

Community-Engaged Sport Safety

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Instructions and Notes

Study Title: Community-Engaged Sport Safety

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Background, Rationale and Context

Football has one of the highest rates of concussion among youth team sports.^{1,2} Although concussions are common in football, subconcussive head impacts, or repetitive head impacts without signs and symptoms of concussion, are a rising concern.^{3–8} Recent studies have begun to study characteristics of subconcussive head impacts.^{9–11} Exposure to cumulative head impact exposure (i.e., the frequency and magnitude of hits) resulting from participation in football (as well as other contact and collision sports) may result in long term sequelae.^{3–8,12–14} Indeed, neuroimaging findings demonstrate a potential cumulative effect of head impact exposure on the brain after a single season.^{15–32} However, some studies have failed to demonstrate a strong and consistent relationship between participation in football and cognitive change after a single season.^{33–38} The association between pre-high school participation in contact and collision sports and later-life neurodegeneration or neurocognitive deficits is also not well-understood.^{3,4,39–44} However, one critical missing component of many prior investigations is high-quality data on head impact exposure. This literature motivates the collection of biomechanical data from head impact sensors to understand exposure and clinical implications of those impacts as to identify solutions to mitigate head impacts in sport.

Youth football organizations often organize players into levels of play by age, or by age and weight. Changes in body size (height and weight) and physical performance (speed, power, endurance) occur in parallel with adolescent participation in youth football, but can occur at different rates.^{45–47} It is thought that older athletes are faster, stronger and may play more aggressively than their younger counterparts.^{45,48–50} We recently published a study that found youth football players with higher pre-season physical performance measures on drills had higher head impact exposure, especially in games.⁵¹ Head impact magnitude is often summarized by the peak resultant linear and rotational acceleration of the head resulting from each hit. A recent study of youth hockey players found that less aggressive players had significantly lower rotational accelerations than more aggressive players during practice.⁵² Lastly, underreporting of concussions has historically been a challenge.^{53,54} Improving knowledge, attitudes, and beliefs may improve reporting and perspectives related to concussion,^{55,56} and may also influence norms associated with high risk behaviors on-field. In this study, we will evaluate the feasibility and appropriateness of targeting individual-level determinants (e.g. knowledge, attitudes, beliefs) to reduce head impact exposure in youth football.

The first study evaluating head impact exposure in youth football demonstrated that most high-level impacts (> 80g) occur during practices, not games.⁵⁷ This result led to rule changes implemented by the Pop Warner League (~9-11% of youth football participants in the US), limiting how much contact (i.e., full-speed drills or scrimmages) a team has and eliminating full speed head-on blocking and tackling drills.⁵⁸ Our group found that limiting time spent on contact in practices resulted in 37-46% fewer head impacts in a season in a youth football team that implemented these rule changes versus two teams that did not;⁵⁹ however, this result has not been tested in other youth teams. Broglio et al. observed an average of 42% fewer impacts per player following a statewide restriction on full-contact high school practices.⁶⁰ I recently led a study that demonstrated that simply reducing time spent in contact may not decrease head impact exposure – contact quality or intensity may be more important, a finding later substantiated by Stemper et al.^{61,62} Increasing head impact exposure is associated with level of play (i.e., youth, high school);

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however, wide variability in the number and magnitude of head impacts occurs within each level of play.^{9,11,57,59,63} Nearly two-thirds of the head impacts a youth football player receives in a single season occur in practice^{9,11,57,59} and head impact exposure during the season is influenced by activities such as the drills conducted as a team.^{59,64} Mechanics of tackling may also affect head impact exposure,⁶⁴⁻⁶⁸ and a recent study showed that incorporating targeted drills into a team's practice resulted in improved tackling technique and reduced head impact exposure.⁶⁹ This study will use combined biomechanics and video to assess and inform attitudes and perceptions of stakeholders surrounding head impact exposure in football and explore multi-level determinants that may be targeted to reduce exposure.

Implementation science and community engagement approaches have not been applied to youth sports.⁷⁰⁻⁷⁶ Community engagement joins community members and researchers to establish and sustain partnerships throughout the research process to build trust, create better communication, and improve health outcomes through action-oriented efforts.^{72,77,78} Community-level interventions address access to resources, the built (i.e., structure) and social (i.e., relationships within the community) environment, and cultural norms of a community.⁷⁹ Youth football leagues are often community-run organizations with limited resources and coaching support from parent volunteers. To develop relevant interventions to improve sport safety, it is critical to design innovative methods to translate research findings into practical strategies likely to be well received by the youth football community. Dissemination of research findings is also a critical step toward making successful interventions a lasting "legacy".⁸⁰ In this study, we will create partnerships in the local community, identify and engage key stakeholders, and develop a model that may be expanded to other youth sports.

Objectives

Whether repetitive head impacts sustained in contact sports such as football lead to structural and functional brain changes is a matter of debate. Nevertheless, changes in the brain over a single season of youth and high school football and later in life have been documented.^{3-8,17,20,22-24,28,32,81,82} With about 2.8-3.5 million athletes between the ages of 6 and 13 participating in youth football each year, there is a critical need to reduce head impact exposure.^{57,83} Several youth organizations have implemented rule changes to reduce contact and concussion risk; however, these rules are not informed by evidence in youth football. Additionally, the most effective targets for reducing head impact exposure and concussion risk and how best to implement change in this setting is unknown. The **objective** of this study is to develop and pilot test an evidence-based intervention to reduce head impact exposure in youth football practices using a community-engaged approach. We will seek to address the following **specific aims**:

Aim 1: Determine the awareness and receptivity to creating a safer practice structure to reduce head impact exposure in youth football among key stakeholders.

Aim 2: Develop an evidence-based intervention to reduce head impact exposure in youth football practices, using a community-engaged approach.

Aim 3: Pilot-test the evidence-based practice structure to reduce head impact exposure and mitigate changes in clinical outcomes in youth football.

We **hypothesize** that (a) determinants at the individual (athlete), interpersonal (team & coach), and community levels (built & social environment) of the social ecological model⁸⁴ may be identified and targeted to reduce head impact exposure in youth football practices, and (b) an evidence-based strategy to reduce head impact exposure in practices may be developed and pilot tested using a community-engaged approach. (c) The reduction in exposure will be associated with a lower rate of change in pre- to post-season clinical outcome measures and cognitive function scores.

Methods and Measures

Design

Two local youth football teams at the middle school level (ages 11-14) will be recruited to participate in this study. Informed consent and signed assent forms will be obtained from parents/legal guardians of participating youth football players. All interested football players on the 2 teams will be enrolled; of those enrolled, 15-20 per team (n=30-40 total) will be randomly selected for instrumentation with head impact sensors using a random numbers table. Head impact sensors embedded in a custom mouthpiece will be used to collect head impact exposure in conjunction with on-field video data for a season. These data will be used to inform guided discussions with stakeholders (parents, coaches, league officials). Using an audit and feedback approach (sharing biomechanical data with the stakeholders), we will facilitate semi-structured focus groups with the coaches (n=8) and parents (n=10) of the participating teams, and key informant interviews with league officials (n=8), to assess the awareness and receptivity to creating a safer practice structure. Participants will be asked to complete a series of cognitive, vestibular/ocular motor, and postural stability tasks pre- and post-season.

An anonymous survey concerning knowledge, attitudes, and practices as well as the perceived needs, perceived benefits, capacity, and barriers to implementing efforts to improve head impact safety will be created and sent to coaches, parents, and league officials (n=153). Data will be combined with published literature to inform the development of an evidence-based intervention using a community-engaged approach. At the end of year 3, two youth football teams at the middle school level will be recruited to pilot test the intervention developed in this study. The football coaches of each team will be prospectively recruited and enrolled. Informed consent will be obtained from adults (coaches and parents/legal guardians of youth athletes) and parents/legal guardians of all participating youth athletes will sign assent forms. Again, all interested athletes on these teams will be enrolled; of those enrolled, 15-20 per team (n=30-40 total) will be randomly selected for instrumentation with head impact sensors using a random numbers table. Athletes will also complete the series of cognitive, vestibular/ocular motor, and postural stability tasks pre- and post-season. On-field activity, skills, and behaviors will be monitored with head impact sensors and on-field video data to evaluate the effectiveness of the intervention at reducing head impact exposure and the acceptability, feasibility, and fidelity of the intervention. The results will be disseminated to the youth football league at the end of the study.

Setting

Biomechanical data collection will occur during youth football practices and games. Stakeholder meetings and key informant interviews will be conducted at the local elementary school, community centers, and Biotech Place in Winston Salem, NC. Clinical outcome data collection and data analysis will be conducted at the WFU Center for Injury Biomechanics, a research lab located at Biotech Place. Additionally, we plan to recruit individuals across the Piedmont Triad and Charlotte Mecklenburg regions in Fall 2024 data collection.

Subjects selection criteria

- **Inclusion Criteria**

Mouthpiece and Clinical Outcome Data Collection:

All athletes participating on the prospective teams will be eligible for the study, including those with braces longer than 6 months.

Focus Groups, Key Informant Interviews:

All parents with athletes participating on the prospective teams and coaches of the prospective teams will be eligible for participation in the study. All league officials of the governing organization will be eligible for participation in the study.

Surveys:

All parents, coaches, and league officials of the governing youth football organization will be eligible for participation in the survey portion of the study.

- **Exclusion Criteria**

Mouthpiece and Clinical Outcome Data Collection:

Athletes will be excluded from participation if they have had braces less than 6 months, or have dental appliances that may impede the fit of the mouthpiece device (e.g., Herbst Appliance).

- **Sample Size**

Study Sample - Athletes: Each year of the study, we will identify two middle school (ages 11-14) football teams for this study. All interested athletes on these teams will be invited to voluntarily participate in biomechanical data collection; of those enrolled, 15-20 per team will be randomly selected for instrumentation with head impact sensors. Informed consent will be obtained from parents/legal guardians of all athletes; participating athletes will sign assent forms. The number of athletes (N=30-40 each year, N=105-130 total) was chosen based on our earlier studies, which reported significant differences in exposures among football conditions with sample sizes of 9⁸⁵, 40⁸⁶ and 30⁸⁷. We aim to accrue sufficient information to assess relationships (e.g. between measures of exposures) and describe variability among exposure levels among conditions and athletes. N=30 provides >80% power to detect correlations of $r \geq 0.50$, i.e. associations of sufficient strength to inform design of the intervention (Aim 3). It also provides sufficient precision for estimating standard deviations: 90% confidence intervals will range from 0.83 to 1.28 SD units. Additionally, a Fall 2022 football cohort (N=14) from Head Kinematics in Sports Study (IRB00049715) will be included in biomechanics data collection and analysis. In Fall 2024, we plan to enroll (n=55) athletes across two of six participating teams to participate in parallel biomechanical and video data collection to evaluate the frequency and severity of head impacts experienced throughout the season.

Study Sample - Stakeholders: Coaches and parents of the participating teams will be recruited to participate in separate focus groups—two for coaches and two for parents. League officials will be prospectively recruited to participate in key informant interviews. Informed consent will be obtained from stakeholders. Each team has one head coach and three to five assistant coaches and approximately 20 athletes. The number of parents (n=40) and coaches (n=35) enrolled in the focus group portion of this study was selected based on the estimated number of athletes (and thus number of parents) and coaches involved with each football team. We expect to recruit 25% of the parents and 100% of the coaches participating on each team. Only one parent per family will be asked to participate to increase the number of families able to participate in discussions. We expect to enroll one-third (n=8) of league officials to participate in key informant interviews.

Study Sample - Surveys: An anonymous survey (7-10 minutes) will be created and sent via email listserv to coaches, parents, and league officials of the local youth football league at the start of the fall football season. There are ~150 football coaches of 51 football teams participating in one of 12 organizations, with ~800 families, and 24 league officials. To obtain a representative sample, we will seek a sample size of N=25 coaches (16.7%), N=120 parents (15%), and N=8 league officials (33%).

Interventions and Interactions

Biomechanics Data Collection:

We will conduct biomechanical data collection from athletes participating on local youth football teams. A custom mouthpiece will be created for each athlete participating in this study. The custom mouthpiece is made of acrylic material, which is a commonly used biocompatible material used to make dental retainers. An accelerometer, gyroscope, inductive charging coil, processor, and batteries are embedded in the mouthpiece. The mouthpiece is worn by the subject on the upper dentition and a soft mouthpiece overlay may be adhered to the mouthpiece. Data from accelerometer and gyroscopes are stored in the device and downloaded after a data collection event. Each athlete will be custom fit to a mouthpiece by having an intraoral scan (TRIOS, Copenhagen, Denmark) of the upper dentition by a trained dental technician. The scan obtains a high-resolution 3-D model used for printing using a Carbon M1 3D printer with Continuous Light Interphase Production. The dental scan is a resolution three-dimensional picture reconstructed from thousands of 2D pictures collected of the teeth. The scan takes approximately 4 minutes to obtain. These will be obtained using a standard procedure performed by a dentist or by a dental technician / hygienist overseen by a dentist. The 3-D printed model is used to create the custom mouthpiece for each individual.

The mouthpiece with sensor will be individually assigned to each participant and will be distributed before each data collection event by study staff. The mouthpiece with sensor will be collected after each data collection event. The distribution and collection of the sensor system with mouthpiece will occur before and after data collection events so minimal time or action will be required on the part of the participants. The mouthpieces will be individually cleaned and stored in a sanitary manner such that contamination between athlete mouthpieces is avoided.

The custom mouthpiece device is made of the same material as dental retainers currently worn in the target populations. These devices are observational devices. The risks of wearing the instrumented mouthpiece are low due to the low total power of the battery used (3.7V, 30mAh) and all electronics and battery will be encapsulated in medical-grade acrylic as a moisture and dielectric barrier. Collaborating researchers at Wake Forest and Virginia Tech have performed pilot studies approved by the respective Institutional Review Board (IRB) with this device and none of the athletes have reported adverse events from wearing the mouthpiece to the research team.

The mouthguard form of the mouthpiece is made of medical-grade acrylic and elastomer polymer mouthguard material (ethylene vinyl acetate). The acrylic and mouthguard material are held together with a form of super glue (ethyl cyanoacrylate). These type of materials have been used in dental applications and preliminary evidence suggests that they are safe for intraoral use [or for use within the mouth].

The Prevent mouthguard is made of USP Class VI (medical grade) or FDA food grade thermoplastic mouthguard material (polyurethane and ethylene vinyl acetate). The iMG complies with CE requirements and FCC regulations for wireless communication. These type of materials have been used in dental applications and preliminary evidence suggests that they are safe for intraoral use [or for use within the mouth].

Another team we will follow in the Fall 2024 season will wear a helmet sensor. The sensor measures the motion of his/her head when your child has been hit. The CUE Sport Sensor is a helmet or headband wearable sensing technology designed to collect key data on the head-impacts our athletes sustain. When paired with the Athlete Intelligence system, they analyze on-field head-

impacts from each game and practice. The data is downloaded off the sensors using a mobile phone and sent to our secure cloud-based system to analyze team, position, and athlete impact profiles while identifying training opportunities based on the data collect to improve the safety and performance of each athlete. Because this is a system designed for the coach as the end user, the coach of the team will receive reports related head impacts of athletes to inform safety and performance.

Participants in this study will be asked to provide consent to collect on-field video footage for the purpose of this study. Videotapes, audiotapes, and/or photographs will be used for presentation purposes and/or for visualization of a specific impact or play to guide focus group discussions. The context of the events leading up to and the events following an impact may be relevant to the study. In any use of this photograph/videotape/audiotape, the subjects name will not be identified. To protect individuals further, individual's impacts will not be discussed during focus group meetings but rather summary statistics represented a collection of events measured by the mouthpieces. During the consent process, the athletes and parents will be made clear that the biomechanical data and matched video collected in this study will be used to guide focus group discussions.

Stakeholder Survey:

An anonymous survey will be sent via email listserv to coaches, parents, and league officials of the local youth football league at the start of the fall football season. Survey questions will be derived from previously published surveys and guided by constructs of a published health behavior model. Where appropriate, responses will be made optional. A cover letter will state that completion of the survey indicates consent to participate. Parents will only complete the survey once, even if they have multiple children participating in football. League officials and coaches will also be asked to complete an additional survey (Organizational Readiness for Implementing Change (ORIC)). An anonymous survey will be sent via email listserv to coaches of local youth football leagues and high schools. Survey questions will be derived from previously published surveys. Data collection will be open one month prior to and during the first month of the football season. We will work with the league to reach as many respondents as possible. To encourage participation, those who complete the survey within the first month of the season will be entered into a raffle to win one of three \$50 gift cards. Email address will be stored separate from the survey response only for the purpose of notifying of the raffle result in order to maintain anonymity of survey responses.

Focus Groups:

During the football season, coaches (n=8, 4 from each team) and parents (n=10, 5 from each team) of the enrolled teams will be invited to participate in separate 60-minute focus groups (two for coaches, two for parents) monthly (Aug, Sept, Oct, Nov), using an audit and feedback approach. At the first (Aug) and last meeting (Nov), coaches and parents will complete the stakeholder survey (Appendix 2). Coaches will also complete a 10-question survey assessing how often the coaches include specific drills in their practice structure and the perceived frequency and magnitude of hits experienced in five common youth football drills: Install, Oklahoma, One-on-One, Open Field Tackling, and Position Skill Work. Sample questions include: "On a scale of 0 to 6, how hard are the head impacts experienced in the Oklahoma drill, with 0 being no contact and 6 being the hardest hit an athlete may receive in a game?" At each focus group meeting, printed weekly practice and game reports will be handed out to each participant. During the first 20 minutes, a summary presentation of the practice and game reports, including *video examples of drills* conducted in the prior month and the *associated biomechanical data* measured from the mouthpiece sensors will be shown to the stakeholders in the form of a PowerPoint presentation. Thirty minutes will be reserved for a semi-structured group interview to discuss what was seen in the video and implications of the data on practice structure in youth football and coaching. Trained focus group leaders will lead

discussion guided by a series of questions and prompts. As the season progresses, questions and prompts may be added to the focus group guide as new topics are introduced by participants in previous focus groups. League officials (n=8) will be recruited to participate in pre-season (Aug) and post-season (Nov) key informant interviews following the same format as the focus groups. Study staff will take notes and collect audio recordings of the discussions. During the last 10 minutes of each focus group meeting and key informant interview, the stakeholders will complete an 8-item scale on the acceptability and feasibility of creating a safer practice structure using the validated Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM).⁸⁸ This survey will be repeated at each meeting to determine changes in perceived feasibility and acceptability over time.

In Fall 2024, Coaches (n=24) and parents (n=30) will be invited to participate in separate, team-specific 60-minute focus groups (six for coaches, six for parents) at pre-season and post-season timepoints to assess domains of the Practical Robust Implementation and Sustainability Model (PRISM)⁸⁹ implementation framework, including organizational needs, capacity, and readiness to adopt the intervention program. We will augment PRISM with the Interactive Systems Framework (ISF)⁹⁰ community factor domain to additionally understand how the community may influence capacity and readiness. Trained focus group leaders will lead discussion guided by a series of questions and prompts. Organizational leaders (n=12) will be recruited to participate in a key informant interview following the same format as the focus groups. Study staff will take notes and collect audio recordings of the discussions. The questions and prompts will remain the same across the two meetings to measure changes in perspectives over the course of the season; however, questions and prompts may be added to the second discussion as new topics are introduced by participants in previous focus groups/interviews. During the last 5 minutes of each focus group meeting and interview, the stakeholders will complete an 8-item scale on the acceptability and feasibility of the intervention program using the validated AIM and FIM surveys.

Identifying Adaptations. We will convene our community stakeholder team (n=12) to participate in monthly meetings (January – March 2025) to review intervention outcomes and assess program fit and necessary adaptations to address organizational capacity and readiness to adopt the intervention program. Guided by the Intervention Mapping process, the intervention program will be refined accordingly, while maintaining essential elements of the intervention program. The stakeholder team consists of youth and high school football coaches, league and school administrators, parents, an athletic trainer, and a director of player development for a local university. We have successful relationships with and support from our community stakeholder team. During the development phase, we had >90% engagement attendance in meetings; 75% of the original stakeholder team has remained engaged through the evaluation phase of our pilot testing. We will add additional stakeholders from the Charlotte metropolitan region to strengthen the diversity and expertise within our team. A written summary will be provided after each meeting documenting discussion and progress.

Within the focus groups and league official interviews, stakeholders will be aware of other stakeholders included in group discussions; however, their identity within the youth football league will remain anonymous. Participants will be informed before the focus group and interviews if the session will be audio or video recorded as well as what will be done with the recordings. Audio or video recordings will only be used for data analysis. Because of the nature of focus groups, confidentiality cannot be guaranteed; however, the research team will provide procedures to maintain confidentiality and will inform participants not to repeat what is said in the focus groups.

Stakeholder Engagement:

Stakeholders will be identified (n=12) and gathered for a presentation of the research findings and round table discussion of needs, concerns, and implications of research findings using a community engaged approach. Possible local stakeholders (n=8) include league officials, coaches, athletes, and parents, representing different levels of interest and influence. To increase generalizability, four stakeholders external to the local football league will be identified, including two high school football coaches and two Forsyth County school administrators. Stakeholder involvement will be voluntary and informed consent will be provided prior to the stakeholder discussions. Stakeholders will be aware of other stakeholders included in group discussions; however, their identity within the youth football league will remain anonymous.

Together with the stakeholders, Dr. Urban will conduct monthly stakeholder meetings to develop an intervention focused on reducing head impact exposure in practice. During the first meeting, stakeholders will be gathered for a presentation of research findings, including identified high-risk activities and skills and results from focus groups, interviews, and surveys, and discussion of needs, concerns, and implications of the research using a community-engaged approach. We will conduct Intervention Mapping through three monthly stakeholder meetings to define, develop, refine, and select a strategy to test for reducing head impact exposure in practices.⁹¹ This will include specifying an action-oriented objective and clearly defining which determinants and level(s) of the social-ecological model will be targeted. Together, we will brainstorm possible methods to achieve the defined objectives. The research team will evaluate the level of evidence to support the proposed methods and work with the stakeholders group to translate proposed methods into strategies. Strategies will be developed and compiled to address the identified level(s) of the social ecological model and program objectives. The strategy selected for pilot testing will be determined by the potential to reduce head impact exposure in practices, alignment with needs of the community, feasibility, acceptability, availability of resources (i.e., coaching staff, tackling dummies), and amount of evidence to support the strategy. Acceptability will be a priority when selecting the strategy as guided by Conceptual Model of Implementation Research, which will be used to develop the implementation plan.⁹² Once the strategy has been selected, we will work with stakeholders to operationalize the approach into discrete components with a clear plan of action and programmatic materials. The safety of the participants will be the utmost priority in the development and testing of the intervention.

We will work with the stakeholders to develop an implementation plan. The implementation plan will define characteristics of the intervention, timeline and degrees of involvement, resources and training materials, and a specific action plan. The Conceptual Model of Implementation Research will guide selection of the strategy/practice structure and development of the implementation plan.⁹² In this model, effective implementation is a function of the organization's readiness for change; resources available for implementation (i.e., training and technical support); support from the organization's leadership; presence of a champion; extent to which the practice structure fits the needs of those affected and involved in youth football practices; and extent to which stakeholders perceive the practice structure reflects their values. We will continually solicit input and feedback from stakeholders on the objectives, guidelines, resources, and evaluation criteria for the practice structure and strategies for effective implementation. Essential elements of implementation will be defined⁹³ (e.g., minutes per practice spent on specified activities, number of practices per week the coach followed the practice structure).

An additional 10 adult stakeholders in the youth football community will be engaged via interviews to provide feedback on the intervention program for future program development.

Intervention:

Before the fall football season (June-July), we will recruit coaches and athletes teams at the middle school level to pilot the practice structure intervention and continuously monitor on-field activity with head impact sensors to evaluate the feasibility, acceptability, and sustainability of the practice structure. Coaches of the teams enrolled in the intervention will be trained according to guidelines established in the intervention development by a trained football advisor (e.g., a former college football player), who will be a resource throughout the season. During the season (Aug-Nov), trained research staff will attend all practices and games to collect biomechanical data and video during each session. Implementation process (i.e., feasibility and potential utility of the implementation strategy) will be monitored. Stakeholders will be gathered intermittently (at most monthly) to provide feedback on feasibility and acceptability of the intervention, including suggestions to improve uptake of the practice structure, if needed, and to identify implementation process strengths.

Fifteen athletes recruited from each intervention team will be assigned an instrumented mouthpiece. All data will be screened to remove impacts that did not occur from a head impact. Video will be reviewed to characterize on-field activity and paired with the head impact sensor data and to determine the extent to which the intervention was implemented. Coaches will complete the 8-item scale assessing the acceptability and feasibility of creating a safer practice structure using the AIM and FIM (Appendix 2) at the start and end of the season.⁸⁸ Stakeholders will complete the surveys at each monthly stakeholder meeting.

Intervention Summary:

The intervention will seek to reduce head impacts in youth football by (1) improving the knowledge and skills of youth football coaches in effective practice planning and use of safe practice drills and (2) changing attitudes and beliefs towards contact in practice. The activities of the intervention are aligned with constructs of Social Cognitive Theory⁹⁴ and Diffusion of Innovation⁹⁵ and are as follows:

1. A pre-season educational clinic will be provided to youth football coaches. The educational clinic will include a panel discussion of high school football coaches around the topic of practice planning, presentations from medical and research professionals on head impact biomechanics and related sports medicine topics (e.g., concussion signs and symptoms, cardiovascular emergencies, heat precautions), and demonstrations of safe practice drills.
2. Coaches will be asked to follow guided practice plans that follow the [NO_PRINTED_FORM]National Federation for High Schools (NFHS)⁹⁶ for football practice drills with moderated time spent on live action or full contact drills. The guided practice plans will designate recommended blocks of time over a 1.5-hour practice that may be spent on the five categories of contact: Air, Bags, Control, Thud/Bump, and Live contact. Three practice plans will be created that designate a full contact practice, moderate contact practice (no drills in the Live category), and limited contact practice (no drills in the Live category).
3. Coaches will be provided a reference booklet with drill explanations, guidance on practice planning and drill selection, and frequently asked questions. The drills for the reference booklet will be gathered from local high school football coaches with knowledge of the NCHSAA handbook and safe practices in football.
4. The intervention coaches will be paired with high school football coach/coaching staff who will serve as a trained football advisor and peer mentor. The intervention coaches will be asked to meet with their peer mentor weekly throughout the season to provide guidance on practice planning throughout the season.

Athlete Stakeholder Groups:

Former youth football players currently participating at the Varsity level of high school football (n=6) and collegiate level (n=6) will be invited to participate in separate (one for high school, two for collegiate) 60-minute discussions before the intervention (July), in the middle of the intervention/football season (October), after the football season (January), and upon completion of analysis of the results (May). The purpose of the stakeholder discussions is to assess the feasibility and potential utility of the implementation strategy and to further supplement our understanding of the intervention feasibility and acceptability. The Exploration, Preparation, Implementation, and Sustainment (EPIS)⁹⁷ conceptual model will be used to guide discussions. During the last 10 minutes of each discussion, participants will be asked to complete modified AIM and FIM surveys.⁸⁸ Questions 1 and 2 of the FIM surveys will be omitted for athlete stakeholders.⁹⁸ These surveys will be repeated at each meeting to determine changes in perceived acceptability and feasibility over time.

Neurocognitive Assessments:

Enrolled athletes may complete a series of clinical outcome assessments pre-and post-season, including measures of neurocognition, postural control, and vestibular/ocular motor symptoms. The parent and child versions of the *Behavior Rating Inventory of Executive Function (BRIEF) Monitoring Form*^{99,100} and *Revised Child Anxiety & Depression Scale (RCADS)*¹⁰¹ will be collected at the baseline and post-study assessments to monitor behavior and mood changes. The elements of the clinical outcome assessments are described below:

ImPACT:

For this study, the web-based version of the ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) will be given to athletes after diagnosis of a concussion. Administration of the test will be monitored by a member of the study staff member trained in the application of the ImPACT test. The ImPACT test takes approximately 20 minutes to complete.

NIH Toolbox:

The NIH Toolbox is a multidimensional set of brief measures assessing cognitive, emotional, motor and sensory function from ages 3-85, meeting the need for a standard set of measures that can be used as a “common currency” across diverse study designs, including repeated measures designs, such as the present study. Specifically, we will use the NIH Toolbox Cognition Battery which is administered on an iPad. The cognition battery consists of tests to assess Executive Function, Attention, Episodic Memory, Language, Processing Speed and Working Memory. Administering this battery will yield summary scores (i.e., Cognitive Function Composite Score and Crystallized Cognition Composite Score), as well as individual measure scores.

Rey Auditory Verbal Learning Test (RAVLT):

The RAVLT assesses verbal learning ability and memory; in this study, only learning ability is evaluated (4 minutes). A series of 15 words is presented to the participant 3 times via audio recording for standardization, and answers are recorded.

Stationary Postural Control/Force Plate:

Consistent with the methodology outlined by Campolettano et al., participants will complete two 30-second trials (one with eyes opened, one with eyes closed).¹⁰² Five measurements will be calculated at each time point (pre- and post-season): anterior-

posterior sway, medial-lateral sway, path length, maximum path velocity, and center of pressure area.

Vestibular/Ocular Motor Screening (VOMS):

The participant will be asked to complete a series of rapid head movements to assess five domains: smooth pursuit, saccades, near point convergence, vestibular ocular reflex, and visual motion sensitivity. Symptom provocation will be assessed by a trained member of the study team. Near point convergence will be averaged across three trials.

Conners' Continuous Performance Test (CPT) Third Edition (CPT-3):

Participants will complete a 14-minute computer-based assessment that evaluates selective, sustained and divided attention, as well as impulsivity and vigilance.

Triggers for Testing:

Triggers refer to the standards an athletic trainer or coach will use to determine whether or not an impacted player should receive further testing. The triggers for testing will be the standard already used by the athletic trainers and will not be altered due to this study. If a concussion is suspected, the athletic trainers typically use the SCAT5 on-field to determine whether to remove an athlete from play. Following removal from play, the athletic trainers use the SCAT5 to assist with a clinical diagnosis of concussion which would trigger further testing. Athletic trainers and physicians will follow normal methods for diagnosis and treatment of a concussion and not be restricted to only the information found in this protocol.

Post-Injury Testing:

Post-injury testing is any testing that is administered after a player has been diagnosed by a team physician or athletic trainer to have a concussion. The records for Post-Injury Testing will only be provided and used for research analysis AFTER a concussion has been diagnosed, pending signed authorization by the players on the Informed Consent document. No additional or different testing will be done because of a player's participation in the study.

Post-injury testing will include baseline cognitive, postural control, and vestibular/ocular motor testing within 24-48 hours after concussion diagnosis.

Outcome Measure(s)

- Primary Outcomes:
 - Number of head impacts, impact rate
 - Mean and 95th percentile number of impacts, linear acceleration, rotational acceleration by session type, activity, skill and behavior
 - Pre- to Post-Season change scores for:
 - ImPACT
 - NIH Toolbox
 - RAVLT
 - Postural Control
 - VOMS
 - Conners' CPT
- Secondary Outcomes:
 - Implementation facilitators and barriers
 - Intervention fidelity
 - Adaptation of the intervention

Analytical Plan

Statistical analysis of biomechanical data will be based on our previous approaches.^{9,11,64} Head impact data will be transformed to the head center of gravity using Matlab (Mathworks, Inc., Natick, MA) and quantified for each session (i.e., practice or game) and practice drill category (i.e., conditioning, tackling) and across drill types (i.e., Oklahoma, one-on-one) in terms of mean number of impacts and impact rate and mean and 95th percentile head acceleration.

Descriptive statistics will be computed from survey responses using SAS. Field notes and recordings from focus meetings will be reviewed by reading transcripts and listening to recordings to identify recurrent themes, issues, and concepts and a thematic framework will be created surrounding the awareness and receptivity of the stakeholders to create a safer practice structure.¹⁰³ Data will be indexed, charted, and mapped using a schematic diagram to guide interpretation of the results. Survey questions and responses will be grouped according to the thematic framework. Perceived feasibility (FIM), acceptability (AIM), and stakeholder survey constructs measured at the initial meeting (Aug) will be compared to the final meeting (Nov).

We will use established qualitative methods^{104,105} to analyze field notes and recordings from stakeholder meetings to iteratively assess the nature of the evidence-based strategies, strengths, and weaknesses, while addressing the availability, acceptability, affordability, and potential barriers with each possible evidence-based strategy. Field notes and recordings from stakeholder meetings will be reviewed by reading transcripts and listening to recordings to identify recurrent themes, issues, and concepts for the creation of a thematic framework.¹⁰³ Attitudes, practices, barriers, needs, and concerns will be categorized. Common themes will be grouped with the aforementioned categories or new categories will be created as themes emerge. Survey responses, transcriptions, and recordings will be indexed and charted based on the classifications identified in the thematic framework. These data will finally be mapped and interpreted to establish associations, explanations, and strategies that target the individual-, interpersonal-, and community-levels influencing behaviors affecting head impact exposure. These data will ultimately inform the development of the practice structure, implementation plan, and evaluation framework.

On-field head impact data for each athlete will be quantified for each practice or game by number of impacts, impact rate, mean, median, and 95th percentile of head acceleration, and location of impact. Impact rates and percentiles (i.e., 50th, 95th) computed from the distribution of accelerations will be compared between unexposed (year 2, published iTAKL and BRP study data^{61,106–108}) and exposed seasons of data collection. Mixed-effects models (in SAS) will be used to assess differences in head impact exposure in practices and games before (year 2, published iTAKL and BRP study data^{61,106–108}) and after the intervention, adjusting for confounding factors, including team. We will examine the consistency of intervention effects on exposure outcomes between teams and among players over time, with the goal of learning how to refine and tailor the intervention to increase adherence and potential effectiveness. Because this is a pilot study, we will lack sufficient power to fully test the effectiveness of the intervention; however, we will gather essential information for a future R01-supported randomized control trial.

All clinical assessment scores will be compared to same age peers at testing time (via published normative values) to control for developmental changes that may occur during the study period. Scores will be normalized (i.e. z-scores) to facilitate comparisons among cognitive tests. Kinematic metrics (i.e., total impacts, 95th percentile accelerations and rotational velocity, RWE) will be time-varying covariates in generalized linear and mixed effects models. The modeling framework, with its random effects structure, will allow for assessment of clinical outcome differences pre- to post-season over time between the intervention athletes and controls. We will also describe whether associations may vary according to athletes' characteristics.

Descriptive data and inferential statistics related to implementation facilitators and barriers (i.e., feasibility, acceptability), fidelity (i.e., extent to which the intervention was implemented as prescribed), and adaptation (i.e., changes) of the intervention will be analyzed. These data will be abstracted from standardized forms collected during on-field observations, video-analysis of practices and games, and brief surveys and field notes from stakeholder feedback meetings.¹⁰³ Common themes will be grouped, and qualitative data indexed and charted. These data will be analyzed to assess the degree to which the practice structure was effective at reducing head impact exposure, was adopted by the youth football coaches, and to identify the key components of the strategy that may be implemented and sustained over time.

Human Subjects Protection

Subject Recruitment Methods

Dr. Urban will work with the league executive board to arrange meetings for coaches, parents, and players to describe the study and provide opportunities to answer questions. She and study personnel will also attend pre-season conditioning sessions to meet with parents, coaches, and athletes not present at the meetings. Those not present at the meetings or pre-season conditioning sessions will be sought out individually by phone for their interest in participating in the study. All interested athletes on these teams will be allowed to participate; of those enrolled, 15 children on each team will be randomly selected for instrumentation with head impact sensors using a random numbers table. Coaches and parents of the participating teams will be recruited to participate in separate focus groups and league officials will be prospectively recruited to participate in key informant interviews. A new set of football coaches and teams will be prospectively recruited and enrolled in the intervention portion of this study using similar recruitment strategies as the controls. Informed consent will be obtained from adults (coaches, parents, and league officials) and parents/legal guardians of all youth athletes and participating athletes will sign consent and assent forms.

To maintain a robust cohort of subjects, we will enroll all interested subjects from each team for possible participation in the study and randomly choose 15 per team for study at the start of the season. Participation will be monitored weekly; if an athlete has attended 50% or less of the practices or games within a 3 weeks, a new subject who enrolled prior to the start of the season will be randomly chosen for biomechanical data collection and given a sensor. We anticipate a possible attrition rate of 15% based on experience from our existing R01s. To ensure that sufficient participants are included, we will work closely with the local youth football league to identify and engage additional teams, if needed.

To reward all subjects for attending appointments to complete baseline, post-injury, and post-season evaluation procedures during the contact sport seasons, a gift card will be awarded, at all appointments, for the subject's additional travel and time to attend the procedures. See the table below for gift card compensation amounts.

	Neurocognitive Testing	Dental Impressions + Head/Face Measurements	Neurocognitive Testing, Dental Impressions, Head/Face Measurements +
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Pre-season/baseline	\$20	\$20	\$40
Post-injury	\$20	N/A	
Post-season	\$40	N/A	

To reward all stakeholders for attending all meetings, focus groups or key informant interviews, a gift card will be awarded, at all appointments, for the additional travel and time to attend the meetings. See the table below for gift card compensation amounts. To encourage participation, participants enrolled in the focus groups and key informant interviews will be entered into a raffle for four Wake Forest Football Tickets. All focus group and key informant interview participants enrolled in the study at the time of the raffle will be eligible to win. Winner will be selected using a random numbers table.

	Focus Groups	Key Informant Interviews	Stakeholder Meetings	Athlete Stakeholder Meetings
Compensation for each meeting	\$20	\$20	\$20	\$20
Number of meetings	4	2	18	4
Total compensation*	\$80	\$40	\$360	\$80

*if all meetings are attended

The gift card will be given to the subject at the time of the meeting. A record confirming receipt by the subjects of the gift card will be kept.

Informed Consent

Signed informed consent will be obtained from each subject. Dr. Urban and trained study personnel will work with the league executive board to arrange meetings for coaches, parents, and players to describe the study and provide opportunities to answer questions. She and trained study personnel will also attend pre-season conditioning sessions to meet with parents, coaches, and athletes not present at the meetings. Those not present at the meetings or pre-season conditioning sessions will be sought out individually by phone for their interest in participating in the study.

Informed consent will be obtained from each subject by the members of the study staff that are not directly affiliated with the prospective football programs or athletic departments. The informed consent form will be presented in individual meetings to each prospective participant in detail. Players, parents, and coaches will be encouraged to ask questions and will be given the opportunity to have all questions answered. The prospective participants will be told their participation is completely voluntary and they will not be pressured into participation. During the consent process, the study staff will work to minimize the possibility of coercion or undue influence. It is estimated that the individual consent process will take approximately 15 minutes per participant. The prospective participants will be spoken to in a one-on-one manner in a conversation that will take place in private, away from the rest of the team to avoid the potential for peer pressure.

Protocol version:

Template updated 9.24.14

An anonymous survey will be distributed to parents, coaches and league officials. A cover letter will be included stating that completion of the survey indicates consent to participate. The identity of those who have completed the survey will not be known to the research team.

Lastly, stakeholder involvement will be voluntary and informed consent will be provided prior to the stakeholder discussions. Stakeholders will be aware of other stakeholders included in group discussions as discussions will be conducted face to face; however, their identity within the youth football league will remain anonymous.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed, consistent with data validation and study design, producing an anonymous analytical data set. Video and biomechanics data will be stored for six years, or five years after the completion of the study, whichever is longer. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Prevent Biometrics creates one of the mouthguards used in this study. Some information is required to create an account to use Prevent, such as your name, email address, password, date of birth, gender, height, weight, and in some cases your mobile telephone number. We may also choose to provide other types of information, such as a profile photo, biography, country information, and community username. Athlete's name and email address will not be provided to Prevent Biometrics. We will use anonymous study identifiers and our generic study email to protect participant confidentiality with the Prevent Biometrics system. The Prevent Privacy Policy is provided in the appendix.

FITBIR

Data from the study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other.

During and after the study, the researchers will send information to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. FITBIR will not be able to contact participants

Data and Safety Monitoring

Dr. Urban and mentor, Dr. Kristie Foley, will be responsible for the overall monitoring of the data and safety of study participants. Data analysis will be overseen and completed by Dr. Urban under the guidance of Dr. Foley and co-mentors. Only members of the research team overseen by Dr. Urban will receive the acceleration data from the mouthpieces and be required to interpret the data. Team medical personnel and coaches will not review or monitor head impact data. Dr. Urban will pilot test the intervention developed in this study and complete data analysis under the supervision of Dr. Foley.

The Wake Forest School of Medicine Institutional Data Safety and Monitoring Board (I-DSMB) will provide independent oversight of methodology and conduct, biostatistics, and ethics of this study. The I-DSMB provides oversight for Wake Forest Baptist Health investigator-initiated, locally conducted clinical trials receiving NIH support. Members of the Wake Forest School of Medicine I-DSMB have expertise in clinical trial methodology and conduct, biostatistics, ethics, and clinical research. The I-DSMB will monitor participant safety, evaluate the progress of the study, review procedures for maintaining the confidentiality of data, and the quality of data collection, management, and analyses. The I-DSMB will have access to all study data, documents and progress information, and will be notified of all changes that are made to the protocol.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix

1. Research Timeline
2. Stakeholder Surveys

Appendix 1. Timeline

Aim	Mentored Research	Year 1			Year 2			Year 3			Year 4			Year 5		
		Fall	Spring	Summer	Fall	Spring	Summer	Fall	Spring	Summer	Fall	Spring	Summer	Fall	Spring	Summer
1	Develop IRB Materials, Subject Recruitment															
	Collect/Monitor Exposure															
	Video/Data Analysis															
	Stakeholder Survey and Analysis															
	Audit and Feedback and Analysis															
2	Data Integration															
	Engage Stakeholders/Develop Intervention															
3	Team & Subject Recruitment															
	Recruite, Train, & Engage Lay Football Advisor															
	Pilot Intervention: Collect/Monitor Exposure															
	Video/Data Analysis															
	Evaluate Effectiveness, Disseminate Results															

Appendix 2. Stakeholder Surveys

Youth Football Stakeholder Survey

We would like to invite you to take part in a research project. The purpose of this research is to understand the knowledge and perspectives related to concussions and hits to the head in youth football. This survey will take about 10 minutes to complete. Your part in this study is anonymous. This means that no one will know if you took part in this study and no one, including the researcher, will know what your answers are. Any reports or publications based on this research will only use group data and will not identify you or any individual as being part of this study. If you have any questions, please contact Dr. Jillian Urban (jurban@wakehealth.edu, 336-716-0947). Completion of this survey indicates that you consent to participate.

Football and Sport History (4-13 questions)

Are you a parent, coach or league official? *Parent; Coach; League Official [check boxes]*

[If Coach]

What level of play do you currently coach? (select all that apply)

Tine Mite Mighty Mite 10U Jr Pee Wee 12U Pee Wee 13U Jr Midget 14U High School Collegiate Semi-Professional Professional Other

Do your children/child participate in football?

Yes No

[If yes]

What level of play do your children/child play? (select all that apply)

Tine Mite Mighty Mite 10U Jr Pee Wee 12U Pee Wee 13U Jr Midget 14U High School Collegiate Semi-Professional Professional Other Not Sure

[If yes]

Do your children/child participate in the Piedmont Youth Football and Cheer League (PYFCL)? *Yes*

No Not Sure

[If yes]

What position(s) do your child/children participate in? (select all that apply)

*Center Offensive guard Offensive tackle Quarterback Running back Wide receiver
Tight end Defensive tackle Defensive end Middle linebacker Outside linebacker Defensive back Special teams Other: _____*

[If yes]

Has your child ever been diagnosed with a concussion?

Yes No Not Sure

[If yes]

Has your child ever been diagnosed with a concussion while participating in football activities?

Yes No Not Sure

Have you ever played tackle football?

Yes No

Protocol version:

Template updated 9.24.14

[If yes]

What levels of play have you participated in? (select all that apply)

Youth High School Collegiate Semi-Professional Professional Other

[If yes]

What age did you start playing football?

<5 years old 5-10 years old 11-13 years old 14-18 years old >18 years old

[If yes]

Have you ever been diagnosed with a concussion?

Yes No Not Sure

[Yes]

Do you feel you have any lasting effects from your concussion(s)?

Yes No Not sure

Knowledge and Beliefs (10 questions)

Directions: These statements about concussions may or may not be true. Please rate how strongly you agree with each statement.

People who have had a concussion are more likely to have another concussion.

Strongly Disagree, Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, Agree, Strongly Agree

A concussion cannot cause brain damage unless the person has been knocked out.

Strongly Disagree, Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, Agree, Strongly Agree

A concussion can only occur if there is a direct hit to the head.

Strongly Disagree, Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, Agree, Strongly Agree

Hits to the head that do not result in concussion may affect brain health after one season.

Strongly Disagree, Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, Agree, Strongly Agree

Hits to the head that do not result in concussion may affect brain health later in life.

Strongly Disagree, Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, Agree, Strongly Agree

Do you feel that efforts should be taken to reduce concussions in football?

Definitely yes Probably yes Not sure Probably not Definitely not

Do you feel that hits to the head that do not result in concussion should be avoided in football?

Definitely yes Probably yes Not sure Probably not Definitely not

Do you think there should be limits on the amount of contact allowed in football practices?

Definitely yes Probably yes Not sure Probably not Definitely not

Protocol version:

Template updated 9.24.14

Do you think there should be limits on tackling drills allowed in football practices?

Definitely yes Probably yes Not sure Probably not Definitely not

In your opinion, what is the greatest opportunity to reduce hits to the head in youth football?

- a) Limitations on contact in practice*
- b) Limitations on drills allowed in practice*
- c) Workshops for athletes to teach proper technique*
- d) Workshops for coaches to learn safe practices in sport*
- e) Rule changes in games*
- f) Safer helmets/equipment*
- g) Reducing equipment worn by athletes (e.g., removing helmet during practice)*
- h) Changing the culture around hits in football (e.g., discouraging celebration of big hits)*
- i) No improvements are needed*
- j) Other, specify:*

Which of the following will be the easiest to put in place?

- a) Limitations on contact in practice*
- b) Limitations on drills allowed in practice*
- c) Workshops for athletes to teach proper technique*
- d) Workshops for coaches to learn safe practices in sport*
- e) Rule changes in games*
- f) Safer helmets/equipment*
- g) Reducing equipment worn by athletes (e.g., removing helmet during practice)*
- h) Changing the culture around hits in football (e.g., discouraging celebration of big hits)*
- i) No improvements are needed*
- j) Other, specify:*

Perceived Susceptibility (5 questions)

Do you think children have more hits to the head while playing football compared to other contact sports (e.g., lacrosse, soccer)?

Much more Slightly more About the same Slightly less Much less

Do you think children have more hits to the head while playing football compared to non-contact sports (e.g., swimming, tennis)?

Much more Slightly more About the same Slightly less Much less

What position do you think has the greatest number of hits to the head in football?

Center Offensive guard Offensive tackle Quarterback Running back Wide receiver Tight end Defensive tackle Defensive end Middle linebacker Outside linebacker Defensive back Special teams Other Equal risk across positions

What position do you think receives the hardest hits to the head in football?

Center Offensive guard Offensive tackle Quarterback Running back Wide receiver Tight end Defensive tackle Defensive end Middle linebacker Outside linebacker Defensive back Special teams Other Equal risk across positions

Do you think children playing football make contact with their helmet (i.e., receive hits to the head) more often during games compared to practices?

Much more Slightly more About the same Slightly less Much less

Perceived Severity (5 questions)

How serious do you think it is for...

your child/children to have a concussion in football?

Not serious at all Somewhat serious Serious Very serious Extremely serious

your child/children to receive a hard hit to the head in football practices?

Not serious at all Somewhat serious Serious Very serious Extremely serious

your child/children receive a hard hit to the head in football games?

Not serious at all Somewhat serious Serious Very serious Extremely serious

How many hits to the head (making contact with his/her helmet) during a single practice or game would cause you concern?

Less than 5 impacts 6-15 16-25 26-50 Greater than 50 head impacts I am not concerned about the number of head impacts Unknown

If your child/children had a concussion in football, would you be concerned about any of the following outcomes:

Missing one or more practice	<i>Yes</i>	<i>No</i>
Missing one or more games.	<i>Yes</i>	<i>No</i>
Missing one or more days of school.	<i>Yes</i>	<i>No</i>
Decreased performance at school.	<i>Yes</i>	<i>No</i>
Decreased performance in football.	<i>Yes</i>	<i>No</i>
Persistent symptoms following concussion.	<i>Yes</i>	<i>No</i>
Increased risk of second concussion.	<i>Yes</i>	<i>No</i>
Short-term (i.e., single season) effects on brain health.	<i>Yes</i>	<i>No</i>
Long-term (i.e., later in life) effects on brain health.	<i>Yes</i>	<i>No</i>

Other: _____

Perceived Needs/Barriers (6-8 questions)

Having a competitive team is more important than reducing hits to the head in football practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

Football teams need to reduce hits to the head in practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

It will be costly to reduce hits to the head in football practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

Reducing hits to the head in football practices will help teams win games.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

Coaches will be willing to change their practice structure to reduce hits to the head.

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Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

League officials will be willing to put policies into place to reduce hits to the head.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

Please provide any additional comment on needs within the football community to create safer practices.

Please provide any additional comment on barriers within the football community to creating safer practices.

Self-Efficacy (3 questions)

My youth football league will be able to reduce hits to the head in practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

My youth football league is willing to commit to reducing hits to the head in practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

My youth football league has the ability to maintain efforts to reduce hits to the head in practices.

Strongly Disagree Disagree Neither Agree nor Disagree Agree Strongly Agree.

Demographic (4 questions)

What is your age?

Under 18 18-24 25-34 35-44 45-54 55-64 65-74 75-84 85 or older

What is your gender?

Male Female Prefer not to answer

How would you best describe yourself?

American Indian/Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander White Other Prefer not to answer

Are you of Hispanic/Latino/Spanish origin?

Yes No Prefer not to answer

Practice Survey for Coaches

The purpose of this survey is to understand how often specific drills are included in your practices and the perceived frequency and magnitude of hits experienced in five common youth football drills. This survey will take about 8 minutes to complete. If you have any questions, please contact Dr. Jillian Urban (jurban@wakehealth.edu, 336-716-0947).

1. What is your age?
Under 18 18-24 25-34 35-44 45-54 55-64 65-74 75-84 85 or older
2. Do you have a child/children who currently participates in youth football?
Yes No
- 3a. [If yes] Do you have a child/children who currently participates in the Piedmont Youth Football and Cheer League (PYFCL)? *Yes No Not Sure*
3. What level of play do you currently coach? (select all that apply)
Tiny Mite Mighty Mite 10U Jr Pee Wee 12U Pee Wee 13U Jr Midget 14U Other, Specify:
4. What other levels of play have you previously coached? (select all that apply)
*Tiny Mite Mighty Mite 10U Jr Pee Wee 12U Pee Wee 13U Jr Midget 14U
High School Collegiate Professional Other Not Sure None*
5. How many years have you coached football (any level)?
0-first year coaching 1-2 3-5 6-10 11-20 More than 20 years
6. How many years have you coached **youth** football?
0-first year coaching 1-2 3-5 6-10 11-20 More than 20 years
7. How many years have you personally played football (any level)?
0 1-2 3-5 6-10 11-20 More than 20 years
8. What levels of football have you personally played?
Youth High School Collegiate Semi-Professional Professional

PRACTICES

9. How many days/week does your team have full contact (i.e., full-speed drills, tackling to the ground) practice?
0 1 2 3 4 5 6 7
10. Do wins/losses affect your practice structure (i.e., what drills are conducted and when) the following week?
 - a) Always*
 - b) Most of the time*
 - c) About half of the time*
 - d) Sometimes*
 - e) Never*

11. How often do you include the following drills in your practice structure?

Install: Intra-team scrimmage of offense & defense game strategies in a game-like situation

Every practice Most practices Some practices A few practices
I never do this drill

Oklahoma: 2 vs 2 or 3 vs 3 tackling drill with tackler, blockers, & ball carrier; Simulate game speed while working to improve blocking, running, & tackling technique in a confined space

Every practice Most practices Some practices A few practices
I never do this drill

One-on-one: 1 vs 1 tackling drill with the 2 athletes starting *less than* 3 yards apart; Improve one-on-one tackling form & technique

Every practice Most practices Some practices A few practices
I never do this drill

Open-field tackling: 1 vs 1 tackling drill with the 2 athletes starting *more than* 3 yards apart; Improve form & technique in full-speed game-like situations

Every practice Most practices Some practices A few practices
I never do this drill

Position skill work: Athletes separate into offense & defense groups; practice offensive- or defensive-specific skills & game strategy

Every practice Most practices Some practices A few practices
I never do this drill

Conditioning: Running, legwork, push-ups, etc

Every practice Most practices Some practices A few practices
I never do this drill

12. On average, how many times do you think a player makes contact with their helmet (i.e., receives a hit to the head) during a full contact practice?

- a) *<5 times per practice*
- b) *6-10 times per practice*
- c) *11-20 times per practice*
- d) *More than 20 times per practice*

13. On average, how many times do you think a player makes contact with their helmet (i.e., receives a hit to the head) during a thud (i.e., low or half-speed drills, no tackling to the ground) practice?

- a) *<5 times per practice*
- b) *6-10 times per practice*
- c) *11-20 times per practice*
- d) *More than 20 times per practice*

14. On a scale of 0 to 6, with 0 being no contact and 6 being the hardest hit an athlete may receive in a game, how hard are the head impacts experienced in each drill?

Install:

0 1 2 3 4 5 6

Oklahoma:

0 1 2 3 4 5 6

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One-on-one:

0 1 2 3 4 5 6

Open-field tackling:

0 1 2 3 4 5 6

Position skill work:

0 1 2 3 4 5 6

15. What do you think contributes most to how often a player makes contact with their helmet (i.e., receives a hit to the head) in practice?
- a) *Tackling technique*
 - b) *Practice drills/structure of practice*
 - c) *Player position*
 - d) *Peer and/or coach pressure*
 - e) *Aggressive behavior/wanting to engage in contact*
 - f) *Other, specify:*
16. Would you be interested in knowing how hard your athletes make contact with their helmet (i.e., receive hits to the head) in practice?
- a) *Very interested*
 - b) *Interested*
 - c) *Slightly interested*
 - d) *Not interested at all*
17. Would you be interested in knowing how often your athletes make contact with their helmet (i.e., receive hits to the head) in practice?
- a) *Very interested*
 - b) *Interested*
 - c) *Slightly interested*
 - d) *Not interested at all*
18. What do you think is the greatest opportunity for improving head impact safety in youth football?
- k) *Limitations on contact in practice*
 - l) *Limitations on drills allowed in practice*
 - m) *Workshops for athletes to teach proper technique*
 - n) *Workshops for coaches to learn safe practices in sport*
 - o) *Rule changes in games*
 - p) *No improvements are needed*
 - q) *Other, specify:*
19. Head impact sensors measure how hard and how often athletes hit their head in sports. Would you be interested in designing a practice plan informed by head impact sensor data?
- a) *Very interested*
 - b) *Interested*
 - c) *Slightly interested*
 - d) *Not interested at all*

Organizational Readiness for Implementing Change (ORIC) – youth football

- [League officials or Coaches] are committed to making football practices safe.
- [League officials or Coaches] are determined to make football practices safe.
- [League officials or Coaches] are motivated to make football practices safe.
- [League officials or Coaches] want to make football practices safe.
- [League officials or Coaches] feel confident that they can keep the momentum going in making football practices safe.
- [League officials or Coaches] feel confident that they can manage the politics of making football practices safe.
- [League officials or Coaches] feel confident that the youth football organization can get people invested in making football practices safe.
- [League officials or Coaches] feel confident that they can coordinate tasks so that efforts to make football practices safe goes smoothly.
- [League officials or Coaches] feel confident that they can keep track of progress in efforts to make football practices safe.
- [League officials or Coaches] feel confident that they can handle the challenges that might arise in making football practices safe.

Adult participants will complete an 8-item scale on the acceptability and feasibility of creating a safer practice structure using the validated Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM).⁸⁸

Football Tackle Technique Survey

We would like to invite you to take part in a research project. The purpose of this research is to understand the knowledge and perspectives related to tackling techniques and hits to the head in football. This survey will take between 5 to 10 minutes to complete. Your part in this study is anonymous. This means that no one will know if you took part in this study and no one, including the researcher, will know what your answers are. Any reports or publications based on this research will only use group data and will not identify you or any individual as being part of this study. If you have any questions, please contact Dr. Jillian Urban (jurban@wakehealth.edu, 336-716-0947). Completion of this survey indicates that you consent to participate.

Survey Questions

1. What level of play do you currently coach? (select all that apply)
 - a) *Youth Tackle*
 - b) *Youth Flag*
 - c) *High School*
 - d) *Collegiate*
 - e) *Semi-Professional*
 - f) *Professional*
 - g) *None*
 - h) *Other*
2. What other levels of play have you previously coached? (select all that apply)
 - a) *Youth Tackle*
 - b) *Youth Flag*
 - c) *High School*
 - d) *Collegiate*
 - e) *Semi-Professional*
 - f) *Professional*
 - g) *None*
 - h) *Other*
3. How many years have you coached football (any level)?
 - a) *0*
 - b) *1-2*
 - c) *3-5*
 - d) *6-10*
 - e) *11-20*
 - f) *More than 20 years*
4. What levels of football have you personally played?
 - a) *Youth Tackle*
 - b) *Youth Flag*
 - c) *High School*
 - d) *Collegiate*
 - e) *Semi-Professional*
 - f) *Professional*
 - g) *None*
 - h) *Other*
5. How many years have you personally played football (any level)?

- a) 0
 - b) 1-2
 - c) 3-5
 - d) 6-10
 - e) 11-20
 - f) *More than 20 years*
6. During your football career, what method of teaching tackling technique were you taught as a player? Please describe the method in the free text box below.
- a) *Free text box*
7. What method of teaching tackling technique is currently used by your coaches to teach proper tackling technique? Please select all that apply.
- a. *Heads-Up Football/CoachUp*
 - b. *Rugby-Style Tackling/Hawk Tackling*
 - c. *Shoulder Tackling System*
 - d. *Other – free text box*
 - e. *Unknown*
 - f. *None*
8. Have you completed any formal training (eg. Webinar, in-person training, etc.) in the methods of tackling technique that you currently use?
- a) *Yes*
 - b) *No*
 - c) *Unsure*
9. How many years have you and your coaches used this method of teaching tackling technique?
- a) *Less than 1 year*
 - b) *Between 1 and 2 years*
 - c) *Between 3 and 4 years*
 - d) *More than 4 years*
10. Which phrases do your coaches use to teach tackling techniques in games and practices? Please select up to five phrases used by your staff most often.
- a) *Eyes on the Hip*
 - b) *Break Down*
 - c) *Chop Your Feet*
 - d) *Shimmy*
 - e) *Plant Your Foot*
 - f) *Head Up*
 - g) *Eyes Up*
 - h) *Shoulder Across*
 - i) *Shoulder on the Hip*
 - j) *Wrap Up*
 - k) *Facemask on Shoulder*
 - l) *Hit, Wrap, Drive*
 - m) *Get Low*
 - n) *Tackle through the Numbers*
 - o) *See What You Hit*
 - p) *Other – free text box*

11. Which practice drills do your coaches use to teach and reinforce proper tackling technique in athletes? Please select up to five drills used in your practices most often.

- a) *Open Field Tackling – 1 on 1 tackling with greater than 3 yards at start of drill*
- b) *Tackle Dummy or Sled – Athlete tackles dummy or sled*
- c) *1 on 1 Tackling – 1 on 1 tackling with less than 3 yards at start of drill*
- d) *Angle Tackle/Eye Opener Tackling Drill – 1 on 1 tackling where athletes approach at an angle*
- e) *Shed the Blocker Tackle Drill – Linebackers and Defensive Linemen shedding blocks*
- f) *Shuffle and Lift Drill/Explosion Lift Drill – Half speed drill where tackler practices rolling hips and lifting ball carrier after initial contact*
- g) *Wave Drill/Linebacker Hole Drill – Tackler must read the hole and tackler ball carrier*
- h) *4 Point Explosion Drill – Athletes begin resting knees and explode forward to push opposing athlete*
- i) *Other – free text box*

12. If your coaching staff uses film review, what is the purpose of reviewing film with your team? Please select all that apply

- a) *We do not review film*
- b) *Review team performance*
- c) *Review athlete specific performance*
- d) *Review game strategy*
- e) *Teach or reinforce technique*
- f) *Highlight big plays/hard hits*
- g) *Other – free text box*

13. How many hours per week does your coaching staff use film to teach and reinforce proper tackling technique in current athletes?

- a) *We do not review film for technique*
- b) *< 1 hour per week*
- c) *1-2 hours*
- d) *2-3 hours*
- e) *3-4 hours*
- f) *>4 hours*

14. In your opinion, how effective is your instruction in practice for athletes to use proper technique during games and scrimmages?

- a) *Very effective*
- b) *Effective*
- c) *Moderately effective*
- d) *Slightly effective*
- e) *Not effective*

Demographic (4 questions)

15. What is your age?

Under 18 18-24 25-34 35-44 45-54 55-64 65-74 75-84 85 or older

16. What is your gender?

Male Female Prefer not to answer

17. How would you best describe yourself?

Protocol version:

Template updated 9.24.14

*American Indian/Alaska Native Asian Black or African American Native Hawaiian or Other Pacific
Islander White Other Prefer not to answer*

18. Are you of Hispanic/Latino/Spanish origin?
Yes No Prefer not to answer

Survey for Intervention Stakeholders

The purpose of this survey is to understand what you think of the practice plan intervention. This survey will take about 10 minutes to complete. If you have any questions, please contact Dr. Jillian Urban (jurban@wakehealth.edu, 336-716-0947).

Guided Practice Plan

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The guided practice plan meets my approval.	①	②	③	④	⑤
2. The guided practice plan is appealing to me.	①	②	③	④	⑤
3. I like the guided practice plan.	①	②	③	④	⑤
4. I welcome the guided practice plan.	①	②	③	④	⑤

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The guided practice plan seems implementable.	①	②	③	④	⑤
2. The guided practice plan drills seems possible.	①	②	③	④	⑤
3. The guided practice plan drills seems doable.	①	②	③	④	⑤
4. The guided practice plan seems easy to use.	①	②	③	④	⑤

Use of Safe Practice Drills

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The use of safe practice drills meets my approval.	①	②	③	④	⑤
2. The use of safe practice drills is appealing to me.	①	②	③	④	⑤
3. I like the use of safe practice drills.	①	②	③	④	⑤
4. I welcome the use of safe practice drills.	①	②	③	④	⑤

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The use of safe practice drills seems implementable.	①	②	③	④	⑤
2. The use of safe practice drills seems possible.	①	②	③	④	⑤
3. The use of safe practice drills seems doable.	①	②	③	④	⑤
4. The use of safe practice drills seems easy to use.	①	②	③	④	⑤

Coach Peer Mentor Program

Acceptability of Intervention Measure (AIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The coach peer mentor program meets my approval.	①	②	③	④	⑤
2. The coach peer mentor program is appealing to me.	①	②	③	④	⑤
3. I like the coach peer mentor program.	①	②	③	④	⑤
4. I welcome the coach peer mentor program.	①	②	③	④	⑤

Feasibility of Intervention Measure (FIM)

	Completely disagree	Disagree	Neither agree nor disagree	Agree	Completely agree
1. The coach peer mentor program seems implementable.	①	②	③	④	⑤
2. The coach peer mentor program seems possible.	①	②	③	④	⑤
3. The coach peer mentor program seems doable.	①	②	③	④	⑤
4. The coach peer mentor program seems easy to use.	①	②	③	④	⑤

Demographic (4 questions)

1. What is your age?

Under 18 18-24 25-34 35-44 45-54 55-64 65-74 75-84 85 or older

2. What is your gender?

Male Female Prefer not to answer

Protocol version:

Template updated 9.24.14

3. How would you best describe yourself?

*American Indian/Alaska Native Asian Black or African American Native Hawaiian or Other Pacific
Islander White Other Prefer not to answer*

4. Are you of Hispanic/Latino/Spanish origin?

Yes No Prefer not to answer