 5 in 2014. The small case does not allow for conclusions -no change in mean impact magnitude between 2013 and 2014 -Impact rates to the front, back, and side declined
Kerr et al[39] (2016) Comparison of Indiana High School Football Injury Rates by inclusion of the USA Football "Heads Up Football" Player Safety Coach	US: Indiana	390 participants-(PSC group-204, EDU group-186)	Cohort Study	1 FB season (2015)	Educational program: HUF	Coaches completed the football-specific coaching education course, and the HUF certification course comprised of 4 modules: concussion, heat and hydration, cardiac arrest, and proper tackling, blocking and equipment fit. The PSC schools had an identified individual that participated in the in-person training program with a master trainer.	- Number of concussions	-17 concussions were reported comprising 11.4% of all injuries - EDU group (88.2%, n=15/17) as compared with the PSC group (11.8%, n=2/17) -In practice, when restricted to concussions only the IRR was lower in the PSC group (0.09 vs. 0.73/1000 AEs; IRR, 0.12 95% CI 0.01-0.94) - In games, when restricted to concussions only the IRR was not significantly different PSC vs. EDU group (0.60 vs 4.39/1000 AEs, IRR, 0.14; 95% CI, 0.02-1.11)
Combs et al[40] (2019) Biomechanic Data-Driven Behavior Modification to Reduce Concussion Risk in High-School Football Athletes	US: Not specified	220 participants (143 intervention; 77 control): 32 classified as high-risk participants	Clustered quasi-experimental (Abstract)	3 FB seasons	Educational program: tackling behavioral	High-risk players attended 3 individual or small group-education sessions over 3 weeks with a mentor who analyzed game film to teach better playing techniques	- Head impact exposure using in helmet accelerometers	- 53% of mentored athletes demonstrated a reduction in high magnitude impacts (>60g) - In mentored players, proportion of head impacts classified as high magnitude dropped 1.07% vs. <1% in non-mentored - 66% of mentored athletes demonstrated a reduction in top-of-head impacts - On average top-of-head impacts dropped 2.75% in mentored athletes and 2.04% in non-mentored
Champagne et al[41] (2019) Data-informed Intervention Improves Football Technique and Reduces Head Impacts	Canada: Not specified	70 participants-(participated in baseline measurements and after intervention): 19 participants agreed to wear helmet accelerometers	Experimental Study	1 FB season (practice only)	Educational program: tackling behavioral	Data-informed behavioral intervention designed to improve both blocking and tackling techniques. Used film analysis from baseline assessment after MID season to help catalyze performance improvement	- Head impact exposures using gForce Tracker	- 30% decrease in total frequency of impacts per session in practice 1 month after introduction of intervention - No difference in cumulative rotational velocity(g): Pre-4047.46±1838.71, Post-3789.98±2170.24 (P=0.6378) - Average cumulative linear acceleration(g) decreased: Pre-272.19±112.78, Post-186.10±80.98 (P=0.0037)
Shanley et al[42] (2019) Heads Up Football Training Decreases Concussion Rates in High School Football Players	US: South Carolina	2,514 participants-(HU: 1818, NHU: 696)	Prospective cohort	2 FB seasons (2015, 2016)	Educational program: HUF	One coach from each HU trained school completed US football safety standards-Heads Up (HU) teaches all aspects of player safety-including proper tackling and blocking techniques	- Number of concussions and rate of concussions	- The risk of an SRC was 1.5 times (95% CI, 1.1-2.1) or 32% lower for players in HU vs. the NHU (4.1 vs. 6.0/ 100players) - In entire cohort- games (61) vs. practice (56) the rate ratio (1.1; 95% CI, 0.73-1.5), however was not significant - SRCs in practice significantly greater in NHU vs. HU (RR=1.9; 95% CI, 1.1-3.2)

Table 2 Cont.
High-school football interventions and regulations[37–44]

Citation(s)	Location	Sample	Study Design	Length of study	Intervention Type	Intervention Description	Outcome measures	Relevant findings
Pfaller et al[43] (2019) Effect of a New Rule Limiting Full Contact Practice on the Incidence of Sport-Related Concussion in High School Football Players	US: Wisconsin	3232 participants- (2287 players in 2012-2013, 945 players in 2014)	Cohort Study	3 FB seasons (2012, 2013 seasons-before rule change, 2014-after rule change)	Rule Change: limiting contact during practice	Competition/full contact was not allowed in the first week and was limited to 75minutes in week 2 (excluding a scrimmage), and to 60min per week (excluding games) in week 3 and beyond	- Number of concussions and rate of concussions	- The rule change resulted in 57% decline in concussions in practices -Concussion incidence was significantly greater in practice during the 2012-2013 seasons (0.76 per 1000 AEs), before the WIAA rule change, than during the 2014 season (0.33 per 1000 AEs), after the rule change (P=0.003). - The competition concussion rate was not changed (5.74 per 1000 AEs in 2014 and 5.81 per 1000 AEs in 2012-2013, P=0.999)
Martini et al[44] (2013) Subconcussive Head Impact Biomechanics: Comparing Differing Offensive Schemes	US: Michigan, Illinois	83 participants- (RFO: 42, PFO: 41)	Cohort Study	2 FB seasons (Illinois-2009) (Michigan-2011)	Educational: Coaching tactical change	The two different offensive schemes consisted of a run first offense (RFO) and a pass first offense (PFO)	- Head impact exposures using HIT	-RFO practices: 8.10±4.83 per player, games: 21.65±18.53 per player; t=-4.59, p<0.05. PFO practices: 4.16±3.15 per player, games: 16.33±19.60 per player; t=-3.93, p<0.05. Significant difference in average number of impacts per practice between RFO and PFO t=4.42, p<0.05. However, head impact frequency during games did not differ between the RFO and PFO -PFO linear accelerations across season greater vs. RFO (28.56±17.84 g vs. 25.67±15.30; t=-16.08, p<0.05).

Table 3

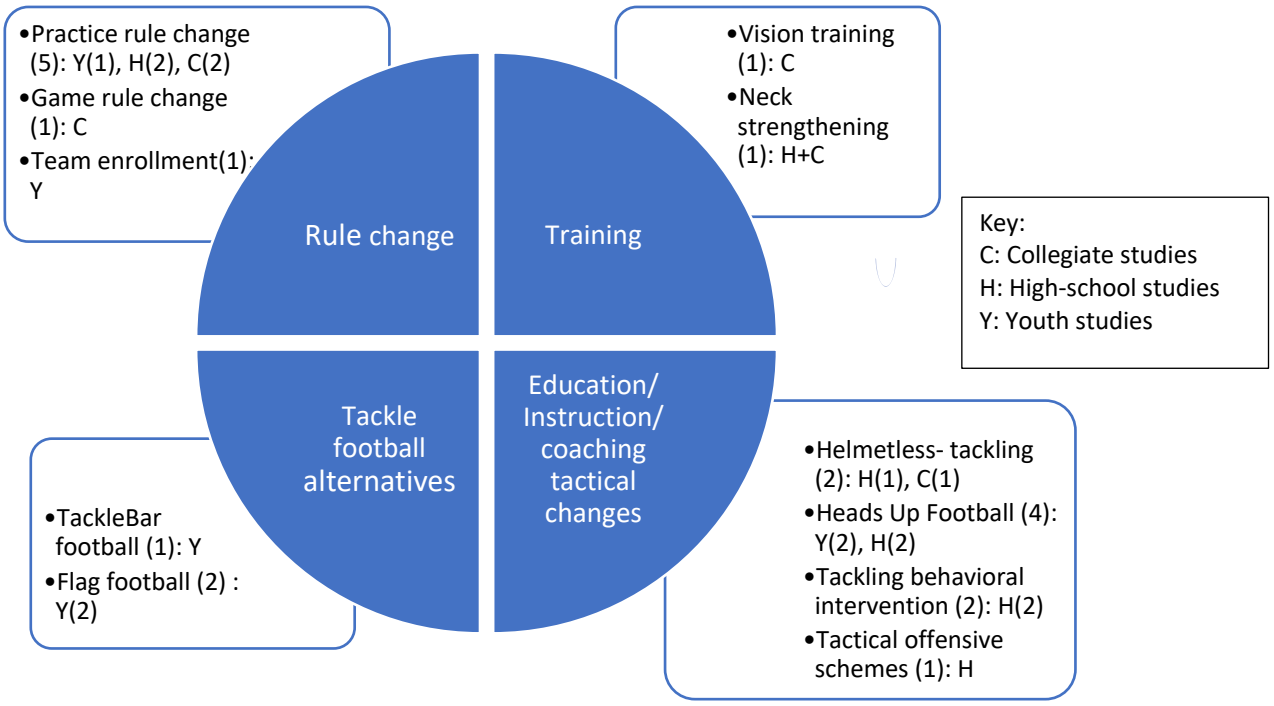
Collegiate football interventions and regulations[45–49]

Citation(s)	Location	Sample	Study Design	Length of study	Intervention Type	Intervention Description	Outcome measures	Relevant findings
Swartz at al[45] (2015) Early results of a helmetless-tackling intervention to decrease head impacts in football players	US: Not Specified	50 participants (Intervention: 25, Control: 25)	RCT	2 FB seasons (2014, 2015) only results from 2014	Educational: Helmetless-tackling	The intervention group participated in a drill of approx 5min w/o helmets and shoulder pads. Drills twice per week during preseason (3weeks) and once per week during season (16 weeks)	- Head impact exposure using xPatch	- End of 1st season: intervention resulted in a 28% reduction in head-impact frequency per AE, the control groups head impacts remained the same (9.99± 6.10 and 13.84±7.27; P=0.009). -The intervention group average of 30% fewer impacts per AE than the control group (9.99± 6.10 and 14.32±8.45; P=0.045)
Stemper et al[46] (2019) Repetitive head impact exposure in College football following an NCAA rule change to eliminate two-a-day preseason practices: A study from the NCAA-DoD CARE Consortium	US: Colorado, New York, North Carolina, Wisconsin, Virginia	342 participants (before rule change: 225, after rule change: 235) some participated in both seasons	Cohort Study	2 FB seasons (2016-before rule, 2017- after rule)	Rule change: restriction on preseason practice	2017- Rule change eliminated 2-a-day preseason practices	- Head impact exposure using HIT systems -Number of concussions	- Overall, athletes sustained an average of 26% more head impacts during the preseason in 2017, and 20% fewer total head impacts during the 2017 regular season($p<0.05$) - 37 concussions: 2016-17, 2017-20, not statistically significant - Preseason contact intensity per athlete increased by 10.8% from 2016 (9.3±6.3 impacts per hour) to 2017 (10.3±6.9 impacts per hour)
Wiebe et al[47] (2018) Association Between the Experimental Kickoff Rule and Concussion Rates in Ivy League Football	US: Rhode Island, New York, New Hampshire, Massachusetts, Pennsylvania, New Jersey, Connecticut	Not specifically mentioned-each Ivy League team has about 100 players	Cohort Study	5 FB seasons (2013, 2014, 2015 - before rule), (2016, 2017- after rule)	Rule change: restriction on game rules	2016 rule change-kickoff line was moved from the 35 yd to the 40 yd line, and the touchback line was moved from the 25yd line to the 20yd line	- Number of concussions and concussion rate	- Mean annual concussion rate per 1000 plays during kickoff plays was 10.93 before the rule change and 2.04 after the rule change (difference, -8.88; 95% CI, -13.68 to -4.09) -159 total concussions (126 before and 33 after rule change) - 7.51 fewer concussions (95% CI, -12.88 to -2.14) occurred for every 1000 kickoff plays after vs. before the rule change
Clark et al[48] (2015) An Exploratory Study of the Potential Effects of Vision Training on Concussion Incidence in Football	US: Ohio	Not specifically mentioned-All University of Cincinnati football team members from the 2006 to the 2013 seasons. 2006: 103, 2007:102 2008: 103, 2009: 109, 2010: 113, 2011: 110, 2012: 109, 2013:105	Retrospective analysis	8 FB seasons (2006, 2007, 2008, 2009-before training) (2010, 2011, 2012, 2012-intervention)	Training: Vision training	During football camp (2.5 weeks) camp players had approx 40min of vision training per day, 6 or 7 days a week. 20 min of dynavision, 7-10min of tachistoscope, 7-10min of Pinhole glasses. During season a maintenance phase using dynavision for 10min	- Number of concussions and concussion rate	- 41 total concussions (35 before and 6 after vision training) -Vision training- 1.4 concussions per 100 player seasons -No vision training- 9.2 concussions per 100 game exposures - Average number of concussions per season: 8.75±1.7 before vision training, and 1.5±1.0 after vision training
Stemper et al[49] (2020) Head Impact Exposure in College Football following a Reduction in Preseason Practices	US: Colorado, New York, North Carolina, Wisconsin, Virginia	334 participants: 2017: 225, 2018: 201. Some players participated in both seasons	Cohort Study	2 FB fall preseasons (2017, 2018)	Rule change: preseason practice restriction	The NCAA in 2018 reduced the total number of allowable preseason on-field practices from 29 to 25	- Head impact exposure using HIT system	- 2017: 47,304 preseason head impacts, 2018: 40,900 preseason head impacts. Statistically significant based on team and position group ($p<0.0001$) - Two teams demonstrated statistically significant increase in the number of recorded head impacts per day from 2017 to 2018 -The number of head impacts per athlete was not significantly different between seasons a median of 174 head impacts (2017) and a median of 161 head impacts (2018) -Team-by-team differences in preseason head impact burden

The types of interventions and regulations studied in articles that met inclusion criteria can be categorized into 4 groups: rule changes, training, education/instruction/coaching tactical changes, and tackle football alternatives. Figure 2 depicts the categorization of studies by intervention and regulation. Seven studies evaluated the effectiveness of rule changes,[1,5,38,43,46,47,49] two studies evaluated the effectiveness of training programs,[48,50] 9 studies evaluated the effectiveness of education/ instruction/ coaching tactical changes,[5,6,37,39–42,44,45] and 3 studies evaluated the effectiveness of alternatives to tackle football.[2–4]

Of the 7 studies that evaluated the effectiveness of rule changes, 5 articles assessed rule changes targeting practice conditions,[5,38,43,46,49] 1 article evaluated rule changes targeting game conditions,[47] and 1 article analyzed the difference between rules for player enrollments.[1] Two alternatives to tackle football were evaluated in studies that met inclusion criteria. These alternatives included TackleBar football and flag football. Players in TackleBar football use the "wrap and rip" technique to remove a bar from the opponents waistline in order for the player to be considered down.[2] In flag football, instead of tackling, players remove a flag from the opponents waistline. One study evaluated the effectiveness of TackleBar football,[2] and 2 studies evaluated the effectiveness of flag football.[3,4] Of the 9 studies that evaluated the effectiveness of education/ instruction/ coaching tactical changes, 4 studies evaluated USA football's Heads Up Football (HUF) program,[5,6,39,42] 2 studies evaluated a Helmet-less Tackling Training (HUTT) Program,[37,45] 2 studies evaluated different tackling behavioral interventions,[40,41] and 1 study evaluated the difference between offensive coaching tactics.[44] Lastly, of the two studies that evaluated the effectiveness of training programs, 1 study evaluated a vision training program,[48] and 1 study was a protocol for a neck strengthening program (TRAIN).[50]

Figure 2
Intervention categories of included studies



Note: There are 21 articles because one article had more than one intervention[5]

Studies analyzing effectiveness of youth football interventions or regulations

Study location: All 6 studies were conducted in the United States across different states including: Arizona (n=3), Indiana(n=2), Massachusetts(n=2), South Carolina(n=3), West Virginia(n=1), Ohio(n=1), Minnesota(n=1), Wisconsin(n=1), and Iowa(n=1).[1–6] Two studies did not specify which state in the U.S.[3,4]

Participants: A total of 10,115 youth football players participated in studies included this review, however some studies that used historical data as a comparison did not mention number of participants. Out of 10,115 youth football players, 2,663 participants participated in the

intervention and 4,286 participants were in control or comparison groups. The number of participants in respective groups does not add up to the total number because some studies did not specify groups. Toninato et al[2] did not mention number of participants in the comparison group and Kerr et al[1] did not specify the number of participants in either group. Player experience, prior years played, was not mentioned in any of the included studies.

Study design: Six studies analyzed the effectiveness of interventions or regulations on head impacts or head injuries in youth football and were included in this review: 5 cohort studies and 1 descriptive epidemiology study.[1–6] Of the 5 cohort studies, 3 were prospective cohort studies.[1,3,4] Participant recruitment varied between study designs. Toninato et al[2] collected data from teams with players that played TackleBar football. Lynall et al[3] recruited players that either played tackle football or flag football and had individuals consent to be in the study. Peterson et al[4] recruited 3 football leagues (2 tackle leagues and 1 flag league). Kerr et al[1] (Sep. 2015) recruited teams that met certain requirements, such as age, located within 30 miles of the university or health care system providing athletic trainer, and had multiple game fields close to allow access for athletic trainers. Kerr et al[5] (Jul. 2015) also enrolled teams based on criteria such as, leagues completing required education or identifying as having no policy or procedure for educating coaches, and having game fields centrally located so athletic trainers could attend. Lastly, Kerr et al[6] (2015) recruited leagues that either completed the educational program or identified as not having policy for educating coaches, and participants consented to be a part of the study.

Length of study: A majority of studies in this age group were conducted over the course of 1 football season. Only one study analyzed 2 football seasons, following teams for both seasons.[1] None of the interventions were studied long-term.

Intervention: The interventions that were analyzed in articles that met inclusion criteria were diverse. Three studies evaluated alternatives to tackle football,[2–4] one study evaluated an educational program,[6] one study evaluated a rule change,[1] and one study evaluated an educational program and rule change.[5] Alternatives to tackle football that were studied included flag football and TackleBar football, of which two studies analyzed flag football.[3,4] Heads Up Football (HUF) educational program was evaluated in two studies.[5,6] In addition to evaluating the HUF educational program, Kerr et al[5] (Jul. 2015) also assessed the effectiveness of a rule change that targeted contact practice restrictions. Players were not allowed to participate in full speed head-on drills with players more than 3 feet apart.[5] In addition contact practice was restricted to a max of 1/3 of practice time.[5] An additional rule that was evaluated addressed how players were enrolled for different teams, age-only (AO) vs. age-weight (AW).[1]

Control/ comparison group: For two of the six studies, comparison groups consisted of players on tackle football teams that had coaches that did not receive formal educational training.[5,6] The three studies that evaluated alternatives to tackle football, utilized tackle football players as a comparison. Kerr et al[1] (Sep. 2015) compared tackle football teams that had different player enrollment rules, AO vs. AW.

Outcome measures: As shown in Table 1, all studies assessed the effectiveness of interventions or regulations on head impacts and injuries using the following outcome measures: head impact exposures, number of concussions, and concussion rates. A majority of studies for youth football evaluated outcomes using number of concussions, and concussion rates as outcome measures. Only two studies measured head impact exposures. Lynall et al[3] measured head impact exposures using Triax Smart Impact Monitors (SIM-G) (14g threshold). Kerr et al[6] (2015) used xPatch accelerometers (10g threshold) to measure head impact exposures. Athletic trainers helped record

and report concussions for three out of the five studies that reported concussion data.[1,5,6] Two studies utilized team personnel, such as the head coach or assistant coach to record injuries.[2,4]

Preliminary intervention effects/ main findings: Of the two studies analyzing the effectiveness of flag football as a safer alternative to tackle football, Peterson et al[4] found that although the concussion rate was higher in flag football it was not statistically significant. Results from Lynall et al[3] showed that tackle football players had a higher head impact ratio during games, practices, and both combine than flag football players.[3] However, flag football in comparison to tackle football players had increased odds of sustaining rotational acceleration head impacts between 2500-7500 rad/sec^2 and reduced odds of sustaining higher magnitude impacts.[3] TackleBar football was another alternative to tackle football that was studied and included in this review. Results showed that the overall injury rate, any injury occurring in practice or a game requiring the attention of a coach or trained professional that required an athlete to sit out, was higher in tackle football. [2] In addition, the rate of concussions in TackleBar football players was lower than the rate in tackle football, 0/1000 athletic exposures (AE) and 0.68/1000 AE, respectively.[2]

The Heads Up Football (HUF) educational program was evaluated in two studies that utilized different approaches. Kerr et al[5] (Jul. 2015) results found that the concussion rate was not statistically different when restricted to games only. The game concussion rate for the intervention group with practice restrictions (HUF+PW), intervention group (HUF), and nonintervention group (NHUF) were 0.68/1000 AE, 1.50/1000 AE, and 1.46/1000 AE, respectively.[5] However, the HUF+PW group had a lower practice concussion rate, 0.19/1000 AE, than the intervention group with only HUF, 0.65/1000 AE.[5] The concussion rate of those in NHUF was 0.58/1000 AE.[5] Kerr et al[6] (2015) also evaluated the HUF program, but included head impact data as well as concussion data. Results from this study indicated that more impacts occurred in the NHUF group (62%, 4637)

than the HUF group (38%, 2841), however when impacts were restricted to games there was no difference between the number of impacts per individual.[6] Although there was a total of 6 concussion in the NHUF group and 0 concussions in the HUF, researchers found that there was no difference between concussion rates when including all players in both leagues.[6]

Lastly, Kerr et al[1] (Sep. 2015) found that concussion rates to be lower in teams organized by age-weight (AW) standards (0.8/1000AE) than age-only (AO) standards (1.2/1000 AE), but this effect was minor.

Studies analyzing effectiveness of high-school football interventions or regulations

Study location: Studies analyzing the effectiveness of football interventions and regulations on head impacts or head injuries for high-school participants were conducted across states in the United States (n=7) and in Canada(n=1) including: Michigan(n=2), Indiana(n=1), South Carolina(n=1), Wisconsin(n=1), and Illinois(n=1).[37–44] Two studies in the U.S. and one study in Canada did not specify states.[37,40,41]

Participants: A total of 6,665 high-school football players participated and completed trials included in this review. Out of the 6,665 participants, 4,647 players were in intervention groups, while 2,097 participated in control/comparison groups. The total number of participants in the different groups does not add up to the total number of participants because two studies had participants that were part of both groups.[38,41] Number of participants included in each study varied remarkably, with a range of 41- 3,232 participants. Only one study accounted for players previous playing experience, mentioning that there was no difference amongst players' experience.[43] Swartz et al[37] mentioned participants playing level (upper-level, entry-level) at the time of enrollment but did not account for the difference in number of years players had been playing football.

Study design: Eight studies evaluated the effectiveness of interventions or regulations in high-school football and were included in this review: one randomized controlled trial (RCT), four cohort studies, one cross-sectional study, one clustered quasi-experimental study, and one experimental study. [37–44] The methods used to recruit teams and participants varied across experimental designs. Shanley et al[42] recruited teams that met certain criteria. Teams had to have a minimum of one athletic trainer, a fellowship-trained primary care sports medicine physician, and receive medical care within the Greenville Hospital System Athletic Training Network.[42] Swartz et al[37] recruited football participants in a group setting amongst entry-level and upper-level teams with at least two years of eligibility and then randomized participants to either the intervention or control group. Broglio et al[38] enrolled participants from one school that were part of a larger multiyear study. Kerr et al[39] recruited high-schools that met the following criteria, located in Indiana, had a high-school football program, and had one athletic trainer. One article only had an abstract published, therefore recruitment information for this study was missing.[40] Champagne et al[41] enrolled participants who consented and no other information was provided in the study. Pfaller et al[43] recruitment consisted of a convenience sample of high schools with players that were on one of the school's interscholastic football teams. Lastly, Martini et al[44] recruited varsity football players from two different schools that had different offensive schemes, pass first offense (PFO) vs. a run first offense (RFO).

Length of study: The length of study for each article varied but was relatively short for all included studies. Study range consisted of 1-3 football seasons. However, length of study does not mean that all participants in both groups were followed for that amount of time. For example, Broglio et al[38] reported data from 2 football seasons, however the first football season was data from participants before the rule change and the second season was data from participants after the rule

change. Only nine players participated in both seasons.[38] The length of study for Pfaller et al[43] was 3 football seasons, however the study followed participants before the rule change for 2 football seasons and participants after the rule change for 1 football season. The length of study for Martini et al[44] was 2 football seasons, but participants in each group were only followed for 1 season. On the other hand, three studies followed their participants in both groups for multiple seasons. Two studies, Shanley et al[42] and Swartz et al[37] followed all participants for 2 football seasons. Combs et al[40] followed participants in the intervention and control groups for 3 football seasons. Champagne et al[41] and Kerr et al[39] followed all participants for 1 football season.

Intervention: The interventions studied in these articles were diverse. Of the 8 studies, 6 studies implemented educational interventions,[37,39–42,44] and 2 studies analyzed the effectiveness of rule changes.[38,43] Only one study randomized participants to the intervention arm of the study.[37] Rule changes in both studies targeted limiting the number of full contact practices.[38,43] Kerr et al[39] and Shanley et al[42] analyzed the effectiveness of USA Heads Up Football (HUF) program. Although both studies analyzed the effectiveness of HUF, Kerr et al[39] analyzed a certain aspect of the HUF program, the inclusion of a player safety coach (PSC). Two studies used data-informed/ data-driven behavioral interventions to improve football techniques.[40,41] Swartz et al[37] implemented a helmetless tackling and blocking intervention (HuTT) and Martini et al[44] analyzed the difference between offensive coaching tactics, a run first offense (RFO) vs. a pass first offense (PFO). The delivery of intervention varied across studies; including trained coaches and research personnel. Rule changes during practices were expected to be upheld by coaches of teams participating.

Control/comparison group: All eight studies used a comparison or control group, with only one study randomizing participants.[37] Control or comparison groups included participants before a rule change, participants participating in football related training as normal, participants on teams with

different offensive schemes, and participants on teams with coaches that did not receive educational training.

Outcome measures: As shown in Table 2, all studies assessed the effectiveness of rule changes or educational interventions using the following outcome measures: head impact exposures, number of concussions, concussion rates, or a combination of these outcomes. Head impact exposures were measured using different accelerometers. Two studies collected data using the Head-Impact Telemetry (HIT) system (threshold 10g),[38,44] one study used SmartImpactMonitors (SIM-G)(threshold of 10g),[37] one used the gForce tracker (threshold of 15g),[41] and one did not mention the type of helmet accelerometer.[40] Validation of head impact exposures and impact thresholds also varied across studies. None of the studies measuring head impacts used video validation to validate impacts. Concussion definitions and methods studies used to collect concussion data were not consistent. Athletic trainers were utilized in three studies to diagnose and report concussions,[39,42,43] and one study was not specific.[38]

Preliminary intervention effects/ main findings: Two studies analyzing the effectiveness of HUF on head injuries found that the number of concussions were lower in the intervention group.[39,42] However, Kerr et al[39] found that this difference was not significant when restricted to games and Shanley et al[42] found that sports-related concussions in practices were significantly greater in the control group. Of the two studies analyzing rule changes, Broglio et al[38] found that no conclusions were able to be drawn about the effectiveness of the rule change on limiting number of concussion due to the small number of concussions, but did find that head impact exposures declined by 41.8% in the intervention group. On the other hand, Pfaller et al[43] found that the rule change resulted in a 57% decline in concussions in practices. Swartz et al[37] demonstrated that a HuTT could reduce frequency of head impacts in games. Data-informed/ data-driven educational interventions in

Champagne et al[41] and Combs et al[40] demonstrated different results. Champagne et al[41] results signified that there was a reduction in total frequency of impacts per season in practices. More than half of the mentored athletes in Combs et al[40] showed reductions in high magnitude impacts above 60g . Martini et al[44] found that differences in number of impacts per player during practices exists between a run first offense(RFO) vs. a past first offense(PFO). Players on teams with RFO had a significantly greater number of impacts during practices than players part of a PFO.[44]

Studies analyzing effectiveness of collegiate football interventions or regulations

Study location: All studies analyzing the effectiveness of collegiate football interventions or regulations on head impacts or head injuries for collegiate players were conducted in states across the United States including: Colorado(n=2), New York(n=3), North Carolina(n=2), Wisconsin(n=2), Virginia(n=2), Rhode Island(n=1), New Hampshire(n=1), Massachusetts(n=1), Pennsylvania(n=1), New Jersey(n=1), Connecticut(n=1), and Ohio(n=1).[45–49] Swartz et al[45] (2015) did not specify state location.

Participants: A total of 726 collegiate football players participated and completed studies included in this review, however this number is not fully representative of all players because two studies did not mention the total number of participants in the study. Clark et al[48] specified the number of players by year, however it is unclear whether players participated in multiple years. Wiebe et al[47] mentioned each team had approximately 100 players but was not specific to be able to include in the total. Of the 726 players, 461 players were in intervention groups, while 475 participated in control/intervention groups. The number of players in each group does not add up to the total number of players because some participants were in both groups. Players previous playing experience was not mentioned.

Study design: Five studies analyzed the effectiveness of intervention or regulations on head impacts or head injuries in collegiate football.[45–49] The types of study designs varied across interventions and regulations. As shown in Table 3, study designs included one RCT, three cohort studies, and one retrospective analysis. [45–49] Only one study design randomized participants. Swartz et al[45] (2015) stratified participants by position and then randomized players to the intervention or control group.

Length of study: The 5 articles varied significantly on the length of study. Length of study ranged from 2-8 football seasons. However, as previously mentioned the length of study does not mean that all participants were followed for the total length of study. Swartz et al[45] (2015) followed participants for 2 football seasons, however only 1 season of results have been published. Stemper et al[46] (2019) and Stemper et al[49] (2020) followed participants for 2 football seasons, however not all players participated in both years. One study followed players for 8 football seasons, but the study did not mention whether players participated during multiple years and researchers retrospectively collected data for the 4 seasons before the intervention was implemented.[48]

Intervention: Of the five studies, three articles evaluated the effectiveness of a rule change on head impacts or head injuries.[46,47,49] Two rule changes in this age group targeted preseason practices and one rule change adjusted the playing conditions for games. [46,47,49] Swartz et al[45] (2015) studied the effectiveness of a helmetless tackling intervention. Clark et al[48] evaluated the effectiveness of a vision training intervention at limiting the number of concussions. Rule changes during practice were expected to be incorporated by coaching staff and rule changes during games were upheld by the league and referees. Interventions were implemented by trained coaches and in one study, Swartz et al[45] (2015), principal investigators were also present for each intervention.

Control/ comparison group: Three of the five studies had participants in control/ comparison groups that played under old rules before a rule change. The last two studies had comparison groups that consisted of players that did not receive training or players that would complete placebo, non-contact football skills for the same length as intervention participants.

Outcome measures: As shown in Table 3, all studies assessed the effectiveness of intervention or regulations on head impacts or head injuries using outcome measures such as head impact exposures, number of concussions, concussion rates, or a combination of these outcomes. Two types of impact sensors were used to measure head impact exposures. Swartz et al[45] (2015) used xPatch head impact sensors (threshold of 10g) and two studies collected head impact data using the Head-Impact Telemetry (HIT) system (threshold 9.6g).[46,49] Studies that reported concussion data were collected by athletic trainers.

Preliminary intervention effects/ main findings: Stemper et al[46] (2019) and Stemper et al[49] (2020) both evaluated preseason rule changes; however, these rule changes were different and thus had different results. Stemper et al[46] (2019) discovered that a rule eliminating 2-a-day preseason practices did not reduce the number of head impacts. Overall, athletes sustained an average of 26% more head impacts during preseason after the rule change.[46] The difference between number of concussions was not significant.[46] Stemper et al[49] (2020) found that a rule eliminating the total number of allowable preseason practices had mixed results across teams. Another rule change that was evaluated in this age group was a rule change that targeted games. In 2016, an experimental rule was implemented in Ivy League football moving the kickoff line and touchback line.[47] This rule change resulted in a reduction in the mean annual concussion rate per 1000 plays.[47] Clark et al[48] results indicated an association of a decrease in the number of concussions amongst football

players that performed vision training exercises. Lastly, early results from a helmetless tackling intervention resulted in a reduction of head impact frequencies per athletic exposures.[45]

Evaluation of Risk of Bias

Out of the 20 studies that met inclusion criteria, 17 articles were assessed for risk of bias. Three studies were not assessed for risk of bias because one study was an abstract with not enough information,[40] one was a protocol,[50] and one was a descriptive epidemiology study.[2] The full assessments using the tool for risk of bias can be found in supplemental Appendix B. Of the 17 articles. Of the 17 articles, 15 were non- randomized trials and were assessed using the (ROBINS-I) tool.[36] Two randomized controlled trials were evaluated using the RoB 2 tool.[35] Results indicated that of the 15 non-randomized studies; 7 were assessed as critical risk of bias,[3–6,41,44,48] 3 as serious risk of bias,[38,39,46] and 5 as moderate risk of bias.[38,39,43,47,49] Both randomized controlled trials that met inclusion criteria for this study had high risk of bias.

Discussion

The number of head injuries in American tackle football is concerning. Prevention of concussions in tackle football have been the primary target of interventions and regulations; however, due to the growing concern of subconcussive impacts and the development of newer technologies measuring head impact exposures, interventions and regulations are now targeting impact exposures as well. This study highlights the effectiveness of previous and current avenues of regulations and interventions in youth, high-school, and collegiate football.

Studies have shown mixed results regarding the extent interventions and regulations can reduce head impact exposures. For example, a reduction in preseason practices, as mentioned previously, showed differences in head impact exposure amongst teams.[49] Some teams showed a decrease in the average of head impact exposure, while another team, under the same regulation

showed an increase in daily impact exposure. Variability in the reduction of head impact exposures may be attributed to different sensors being used to measure head impact exposures and confounding domains. In addition, daily head impact exposures have been found to be influenced by many variables including, practice duration, contact intensity, and time spent performing high risk practice drills.[52] This might suggest a need for rules that are inclusive and can directly target the variables that influence daily head impact exposures on a team basis.

Head impact exposures measured in the studies included in this review were measured with not only different devices, but also devices that have variable threshold values, and devices with different measurement errors. In addition, some studies verified impacts with video validation while others failed to do so. A systematic review of head impact measurement devices found that measurement error with nonhelmeted devices was, "as high as 50% for peak resultant linear acceleration and angular acceleration."[53] One of the RCT included in this review measured head impact exposures with this device (xPatch), therefore results from this study have a high risk of bias, which was found to be true in risk of bias assessment.

The threshold values of devices used in this study ranged between 9.6g-15g. While 5g is a small percentage of the range seen, most impacts for tackle football players are found in this range with a median of 19g for youth football players.[54] Therefore, it makes it difficult to interpret results together across studies. Standardization of the threshold may help to be able to synthesize results for a better understanding of the effectiveness of regulations.

Due to many confounding domains that may have influenced outcomes, the risk of bias was relatively high for each study included in this review. Risk of bias tool assessed domains of bias including study design, conduct, and reporting.[35,36] Therefore, results must be cautiously interpreted. Five confounding domains that may have influenced intervention outcomes include

players previous playing experience, previous concussion history, perception of risk and coaches coaching experience and perception of risk. The extent to which these confounding domains may have influenced the results is unknown. A known previous concussion history has been identified as a risk factor for subsequent concussions.[55]

To our knowledge, to date there have been no studies that have evaluated the effectiveness of a rule change on head impacts over multiple years after implementation. In addition, many of the current studies that analyze rule changes fail to follow the same participants before the rule change and after the rule change. For example, Broglio et al[38] did not follow the same participants therefore contributing to potential risk of bias. Future studies should try to implement these changes in their design. In addition, some regulations have already been implemented, but the effectiveness of these regulations have not been studied or published in research papers.

Limitations

There were a number of limitations associated with conducting this review. The first limitation of the present review was the number of reviewers. Only one reviewer screened articles, extracted data, and evaluated the risk of bias for each article. The Institute of Medicine does not recommend a single reviewer for a systematic review due to potential biases.[56] Although, this study has some characteristics of a systematic review, it ultimately falls short of a traditional systematic review and therefore, should be categorized as a systematized review.[57] Potential biases in this review may be present in article selection, analysis, and evaluation of risk of bias. A second reviewer was only consulted for further review when inclusion and exclusion was unclear for an article during a full text screen. Another limitation during the literature search, while systematized, was that a hand search was not performed, and only English language articles were included. This may be a limitation because some relevant articles could have been missed. However, relevant

articles were likely to appear in the six databases that were searched. In addition, the majority of American football is played in the United States, therefore studies are likely to be in English.

Similar to the limitations of a previous systematic review of concussion prevention strategies, a limitation of this review was the methodological quality of studies included in this review.[33] Only a select few articles were randomized controlled trials, which presents obstacles for synthesizing and interpreting results.[33] The limitations of this present study highlights the need for high-quality methodological studies evaluating the effectiveness of interventions and/or regulations on head impacts and head injuries in youth, high-school and collegiate tackle football.

In addition, due to the lack of long-term studies following participants, the relationship between frequency, magnitude, and location of impacts and long-term neurocognitive health is not well understood.[44] Long-term studies following individual football players may be valuable to help understand the relationship in order to make further recommendations for regulations and interventions in tackle football.

Appendices

Appendix A
List of search query and results for each database

Database	Query	Final Results	Date
PubMed	(football[MeSH] OR football[tiab]) AND (Head [MeSH] OR Head [tiab] OR Brain Injuries, Traumatic[MeSH] OR brain concussion/ prevention and control [MeSH] brain injury*[tiab] OR concussion[tiab] OR brain contusion[tiab] OR TBI[tiab] OR MTBI[tiab] OR SRC[tiab] OR head impact*[tiab]) AND (Head protective devices[MeSH] OR "prevention and control" [Subheading] OR head protective device*[tiab] OR helmet[tiab] OR protect* equipment[tiab] OR protect* gear[tiab] OR HEADS Up[tiab] OR coach* education[tiab] OR head impact exposure[tiab] OR head impact burden[tiab] OR practice reduc*[tiab] OR safe tackling[tiab] OR safe tackle[tiab] OR organizational policy[MeSH] OR rule modification[tiab] OR injury risk[MeSH] OR injury rates[tiab] OR full contact[tiab])	548	20-Feb
Embase	('football'/exp OR football OR football:ti,ab,kw) AND ('traumatic brain injury'/exp OR 'traumatic brain injury' OR 'brain contusion'/exp OR 'brain contusion' OR 'head injury'/exp OR 'head injury' OR 'concussion'/exp OR concussion OR 'brain concussion'/exp OR 'brain concussion' OR 'brain injury'/exp OR 'brain injury' OR 'sports related concussion'/exp OR 'sports related concussion' OR 'traumatic brain injury':ti,ab,kw OR 'brain contusion':ti,ab,kw OR 'head injury':ti,ab,kw OR concussion:ti,ab,kw OR 'brain injury':ti,ab,kw OR tbi:ti,ab,kw) AND ('helmet'/exp OR helmet OR 'sports equipment'/exp OR 'sports equipment' OR 'protective equipment'/exp OR 'protective equipment' OR 'head impact'/exp OR 'head impact' OR 'organizational policy'/exp OR 'organizational policy' OR 'injury risk'/exp OR 'injury risk' OR 'heads up':ti,ab,kw OR 'coach education':ti,ab,kw OR 'head impact burden':ti,ab,kw OR 'practice reduc*':ti,ab,kw OR 'safe tackling':ti,ab,kw OR 'safe tackle':ti,ab,kw OR 'rule modification':ti,ab,kw OR 'injury risk':ti,ab,kw OR 'injury rates':ti,ab,kw OR 'full contact':ti,ab,kw)	833	20-Feb
PsycInfo & Eric	Football AND (traumatic brain injury OR brain contusion OR head injury OR concussion OR brain concussion OR brain injury OR sports related concussion) AND (helmet OR sports equipment OR protective equipment OR head impact OR organizational policy OR injury risk OR injury rates OR heads up OR coach education OR head impact burden OR practice reduc* OR safe tackling OR safe tackle OR rule modification OR full contact)	161	20-Feb

Appendix A Cont.
List of search query and results for each database

Database	Query	Final Results	Date
Cochrane	Football AND (traumatic brain injury OR brain contusion OR head injury OR concussion OR brain concussion OR brain injury OR sports related concussion) AND (helmet OR sports equipment OR protective equipment OR head impact OR organizational policy OR injury risk OR injury rates OR heads up OR coach education OR head impact burden OR practice reduc* OR safe tackling OR safe tackle OR rule modification OR full contact)	59	20-Feb
Global Health	Football AND (traumatic brain injury OR brain contusion OR head injury OR concussion OR brain concussion OR brain injury OR sports related concussion) AND (helmet OR sports equipment OR protective equipment OR head impact OR organizational policy OR injury risk OR injury rates OR heads up OR coach education OR head impact burden OR practice reduc* OR safe tackling OR safe tackle OR rule modification OR full contact)	91	22-Feb
All Databases	**Total Results**	1692	
	Removed Duplicates	1192	

Appendix B
Risk of Bias table with links to completed RoB tool[35,36]

Citation	Overall Risk of Bias	Google link w/completed tool
Swartz et al[37] (2019)	High risk of bias	https://drive.google.com/file/d/1Wod0ppUQputvTr9R-GOGcoE8G1_aAjDP/view?usp=sharing
Swartz et al[45] (2015)	High risk of bias	https://drive.google.com/file/d/14Tf5vvrqptjcL3DFQi9w3zKvHJj07be4/view?usp=sharing
Clark et al[48] (2015)	Critical risk of bias	https://drive.google.com/file/d/1R20hASum9EM04qyOO6VlqOld-DkuMKiV/view?usp=sharing
Shanley et al[42] (2019)	Serious risk of bias	https://drive.google.com/file/d/1C1Wk0aFu5lp-Ht9VoFrO_EMGqkS2ET4B/view?usp=sharing
Broglio et al[38] (2016)	Moderate risk of bias	https://drive.google.com/file/d/1knbN49QW-MC9UOhHBj_2zSfU4R7Umsod/view?usp=sharing

Kerr et al[1] (Sep. 2015)	Serious risk of bias	https://drive.google.com/file/d/1bLz-az_Ax-pzZM_uvv3IG81SMY2HAoc0/view?usp=sharing
Champagne et al[41] (2019)	Critical risk of bias	https://drive.google.com/file/d/1jZpKLxzeGP_VpA47Ldsgxv-MVUFt7inv/view?usp=sharing
Kerr et al[39] (2016)	Moderate risk of bias	https://drive.google.com/file/d/1aEp9lRQWQI30d1niw2L8lCCPhOYqIeKN/view?usp=sharing
Stemper et al[49] (2020)	Moderate risk of bias	https://drive.google.com/file/d/1UZKx7UMmWwej6pw4DxQKLyG_AK_QB_-H/view?usp=sharing
Martini et al[44] (2013)	Critical risk of bias	https://drive.google.com/file/d/1ZBy8he62Vp697TL8ixlpYZnWlCLSpeuf/view?usp=sharing
Wiebe et al[47] (2018)	Moderate risk of bias	https://drive.google.com/file/d/15lwPqWksjEtC6zAZ2L_uWmK9fnj8vDfG/view?usp=sharing
Pfaller et al[43] (2019)	Moderate risk of bias	https://drive.google.com/file/d/1TI__bq4GoFUH0h2_td_fXYcAM7fZNFDr/view?usp=sharing
Stemper et al[46] (2019)	Serious risk of bias	https://drive.google.com/file/d/1u4su4DSnGGAsJqa3m3aCalYGXn6nhgoh/view?usp=sharing
Kerr et al[5] (Jul. 2015)	Critical risk of bias	https://drive.google.com/file/d/1IMPht4SLooMbMSQPu29xUqjg0M52jTxp/view?usp=sharing
Kerr et al[6] (2015)	Critical risk of bias	https://drive.google.com/file/d/1W1sEX-M6Ua3E-oD9v1Expio66xjZpPfT/view?usp=sharing
Lynall et al[3] (2019)	Critical risk of bias	https://drive.google.com/file/d/10FUAJxiZXvj-Ei4m9pgVAHYGGNYK7Hxq/view?usp=sharing
Peterson et al[4] (2017)	Critical risk of bias	https://drive.google.com/file/d/1MWByxzsNWr2NZdUQApLdBLP_JTL34ig1/view?usp=sharing

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