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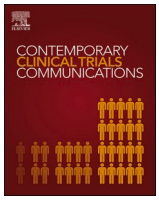

Protocol for COACH, an evidence-based intervention for improved head impact safety in youth American football developed using a community-engaged approach

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ABSTRACT

Subconcussive, repetitive head impacts sustained in collision sports may negatively affect brain health. American football practices are controlled environments amenable to intervention. Engaging community members is essential for successful development, implementation, and sustainability of viable interventions. The objective of this study is to develop and pilot test an evidence-based intervention to reduce head impact exposure in youth American football (i.e., football), using a community-engaged approach. This manuscript describes the co-design of the intervention and associated implementation plan and the study protocol for evaluating the effectiveness and feasibility of the intervention and implementation plan. In the first part of this study, focus groups with parents and coaches, and individual interviews with organizational leaders associated with two teams at the middle school level were conducted. An anonymous survey assessing beliefs and perceptions of non-concussive head impacts was given to parents, coaches, and organizational leaders within the local youth football league. Following the football season, qualitative and quantitative data describing determinants of head acceleration events in football were shared with 12 stakeholders of coaches, league and school administrators, parents, an athletic trainer, and local university player development director. Together, we co-designed COACH (COmmunities Aligned to reduce Concussion and Head impact exposure) and implementation plan using a strategic planning approach. The preliminary effectiveness and feasibility were assessed in the second part of this study. Youth football players participating on the teams in year 1 (control teams) were fitted with mouthpiece-based head kinematic sensors which measure head acceleration events (HAEs). HAEs were collected and quantified during team activities. Preliminary effectiveness of the intervention to reduce HAEs was measured among two new teams pilot testing COACH with mouthpiece-based sensors, while simultaneously monitoring implementation of the intervention. We report our study design and evaluation, and opportunities and challenges with our approach. The results will inform a future full-scale pragmatic trial to assess the implementation and effectiveness of the intervention program.

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1. Background

American football, henceforth termed football, has one of the highest concussion rates among youth team sports [1,2]; however subconcussive head impacts (i.e., repetitive head impacts without signs and symptoms of concussion) are concerning [3–6]. Collisions often result in a head acceleration event (HAE) which is an acceleration response of the head that may be caused by direct head contact (via helmet; i.e., head impact) or indirectly via the body. Wearable devices are used to measure HAEs; video and kinematic signal analysis facilitate delineation of direct and indirect HAEs [7]. Characteristics of concussive and subconcussive HAEs in football have been evaluated [8–13]. Tackling is associated with greater magnitude HAEs [14], while blocking is associated with more frequent HAEs [13]. Regardless, direct HAEs (i.e., head impacts) are greater in magnitude than indirect HAEs [9].

Football blocking and tackling technique has evolved to limit concussion risk. Players are often instructed to remove their head from contact during collisions; despite this, most youth football HAEs occur in practice [8,15] and HAEs in practice are influenced by practice drills [16]. Live practice drills, such as full speed one-on-one tackling, are associated with significantly greater HAE magnitudes compared to limited contact drills [10,16–18]. However, simply reducing *time* spent in contact may not decrease HAE exposure, as contact quality (i.e., proper technique) or intensity (i.e., greater closing distance, multiple iterations) are important [18,19]. The intensity of contact in practice drills may be reduced by conducting drills at half speed or by limiting tackling to the ground. Few national governing bodies of youth football (e.g., USA Football) [20] and nearly all state high school athletic associations (e.g., North Carolina High School Athletic Association; NCHSAA) [21] have introduced graduated levels of contact as a means of limiting contact in practice. Graduated levels of contact are effective at limiting head impacts in high school football practices but have not been evaluated at the youth level [17,17,20,21].

Implementation and enforcement of injury prevention strategies in community-based sports is a challenge as needed support and expertise are lacking [22–24]. Existing programs, including the Centers for Disease Control and Prevention (CDC) HEADS UP program, show promise in improving communication of concussion safety among youth coaches and leagues [25]; however, previous studies have demonstrated youth in communities with greater poverty and lower socioeconomic status were more likely to participate in youth football leagues where coaches had not completed concussion education programs for youth football coaches [22]. Furthermore, volunteer coaching, limited facilities and financial resources, and lack of on-site medical care (e.g., athletic trainers) pose barriers to implementing and enforcing such injury prevention programs [22–24]. 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 [26–28]. To develop feasible and appropriate interventions to improve sport safety, it is critical to design interventions that will translate into real-world settings. Therefore, the objective of this study was to develop and pilot test an evidence-based intervention aimed to reduce head impact exposure in youth football practices. Additionally, the study protocol was developed for a career development award (PI: Urban) and, thus, designed to provide the requisite skills and experience to develop and test sustainable interventions. This manuscript details (Objective 1) the co-design of the intervention program COmmunities Aligned to reduce Concussion and Head impact exposure (COACH), and associated implementation plan, and (Objective 2) the study protocol for evaluating the preliminary effectiveness and feasibility of COACH. In Objective 1, we will outline the process of identifying intervention targets and the strategic planning process and community-engaged approach taken to identify, develop, and refine the evidence-based strategy to reduce head impacts in practice and associated outcomes. In Objective 2, we will outline the study protocol to measure the preliminary effectiveness of COACH using head acceleration sensors and assess the feasibility of implementing COACH among youth community football teams. The aim of this endeavor was to assess the feasibility of implementing COACH among youth football teams. We also sought to understand how coaches will interact with and use COACH, and plan for adaptations and other considerations necessary to develop a full-scale pragmatic trial with sufficient rigor and statistical power to assess the effectiveness of implementing COACH to reduce head impacts and concussion risk.

2. Methods

2.1. Overall study design

The co-design of COACH involved one year of formative research and a second year of strategic planning with a community stakeholder team. In the first year, stakeholders (parents, coaches, organizational leaders) from a North Carolina youth football league and athletes participating on 12U (ages $\leq$12) and 13U (ages $\leq$13) teams at were recruited to participate. Instrumented mouthpiece sensors were used to collect HAEs among athletes with on-field video data to inform discussions with coaches and parents via semi-structured focus groups and organizational leaders (henceforth referred to as leaders) via key informant interviews. HAEs collected in this season also served as control data. An anonymous survey was deployed to assess knowledge, attitudes, and perceptions of stakeholders related to youth football head impacts and practice structure. These data combined with published literature informed the development of an evidence-based practice intervention using a strategic planning process and community-engaged approach to develop COACH over 6-months in the subsequent year (year 2). The study protocol to pilot test COACH and evaluate the effectiveness and feasibility will be employed in the third year of this study. COACH will be pilot tested among two new 12U and 13U teams. On-field activity will be monitored with mouthpiece sensors and video to evaluate the preliminary effectiveness and fidelity of COACH. Feasibility and acceptability of COACH will be monitored throughout the pre-implementation and implementation phases of this study. This study was approved by the Wake Forest University School of Medicine Institutional Review Board. Informed consent was obtained from adults (parents, coaches, leaders) and parents/legal guardians of all athletes; participating athletes signed assent forms. This study was funded by the National Institute of Child Health and Human Development (NICHD) as part of a K25 Mentored Career Development Award (K25HD101686, PI: Urban).

3. Development of the intervention program and implementation plan to reduce head impacts in youth football

The following sections outline the process of identifying determinants of HAEs to inform intervention targets and the strategic planning process and community-engaged approach taken to identify, develop, and refine the evidence-based strategy to reduce head impacts in practice and associated outcomes. A stepwise guide outlining this approach is provided in Fig. 1.

3.1. Activity and head acceleration monitoring in youth football (Year 1, step 1)

This section outlines the methods to monitor on-field activity and head accelerations experienced by youth athletes. The study sample and associated data also represented control athletes in the pilot feasibility study. Recruitment, enrollment, and study design for this sample are described herein.

Study Sample. In year one, we identified one 12U and one 13U level football team for the control arm of the study. All interested athletes on these teams were invited to voluntarily participate in biomechanical data collection with mouthpiece sensors until we met our enrollment criteria (n = 15 per team, n = 30 total). Additional athletes were

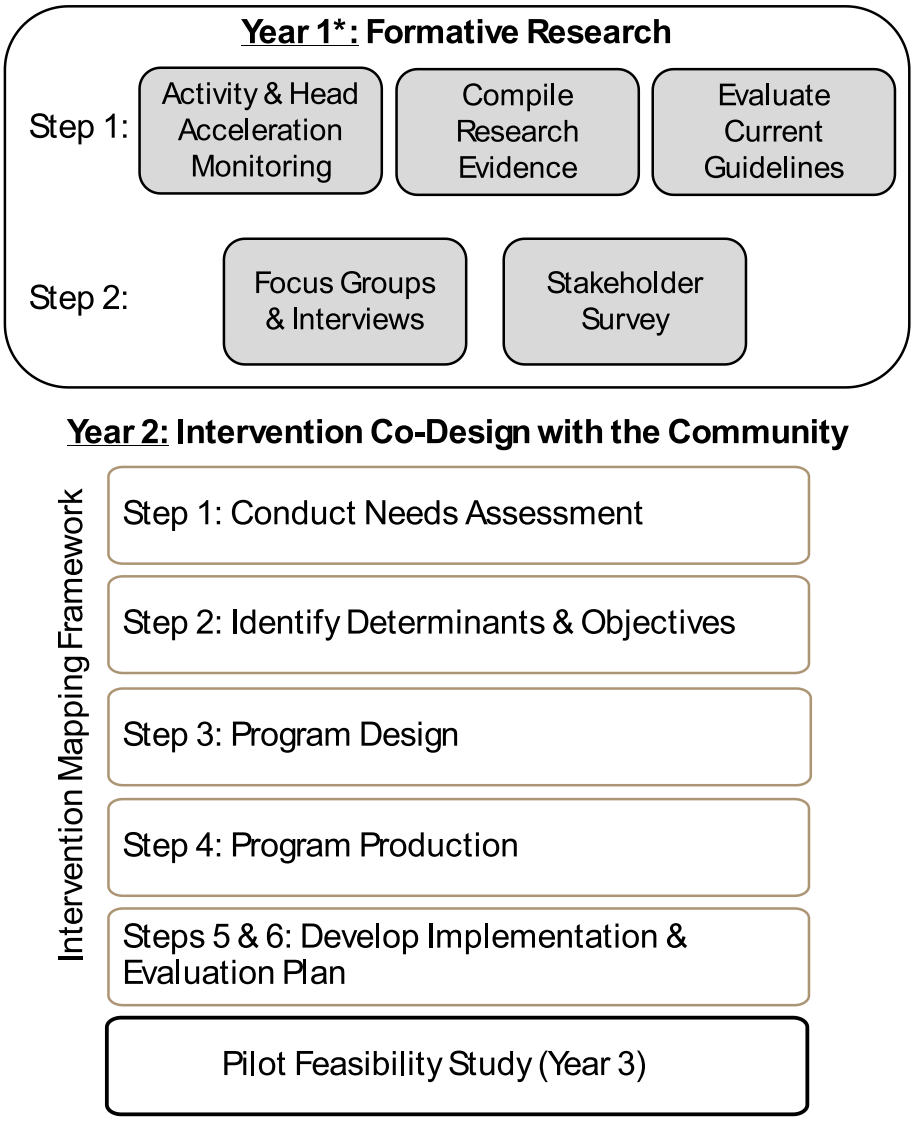

Fig. 1. Outline of steps to complete the first objective of this study. *Several years of observational research assessing on-field activities and head acceleration monitoring in youth football informed the present study. This was compiled from prior research evidence.

enrolled as budget allowed to account for attrition (e.g., athlete quits or sustains a season-ending injury).

Biomechanical Data Collection. Enrolled athletes were assigned a validated instrumented mouthpiece, measuring frequency and magnitude of HAEs [9,10,29,30]. The mouthpiece contains an accelerometer, gyroscope, and battery and is assigned to each player and sanitized, charged, and distributed before each session by study staff. Data collection occurred during all practices and games. Data was screened to remove events that did not occur from a HAE (e.g., running) using time-synchronized video data collected at each session. Data collection followed best practices outlined by the Consensus Head Acceleration Measurement Practices (CHAMP) [7].

Video Collection and Analysis. Team activities were recorded in real-time by trained research assistants using time-synchronized video and standard data entry forms [7,31–33]. A MATLAB graphical user interface was used to semi-automatically code characteristics associated with each event measured by the mouthpiece by visualizing the kinematics (linear acceleration, rotational acceleration, rotational velocity) of the event side by side with video. Practice and game classifications were paired with biomechanical data based on the timestamp, assigning appropriate metadata for each HAE [13,33–35].

Biomechanics and Video Data Summary. Team practice and game reports were created for coaches to facilitate discussion of head impacts. Reports were provided weekly for the first six weeks of the season, followed by one end of season summary. Practice reports included the average number of HAEs per player each week and the season average to date. The number of HAEs and time spent on specific drill categories each day were reported; season averages of each were also provided. Similarly, for games, the average number of HAEs per player and a breakdown of impacts by field position (open-field or line of scrimmage) [12] and player position (offense or defense) were summarized.

3.2. Focus groups and interviews: recruitment, enrollment, and study design (Year 1, step 2)

Study Sample. In year one, coaches and parents with athletes on one 12U and one 13U team participating in parallel biomechanical data collection (see ***Activity and Head Acceleration Monitoring in Youth Football***) were invited to participate in four focus groups. Focus groups included only parents or coaches of the respective team. Leaders from different organizations within the same league were invited to participate in a single one-on-one interview. Leaders served various roles, including president and athletic/football director.

Development of Data Collection Materials. Semi-structured focus

groups and interviews were conducted by a single study team member. Experiences and perspectives of being a youth football coach or parent were discussed at the first focus group. During the second focus group, video of football collisions and head acceleration data were presented; parents and coaches shared their perceptions of contact and reflected on the data. At the third focus group, coaches discussed practice drills and coaching football technique while parents discussed concussions and clinical implications of subconcussive head impacts. The fourth discussion was a focus group (for coaches) or an interview (for parents) to review and discuss head acceleration data from the season. The first through third focus groups were 1 h and conducted in person, while the fourth was virtual. Virtual, 30-min leader interviews focused on their unique experiences and perspectives.

During the last 5 min of each focus group and interview, participants completed an eight-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) [36]. Leaders and coaches completed 10 additional questions pertaining to Organizational Readiness for Implementing Change (ORIC) [37]. Coaches completed a survey detailing their practice structure, including drill frequency and perceived severity of certain drills.

Qualitative Analysis: Focus group and interview audio was recorded with a note taker documenting details according to the semi-structured guide. Focus group recordings were initially transcribed using Otter. ai (Otter.ai, Inc, Mountain View, CA). A research team member reviewed and corrected the transcription. A combination of deductive and inductive coding was completed to develop a codebook specifying the code, code definition, exclusion criteria, and representative quote(s). Codes were added as new topics emerged. Two research team members independently coded each transcript using ATLAS.ti 22.0.6.0 [38]. The research team members met to discuss coding and resolve discrepancies. Once coding was completed, code reports were run for each code.

The Rapid Assessment Process (RAP) was used to analyze interviews with leaders [39]. Domains corresponding to individual questions and in accordance with the order of the guide were developed into a matrix. A member of the research team listened to audio recordings and completed the matrix, capturing the main points of the discussion and representative quotes. Matrix data were organized by respondent and domain for concurrent analysis of all responses [40] A second research team member reviewed the matrix and summary by domain to identify and address any gaps in the summary. Focus group and interview data were integrated and analyzed for thematic content by two study team members [41].

3.3. Stakeholder survey (Year 1, step 2)

Parents, coaches, and leaders of the league were invited to complete a one-time online anonymous survey via REDCap regarding perceptions of subconcussive head impacts and strategies to reduce head impacts in youth football. The survey was sent to the president or football director of each organization to distribute to the parents and coaches within their organization at the start of the football season. Two reminder emails were sent one week apart, and an additional reminder email was sent at the end of the season to coaches via leaders.

The survey was comprised 23 questions measuring knowledge, beliefs, perceived susceptibility, perceived severity, and self-efficacy. Football and sport participation (e.g., role, football experience) and demographics (e.g., age, sex, race, ethnicity) were measured. When possible, survey questions were derived from previously published surveys regarding concussion [42–44] and guided by constructs of the Health Belief Model [45].

3.4. Brief results: informing intervention development

Step 1. The results of Step 1 have resulted in two publications. In the first publication, we summarize 5292 head acceleration events were collected and evaluated from 30 athletes [33]. The median (95th percentile) peak resultant linear acceleration, rotational acceleration, and rotational velocity was 9.5 g (27.0 g), 666.4 rad/s^2 (1863.3 rad/s^2), and 8.5 rad/s (17.4 rad/s), respectively. Athletes experienced six (22) head acceleration events per athlete per session (i.e., practice, game). Competition had a significantly greater mean number of HAEs per athlete per session and mean peak rotational acceleration; however, a greater proportion of HAEs over the season were attributed to practice. Peak resultant rotational kinematics varied significantly among athlete positions. Direct head impacts had significantly greater mean kinematics (13.9 [13.3–14.5] g, 919 [861–981] rad/s^2, 10.0 [9.5–19.5] rad/s) compared to indirect head acceleration events (8.2 [7.9–8.6] g, 632 [593–673] rad/s^2, 7.6 [7.2–8.0] rad/s, from body collisions (all $p < 0.001$) and were, thus, targeted to be reduced in the intervention program.

We have led three published assessments of practice drills conducted by youth football teams, including the published study from year 1 of this project [10,16,18]. Across all our drill studies, we have demonstrated that single player versus player drills with greater closing distance, and higher intensity (e.g., open field tackle, angle tackle) are associated with the greatest mean peak resultant linear acceleration and rotational acceleration. Additionally, multiplayer versus player drills (e. g., team scrimmage, inside run, and Oklahoma) result in the greatest impact rates and total number of head impacts collected in practices. In one analysis of six teams, we found that 76 % of impacts were attributed to three common drills: Scrimmage/Install, Oklahoma, and Position Skill Work, but significant variations in head impact exposure were observed among teams [16]. In an additional study, we found that control teams averaged nearly 40 min per practice in live drills, including tackling and scrimmage, with many practices meeting or exceeding 60 min of live time per practice [46]. This has been further substantiated by the drills observed and measured among other teams and reiterated in our stakeholder meetings [16,18,34]. Lastly, we found that a team's drill setup and practice structure affect the frequency and severity of head impacts experienced (i.e., their head impact exposure) [10,16]. For example, one of the six teams spent the greatest proportion of practice on minimal to no player versus player contact drills compared to other teams, but had the highest median and 95th percentile linear acceleration in practice. These studies emphasize the influence of coach-directed activities (e.g., practice drills) on head impacts in youth football. It also provided key data to inform development of the intervention program, such as the need to incorporate alternative levels of contact outside of live tackling. These findings were further supported by previous research evidence indicating a need to reduce direct head impacts in practice via coach-directed activities [46–51].

Step 2. In our focus groups, we found parents place trust in their child's coaches and expect them to have the knowledge and skills necessary to teach athletes proper skills and techniques to prevent injuries. Organizational leaders described their role in setting expectations of coaches but recognized the coaches' autonomy in determining the activities of the team and responsibility for the safety of the athletes. Coaches who teach players techniques that are not aligned with current practices and coaches who prioritize winning over safety were identified as concerns for player safety. The results of this portion of the formative research demonstrate the important role coaches play in the personal and technical skill development and safety of youth football players.

In our stakeholder survey, we learned that parents perceived the susceptibility and severity of head impacts in football to be greater than coaches and organizational leaders; however, coaches and organizational leaders had greater beliefs and self-efficacy surrounding head impact safety efforts in football compared to parents. Parents and coaches/leaders indicated their perspectives on opportunities to reduce head impacts in youth football; workshops for athletes to teach proper technique, safer helmets/equipment, and workshops for coaches to learn safe practices were most common. Coaches and leaders prioritized

workshops for coaches whereas parents prioritized technique workshops for athletes. This informed beliefs and perceptions among football stakeholders as well as the type of injury prevention strategies parents, coaches, and leaders may be most supportive of.

3.5. Community stakeholder team: recruitment, enrollment, and study design (Year 2)

In year two, local community members were recruited to co-design an evidence-based intervention and implementation plan. They included leaders, coaches, former football players, parents, an athletic trainer, director of player development for a local university, and two head high school football coaches (n = 12). We leveraged successful community relationships to build a cross-section of stakeholders with different levels of interest and influence [34,52–54].

We defined the purpose of the research study was to work collaboratively to develop a strategy to reduce head impact exposure in youth football practices. We conducted five monthly virtual stakeholder meetings guided by tools in the Community Tool Box [55] and Intervention Mapping [56] framework to develop the strategy. The Community Tool Box is a free, online resource to help guide individuals and groups working with communities to improve health and positive social change. Intervention Mapping is a program planning framework providing a systematic approach to intervention development, implementation, and evaluation.

At our first meeting, we defined the collaboration objective and priorities, including goals, expectations, and constraints. We explained stakeholder involvement would be used to develop and select the strategy to be tested. If a stakeholder was not able to attend the group meeting, a one-on-one follow up was scheduled within 1–2 weeks. In the subsequent meetings, we conducted Intervention Mapping to define, develop, refine, and select a strategy to test for reducing head impact exposure in practices [56]. Separate semi-structured guides were developed for each discussion according to the Intervention Mapping framework (Fig. 1), with input from the research team. Group discussions were moderated by a single study team member. A written summary was provided after each meeting. The strategy selected for pilot testing was determined by the perceived potential to reduce practice head impacts, community needs alignment, feasibility, acceptability, resource availability (e.g., tackling dummies), and evidence to support the strategy. An action-oriented objective was defined. The social-ecological model [57] is a prevention framework considering the dynamic relationship between individual, interpersonal, community, organizational, and policy factors influencing health. Determinants and level(s) of the social-ecological model [57] targeted with the strategy were also defined. Acceptability was prioritized to select the strategy as guided by Conceptual Model of Implementation Research, which was used to develop the implementation plan [58]. With the selected strategy, we worked with stakeholders to operationalize the approach into discrete components with a clear plan of action and programmatic materials.

The Intervention: Intervention targets were defined as: (1) improve the knowledge and skills of youth football coaches in effective practice planning and use of safe drills, and (2) change attitudes and beliefs of coaches toward contact in practice. Stakeholder meetings elucidated that high school coaches are early adopters of safe practices because of NCHSAA guidelines for contact in practice. The NCHSAA guidelines outlines five levels of contact during drills: Air, Bags, Control, Bump/Thud, and Full Live Action Contact (Table 1). The NCHSAA indicate when student-athletes may "hit" or have body-to-body contact and time limits on the amount of live action contact during pre-season (15 min per day) and regular season (15 min per week). The American Youth Football (AYF) handbook indicates that practice contact restrictions should be implemented per applicable National Federation for High Schools (NFHS) guidelines or state law. While North Carolina, the location of this study, does not require non-high school interscholastic football programs to follow NCHSAA guidelines, we used this as the basis of our intervention. We co-created the intervention program, COACH, with our community stakeholder team guided by Social Cognitive Theory and Diffusion of Innovation and defined short- and long-term programmatic outcomes. We identified high school coaches as key to the development and implementation of COACH.

Table 1
Graduated levels of contact [20,21].

Level of Contact	Description
Air	Athletes run drill unopposed without contact
Bags	Athletes run drill against hand-held bag or soft surface
Control	Athletes run drill at coach-assigned speed; pre-determined "winner"; contact stays above the waste and players stay on feet
Thud	Drill run at competitive speed with no wrapping up of a ball carrier; players stay on feed with quick whistle indicating end of drill
Live	Drill is run in game-like conditions; athletes may be tackled to the ground

3.6. Implementation strategies

We developed a logic model of programmatic elements used to encourage adoption of NCHSAA guidelines and evaluate intervention outcomes (Appendix). Intervention Mapping Steps guided the development of the logic model, contextual factors, and program design. The Community Toolbox guided the consideration of inputs/resources (e.g., youth coaches, high school coaches, equipment, environment) and constraints (e.g., time/availability of coaches, funding, culture of football). The implementation strategies were developed and refined through stakeholder meetings (Intervention Mapping, Steps 4 and 5) and consist of a pre-season coaches' clinic, guided practice plans, a resource booklet, and peer mentorship during the football season. Intervention outputs and effects were discussed and outlined throughout during stakeholder meetings (Intervention Mapping, Step 6).

Our goal was to use COACH to influence youth coaches to adopt NCHSAA guidelines and associated levels of contacts. A description of the COACH implementation strategies outlined in Fig. 2 are provided below.

Resource Booklet: A resource booklet was developed to provide youth football coaches a resource to support development of practices that are aligned with NCHSAA guidelines. It outlines best practices to develop football skills and techniques of athletes for performance while keeping them safe. It contains practice pointers on efficient use of time as well as "do's and don'ts" for player safety. There are over 40 drills identified by high school coaches as important for player skill development and safety and includes suggestions for effectively planning practice. Drills are organized by the five NCHSAA levels of contact and include a definition of the purpose of the drills, player positions involved, role of the athletes, skills to be developed in the drill, key phrases to enforce proper technique, and a schematic layout and YouTube video of the drill.

Guided Practice Plans: The resource booklet also contains pre-filled and blank practice templates for "helmets only" (i.e., air and bag drills allowed), "shells" (i.e., air, bags, control, and thud drills allowed), and "full pads" (i.e., all five levels of contact allowed) practice with 5-min periods outlining the recommended levels of contact to be incorporated throughout practice. The pre-filled templates define the practice focus by position group (e.g., linemen: blocking schemes; skill athletes: routes and coverage). Specific drills within each 5-min period are provided with the page number referenced for additional information (see Resource Booklet).

Coaches' Clinic: Before the football season, a pre-season coaches' clinic was developed to supplement the resource booklet. The clinic agenda included a moderated panel of high school head coaches on practice planning, biomechanics and sports medicine talks about

Fig. 2. Elements of the COACH implementation strategy: guided practice plans, resource booklet, coaches' clinic, and peer mentor.

concussion and other injury prevention topics, and on-field demonstrations of drills. The moderated panel of head high school coaches included four reputable coaches in the county and was moderated by a researcher and former head high school football coach. Prompts included, "Why is it important to plan out your practice before your athletes step on the field?", "What is your philosophy around contact in practice?", and "The North Carolina High School Athletic Association recently updated their guidelines to limit live contact in practices to 15 min per week. How have you and your coaching staff adapted to these changes without having live contact every practice?" The biomechanics talk discussed what can be learned from wearable sensors, how we collect data, and the types of collisions and drills that contribute to greater head impact exposure. Sports Medicine talks discussed the following topics: concussion signs and symptoms, what to do if a concussion is suspected, return to play following concussion, prevention and management of exertional heat illness, sudden cardiac arrest and cardiopulmonary resuscitation (CPR), as well as nutrition, hydration, and strength training in youth. Finally, the on-field demonstrations of drills were conducted on a large collegiate indoor practice field. Drills were guided by the drills and content in the resource booklet, instructed by high school coaches, and demonstrated by collegiate football players.

Peer Mentor: Finally, youth football coaches were able to select a local high school head coach who would be a resource and mentor to them throughout the season. The youth and high school football coaches were encouraged to meet weekly to check in on how practices and games were going, discuss what the team is struggling with, and how to adjust practice plans to meet the needs of the team.

4. Protocol for evaluating the preliminary effectiveness and feasibility of COACH (Year 3)

The following section outlines the study protocol to measure the preliminary effectiveness of COACH using head acceleration sensors and assess the feasibility of implementing COACH among youth community football teams.

4.1. Intervention: recruitment, enrollment, and study design

Study Sample: Teams/Coaches. In year three, we will work with the local youth football league to identify two 12U and 13U teams to pilot test the COACH intervention program. We will have individual meetings with prospective coaches to describe COACH, goals, and expectations of the study. Informed consent will be obtained from coaches.

Study Sample: Intervention Athletes. Once the coaches participating in COACH are identified, we will work with them to arrange meetings with parents and players to describe the intervention and provide opportunities to answer questions. Informed consent will be obtained from parents/legal guardians of all youth athletes; participating athletes signed assent forms.

Study Sample: Control Athletes. The study sample of control athletes is described in ***Activity and Head Acceleration Monitoring in Youth Football (Year 1, Step 1).***

Experimental Design and Methods. Before the fall football season, participating coaches will be trained according to guidelines established with our community stakeholder team. Youth coaches will select a peer mentor (e.g., local high school head coach), as a resource for the coaching staff throughout the season. During the season (Aug–Nov), trained research staff will attend all practices and games to collect biomechanical data and video. Implementation process (i.e., feasibility and potential utility of the implementation strategy) will be monitored. The community stakeholder team will be gathered twice during the season to provide feedback on feasibility and acceptability of the intervention, including suggestions to improve uptake of COACH and to identify implementation process strengths.

Data Collection. Fifteen athletes will be recruited from each team (n = 30 total) and assigned an instrumented mouthpiece. Mouthpiece data will be processed as described in the control section. Video will be reviewed to characterize on-field activity, pair with head acceleration data, and determine the extent of intervention implementation. Coaches will complete the AIM and FIM surveys at the start and end of the season [36].

4.2. Outcomes and statistical analysis plan

Data collection is complete, and the analysis plan is outlined below.

Primary Outcomes. We acknowledge that this study lacks sufficient power to fully test the effectiveness of the intervention; however, we will gather essential information informing the feasibility of a future

pragmatic trial with a stepped-wedge design. Primary outcomes include specific indicators of pilot feasibility [59]. Recruitment and retention will be tracked. AIM and FIM scores collected from enrolled coaches at pre- and post-season timepoints will inform the perceived feasibility and acceptability of each component of the implementation plan. 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. Five essential elements of COACH will be monitored to determined extent to which coaches implemented the intervention as intended: coaches submit a practice plan, coaches follow the practice plan, coaches incorporate alternative levels of contact, coaches limit live contact in practice, coaches incorporate drills that are in the resource booklet. Three non-essential elements to be evaluated include: coaches appear to have explained the drills prior to completing them, coaches stop a drill to correct poor technique, coaches engage peer mentor. 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 meetings [60]. Common themes will be grouped, and qualitative data will be indexed and charted. An implementation fidelity score will be calculated for each week to assess the degree of intervention adoption by the youth coaches, and to identify key components of the strategy that may be implemented and sustained over time.

Secondary Outcomes. COACH aims to reduce head impacts in youth football practices. Data from the mouthpiece will be quantified for each athlete for each practice or game by impact rate. Total number of impacts, mean, median, and 95th percentile of head kinematic measures will be calculated from the impacts collected over the season and by session type. These metrics will be compared between control and intervention seasons. Mixed-effects models will be used to assess differences in HAEs in practices and games before and after the intervention, adjusting for confounders, including team. We will examine the consistency of intervention effects on exposure outcomes between teams and among players over time to learn how to refine and tailor COACH to increase adherence to COACH guidelines and potential effectiveness.

5. Discussion

The study design combines biomechanics, focus groups, interviews, and surveys with community members and stakeholders to inform the development of an evidence-based intervention to reduce head impacts and concussion risk in youth football practices. Using a community-engaged approach, biomechanical evidence informs the basis of the intervention, while strategies for addressing the biomechanical reduction targets were guided by behavior change theories and implementation science frameworks in collaboration with community stakeholders. 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 [61,62]. Co-design of intervention programs with the community has been effective in developing feasible and acceptable prevention strategies in clinical and community settings and has been recently adopted for sports injury prevention [63–66]. As future studies will continue to adopt community-engaged approaches toward the development and evaluation of intervention programs, we have reflected on the opportunities and challenges inherent to working with the community and our research approach.

The formative work conducted in year one provided important evidence to identify HAE determinants and context related to the youth football environment to inform the development of the intervention. Specifically, this work helped guide the early meetings with the stakeholder team and highlighted the type of events and activities that influence HAEs in youth football (e.g., live, full speed tackling drills) and the necessity to focus on coach-directed practice activities. It also highlighted the important role coaches play in the personal and technical skill development and safety of youth football players, as well as stakeholder priorities and perceptions of opportunities to reduce the frequency and magnitude of head impacts in youth football. This information was used to develop a brief presentation for our first stakeholder meeting (January 2023). In this stakeholder meeting, we discussed why we love football and the need to balance benefits and risks involved in the sport. We reviewed literature and research findings from year one, and discussed the knowledge and skills coaches need to effectively instruct athletes, as well as areas for improvement in youth athlete skills (Intervention Mapping, Step 1, Fig. 1). Following the meeting, members of the research team (JU, MM, TH) relistened to the meeting recording to create a 1-page summary of the discussion that was shared back with the stakeholders. We found this to be an important and critical step in synthesizing the discussion of the prior meeting and planning for the next meeting. It has also proven to be a helpful resource to return to.

After creating the summary document, we identified gaps in the discussion to fully inform determinants and objectives of the program (Intervention Mapping, Step 2, Fig. 1). In second meeting (February 2023), we discussed how coaches teach athletes using drills in practice as well as attitudes and beliefs toward contact in practice. There were several key themes that emerged from this meeting include a need for coaches to teach *how* to tackle, instead of encouraging big hits, and the need for coaches to understand *why* each drill is being conducted. Furthermore, the stakeholder team identified gaps in instruction at the youth level of football, including applying outdated strategies (e.g., having kids lay on back and run at one another) based on prior participation in youth or high school football, and lack of knowledge and awareness of what "words to use, drills to use, or reasons behind strategies in practices". Finally, the stakeholder team identified current attitudes and beliefs towards contact, recognizing that many parents and coaches cheer on "big hits" and feel the need to build up toughness of athletes. This discussion further reinforced topics discussed in our focus group discussions and helped us establish our intervention targets. We also identified theory-based change methods to guide preliminary program components. Importantly, we identified that high school coaches are early adopters of safe practices because of state guidelines around practice and motivated to limit contact in practice for a full and healthy team to compete on Friday. Therefore, we aligned our programmatic materials with state guidelines for contact in practices used by local high school coaches (NCHSAA).

Steps 3 and 4 (Fig. 1) of the intervention mapping framework guided our third (March 2023) and fourth (April 2023) meetings with stakeholders. In the third meeting, we proposed the idea of guided practice plans, discussed pros and cons of this concept, the amount of flexibility needed to build into the practice plans, possible challenges we may face, and what would be needed to facilitate changes in attitudes and beliefs. We also proposed the idea of the peer mentor and discussed parameters around this element of the program. Finally, we identified the need to have high school coaches lead training associated with the program. Based on this meeting, we further refined the implementation plan to include a pre-season clinic for coaches and reference materials to supplement the guided practice plans. In the fourth meeting, we discussed the content and details of the coaches' clinic, details of guided practice plans and format, content of the reference materials and format, and logistics of the peer mentor program. From this, we further refined the program to include live demonstrations of drills at the clinic and began to develop final programmatic materials. In the final development meeting (May 2023, Intervention Mapping, Step 5, Fig. 1), the stakeholder team gave final feedback on the format of all programmatic elements. Expectations of programmatic engagement was discussed throughout meetings three through five and informed the final essential and non-essential elements of the intervention evaluated in the study (Intervention Mapping, Step 6, Fig. 1).

5.1. Lessons learned and challenges

Relationship and trust building takes time but is important for effective engagement. A key factor contributing to study success is our partnership and history working with the local youth football community. We have conducted observational studies of head impact biomechanics and clinical outcomes with local youth and high school programs since 2012, leading to positive relationships and trust. This facilitated our identification of teams and strong community stakeholder team. Focus group, interview, and survey data informed our approach to stakeholder engagement and were valuable in developing intervention targets with our stakeholder team. Additionally, we discovered that every person on our stakeholder team knew at least one other person on the team through connections they personally made in the community. This was unexpected but facilitated a greater connection among the stakeholder team.

Coordinating research activities among busy volunteer stakeholders is challenging during the sports season; arranging meetings parallel to existing events and offering virtual meeting options increased community member engagement. We found that having parent focus groups during practice facilitated participation as it gave parents something to do while waiting for their child. In addition to finding a convenient time for parents, we provided dinner (e.g., sandwiches, Gatorade) that they could take to go. Coaches, on the other hand, preferred to meet after practice, or a weekend time convenient to them. Meeting after practice was beneficial for coach participation; however, it was difficult to find a quiet meeting place and often felt rushed due to practice ending late. Meeting at an alternative time and location presented different challenges, as other activities (e.g., church, household tasks, televised football games) often conflicted. Coaches are volunteers with jobs and families, and become very busy during the football season, making scheduling and coordinating of research activities a challenge. Conducting meetings virtually or outside of the football season may help limit the burden on coaches' participation.

We conducted all community stakeholder meetings virtually due to scheduling challenges and stakeholder preference. Virtual meetings allowed us to group individuals with different responsibilities and geographic locations without added travel or coordination, greatly increasing engagement. We also scheduled one-on-one follow ups for those unable to attend group meetings. We hypothesize that having in-person meetings would have increased collegiality; however, we did not feel virtual meetings inhibited our ability to meet stakeholder meeting goals.

The pilot feasibility study will afford the opportunity to understand how coaches will interact with and use COACH. It will also provide preliminary evidence indicating if COACH is deemed acceptable and feasible by the target population, and efficacious in reducing HAEs in practices. It will also inform necessary adaptations prior to broader implementation. In the next phase of this project, we will rigorously and pragmatically evaluate the COACH intervention program in a real-world setting using a Hybrid I stepped wedge clinical trial study design, while monitoring factors influencing implementation, including organizational capacity and context.

5.1.1. Limitations

Because this was a pilot study, we lack sufficient power to fully test the effectiveness of the intervention. Participants represented a limited sample of parents, coaches, leaders, and teams from a single youth football league operating under guidelines of American Youth Football whereby limiting generalizability. Teams pilot testing the intervention volunteered for participation in the program which may lead to bias in their experience with the program. We plan to conduct a full-scale pragmatic trial with sufficient rigor and statistical power to assess the effectiveness of COACH to reduce the risk of adverse clinical outcomes associated with head impact exposure.

6. Conclusions

Implementation science and community engagement approaches have valuable methods and strategies to improve the translation of evidence-based interventions into practice [67–69], but few studies have applied these approaches to sports injury prevention [70,71] and in youth settings [72–75]. Sports injury prevention strategies are often informed by clinical, epidemiological, and/or biomechanical evidence [50,76–80]; however, the best strategy for injury prevention is not useful if it is not adopted or sustained by the target population. Community engagement facilitates trust building, communication, and improved health outcomes through action-oriented efforts [28,81] Youth football leagues are diverse, often under-resourced and with coaching support from parent volunteers [22,23,82]. These and other factors constitute challenges to the implementation of strategies to prevent and treat serious injuries among the children in these communities.

Our team has successfully collaborated with community stakeholders to co-create and pilot test a strategy to reduce head impacts and concussion risk in youth football practices. Results of this study demonstrate the value of engaging community members in the co-design and implementation of evidence-based injury prevention programs in youth sports. This study also serves as critical a critical pilot informing a future pragmatic evaluation of the effectiveness of COACH on a larger scale, while monitoring factors that influence implementation. We seek to continue to develop and refine acceptable, practical, and feasible injury prevention strategies for millions of athletes participating in community youth sports.

CRediT authorship contribution statement

Jillian E. Urban: Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Justin B. Moore:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization. **Madison E. Marks:** Writing – review & editing, Project administration, Methodology, Data curation. **Ty D. Holcomb:** Writing – review & editing, Methodology, Data curation. **Robert Patterson:** Writing – review & editing, Methodology. **Alexis McCoy:** Writing – review & editing, Methodology. **Christopher M. Miles:** Writing – review & editing, Supervision, Methodology. **Joel D. Stitzel:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Kristie L. Foley:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Stitzel and Urban hold a patent for the mouthpiece form factor described in the protocol.

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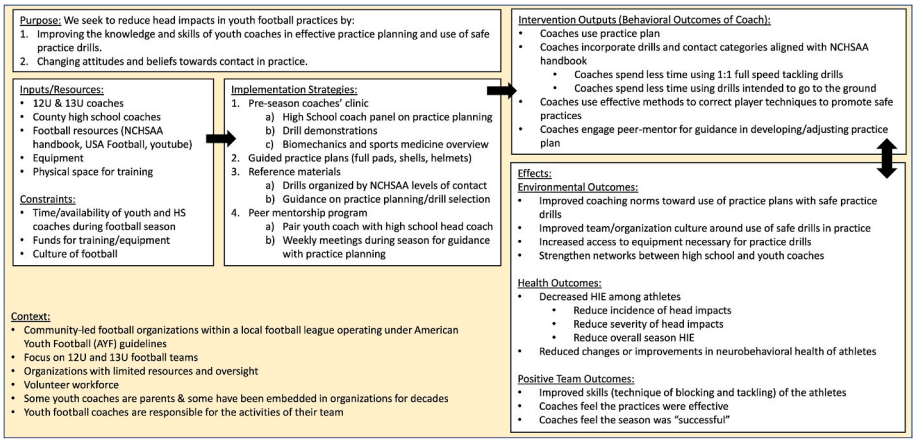
Appendix

Logic model outlining activities of COACH to implement and evaluate adoption of NCHSAA guidelines for contact in practice among youth football coaches.



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