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Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition and Reporting of, & Response to Concussions in Middle School-Aged Athletes.

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Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition and Reporting of, & Response to Concussions in Middle School-Aged Athletes.

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An abstract of A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health in Rollins School of Public Health, Emory University, Atlanta GA 2016

Abstract

Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition and Reporting of, & Response to Concussions in Middle School-Aged Athletes.

By Unini Odama, MD

Sporting activities remain an integral part of most societies. Therefore, it is of great benefit to discuss and create safer ways to play and enjoy sporting activities without the grave consequences that could occur from unreported or untreated concussions. Rationale: In spite of what is known, regarding the attitudes, behavior, gender differences, and concussion rates in high school and collegiate athletes, there is a gap of knowledge that exists regarding determinants of, and behavior regarding concussions in athletes younger than high school. Therefore, this proposal aims to a) understand concussion-related behavior in middle school-aged children b) develop a social cognitive theory based, concussion prevention App based intervention c) increase the recognition and reporting of, and response to concussions among middle school-aged children and adolescents. Research questions: 1) What are the social and behavioral determinants of concussion in youth athletes? 2) Are there gender differences in awareness, knowledge, attitude, behavior, perception, value, self-efficacy pertaining to sports concussions in middle school aged students? 3) How does an interactive App based intervention affect attitudes and behavior regarding sports-related concussions in middle school aged children? Method: After IRB approval, a Pilot School in the Southeastern US will be conveniently selected. Middle School-aged participants with assents and parental consents will be recruited (n=384). Intervention: An interactive concussion prevention app will be developed and used weekly for six months during a physical education class to increase recognition of concussion symptoms, and empower participants to report and respond to concussion symptoms. Instruments: We will use a mixed-methods approach via pre-and post-intervention surveys and focus groups to capture data on middle school participants' knowledge, attitudes, and beliefs regarding concussions. Analysis: We will use Epi-info and Stata statistical package for the primary analysis of the quantitative data. The trends and patterns of behavior regarding concussions will be analyzed according to the procedures outlined in Patton (2014). An evaluation of the intervention will be completed before disseminating the results. Lessons learned from this pilot study will be helpful in developing larger scale programs targeted at primary and secondary prevention of sports-related concussions in youth athletes.

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2016

Acknowledgements

First and foremost, I would like to thank God who enabled a 'downstream nephrologist' to swim upstream to think, and talk about "brain matters." It would have been practically impossible for me to discuss ways to prevent sports-related concussions in youths, without His wisdom, guidance, and favor.

I would also like to thank my husband, Ifeanyi, who has been steadfastly supportive of all my endeavors, always making sure that I had protected time for my studies and that I was well nourished. I thank him for his love and encouragement which has made all the difference. My children, Jeanine, Joshua and Jada's input, have been invaluable because they constantly challenge me to think outside the box and embrace technology as a way of communicating with youths. They also have encouraged me to be the best that I can be.

I would like to thank Dr. Baldwin for his understanding, willingness, time, effort, and leadership as the supervisor of this thesis project. My field advisor, Dr. Greenspan's astuteness, kindness and invaluable support cannot be overemphasized, and I thank her very much.

Special thanks to my thesis reviewers, Dr. Westfall for his kind assistance, mentorship, and prompt detailed feedback, Ms. Hinmann and Ms. Carlson for their keen attention to detail and insightful comments.

Many others have contributed to the success of this project. Dr. Noonan infected me with her love for the science of social behavior, and she challenged me to find creative solutions to public health problems such as concussions; Drs. Gaydos and Leon helped me in the early and critical stages of my thesis; Moose and Dr. Miner quietly, yet importantly, encouraged and supported me throughout my public health journey at Rollins; my colleagues and peers who never turned me away, but instead helped me find solutions to often vexing questions and challenges. I cannot thank all of them enough.

Finally, words fail me, when I think of my role models. These two septuagenarians have always raised the bar high, challenging, encouraging and persuading me to reach for the stars. They are the biggest and brightest stars, still actively shining their light; I am but a 'tail of dust in their shadow.' It is impossible for me to express my gratitude adequately to my role models--my mom and dad.

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Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition, Reporting, & Response to Concussions in Middle School-Aged Athletes

CHAPTER I

Introduction

A concussion or mild traumatic brain injury (mTBI) is "a complex pathophysiological process affecting the brain". Sports-related concussions can be induced by biomechanical forces caused either by direct or indirect trauma to the head, face, neck, or elsewhere on the body with an impulsive force transmitted to the brain. "This results in a rapid onset of, and usually short-lived impairment of neurological function, which largely reflects a functional disturbance rather than a structural injury and as such no abnormality is seen on standard structural neuroimaging studies." (McCrory et al., 2013). Concussions may present with a wide range of clinical signs and symptoms, including physical signs (e.g., loss of consciousness, dizziness, vomiting), behavioral changes (e.g., irritability), cognitive impairment (slowed reaction time), sleep disturbances (e.g., drowsiness), somatic symptoms (e.g., headaches), cognitive symptoms (e.g., feeling "in a fog"), and /or emotional symptoms such as emotional lability (McCrory et al., 2009).

Reports from the Centers for Disease Control and Prevention (CDC) estimate that 4 to 5 million concussions occur annually, with rising numbers among young athletes (Centers for Disease Control and Prevention, 2012). In addition, an estimated 90% of diagnosed concussions do not involve a loss of consciousness (Centers for Disease Control and Prevention, 2012). Among individuals 15 to 24 years of age, in the United States (US), an estimated 300,000 sports-related concussions occur annually, and sports are second only to motor vehicle crashes as the leading cause of concussions (Marar, McIlvain, Fields, & Comstock, 2012). This is likely a significant underestimation of the true burden of concussions because many patients only seek care in nonemergency settings, such as, physician offices, or are evaluated on the sidelines of athletic events by non-physicians, i.e., athletic trainers. Neither of these encounters is routinely captured in systematic databases. Still others never seek care. (Babcock & Kurowski, 2016). Additionally, since impairments in neurological function caused by concussions often present with a rapid onset, and tend to resolve spontaneously, many concussions are neither recognized by athletes nor observed by coaches or athletic trainers (Valovich McLeod, Bay, Heil, & McVeigh, 2008). As a result, many concussions simply go unrecognized, unreported, and untreated.

It is estimated that seventy-five percent of U.S families with school-aged children have at least one child who participates in organized sports (National Center for Sports Safety, 2012; Safe Kids USA, 2013). According to the 2014 Aspen Institute,

"Project Play Survey of Parents on youth sports issues," **nearly nine out of 10 parents have concerns about the risk of injury (87.9%)**. Parents were more concerned about injuries than any other issue, including the quality or behavior of coaches (81.5%), cost (70.3%), the time commitment required (67.9%), and the emphasis on winning over having fun (66.1%). In the same survey, **about a quarter of parents had considered keeping their child out of a sport due to concussion risks,** with tackle football registering the greatest level of concern (Aspen Institute, 2014).

Sporting activities, however, remain an integral part of most communities, often acting as an important social connector for them. Importantly physical activity, sports participation, and play in general are great ways for children and teens to build and maintain healthy bones and muscles. Sports also lower their chances of depression and chronic diseases (such as diabetes), help them learn leadership and teamwork skills, and do well in school. (Centers for Disease Control and Prevention, 2010; U.S. Department of Health and Human Services., 2008). It is, therefore, of great benefit to discuss and create safer ways to play and enjoy sporting activities, without the grave consequences that could occur from unreported or untreated concussions. Unfortunately, the framework which provides guidelines, rules, and regulations for youth sports has been established with very little scientific evidence (Institute for the Study of Youth Sports., 2004).

An important tenant of public health is the focus on primary prevention of disease and injury. Therefore, concussion prevention interventions should begin early in childhood, to intercept the occurrence of concussions and avert their potential short and long term sequelae. Theories and frameworks enhance the ability to understand health behavior and its determinants. They also provide models for creating healthpromoting interventions, in this instance, concussion prevention programs.

Understanding the social determinants such as peer and coach influence, self-esteem levels, cultural and gender differences is important. Also, understanding the behavioral determinants of sustaining a concussion, such as knowledge, attitudinal and behavioral variations, particularly in vulnerable and understudied populations like those younger than high school age (Institute of Medicine of the National Academies., 2013) is crucial. Subsequently, the social and behavioral risk factors specific to this subgroup of athletes can be targeted and used to formulate interventions that would lead to healthy sporting behavior such as increasing recognition and reporting of, and response to concussions among young athletes. The ultimate goal is to intervene early while athletes are young, thereby preventing sports-related concussions and their sequelae.

Statement of the Problem

The human brain is a complex system of connections that continues to be refined and reshaped throughout an individual's lifespan. During development, rapid changes in synapses, myelination, and metabolism occur, with the brain achieving adult-like connections by the mid-20's. Therefore, concussions in young children and adolescents are of particular concern as they are still undergoing developmental brain changes leading to a greater impact of injury at this age (Institute of Medicine and National Research Council., 2014). A prior concussion puts young athletes at increased risk of another concussion. Also, children and adolescents take longer to recover than adults (Centers for Disease Control and Prevention, 2012).

Alarmingly, the CDC reported an overall increasing rate of TBI-related emergency department (ED) visits from 2001 through 2010, with **concussions representing 75% of the visits** (Centers for Disease Control and Prevention., 2015). Even though children 0 to 4 years of age had the highest rates of any age group for TBI-related ED visits, the next highest age group was 15-24-year-olds (Centers for Disease Control and Prevention., 2015). These findings were supported by multiple studies of TBI and concussion diagnosis incidence in EDs, including a 2010 article demonstrating an 8-fold increase in ED visits for TBI (compared with all ED visits) from 2006 to 2010 (Bakhos, Lockhart, Myers, & Linakis, 2010). These available data may greatly underestimate the total TBI burden, as many individuals suffering from mild or moderate TBI do not seek medical advice (Faul, Xu, Wald, Coronado, & Dellinger, 2010).

Approximately one-third of children and adolescents with concussions will experience diverse patterns of physical, cognitive, or emotional symptoms beyond one month after an injury that can affect everyday functioning and quality of life (Eisenberg, Meehan, & Mannix, 2014). Risk factors have been identified for persistent postconcussive symptoms, such as **adolescent age**, headache, nausea or vomiting, dizziness, and **prior concussion** (Babcock et al., 2013; Zemak, Farion, Sampson, & McGahern, 2013).

Even though most athletes have heard about concussion, young athletes may be unable to identify if their symptoms are caused by a concussion or another condition (Register-Mihalik et al., 2013a; Chrisman, Quitiquit, & Rivara, 2013). The inability to promptly recognize and report a concussion could lead to a delay in concussion diagnosis

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and treatment. This delay in diagnosis and treatment could be fatal.

THEORETICAL FRAMEWORK

Significant contributions from various disciplines of life such as sociology, psychology, child development, philosophy, medicine, and education provide a wide variety of perspectives to guide inquiries and interventions. This multi-level perspective, otherwise called an ecological approach, can help identify and increase understanding of the relationships among the various causes of health problems, within and across multiple levels (McLeroy et al., 1993). Five level ecological models for adolescent behavior have been described by Blum et al., (2002) while the CDC has adopted a four-level socialecological framework for disease prevention. (Blum, McNeely, & Nonnemaker, 2002; Center for Disease Control and Prevention. 2015).

The CDC's framework recognizes the individual, or intrapersonal, relationships or interpersonal, community, and society ecological levels. Each level represents a key point in disease or injury process, thus offering an opportunity to intervene for prevention. The individual and interpersonal levels of the social-ecological model (SEM) will be the focus of the first phase of our study; subsequent phases will involve the community. The SEM will enrich our understanding and identification of athlete concussion risk, and protective health behavior, as well as the factors that come into play during interpersonal relationships with other athletes, peers, coaches and athletic directors, regarding concussions in youths. Furthermore, the decision to adopt a healthy protective behavior, rather than an unhealthy risky behavior, does not merely lie with the individual athlete, but can also be influenced by social and cognitive factors. Social cognition is concerned with how individuals make sense of social situations and focus on individual cognitions or thoughts as processes which intervene between observable stimuli and responses in specific real world situations (Fiske & Taylor, 1991). Social factors such as peer influences, role modeling by another athlete, coach influence and parental models, self-esteem, cultural values, and access to medical care are important factors in health behavior (Norman, Abraham, & Conner, 2000); Bandura, 2000).

Likewise, cognitive factors play a role in the choice of individual health behavior. For example, knowledge about the link between certain health risk behaviors and injury is important for an individual to make an informed choice (Norman, Abraham, & Conner, 2000). Additionally, cognitive risk factors (Bandura, 1986; Bandura, 2004), such as decreased perceptions of concussion risk, perceived social pressures to continue to play through pain, decreased self-efficacy in reducing risk by reporting concussions, insisting on staying out a game, or avoiding high impact sports, as well as emotional factors, can all influence behavior towards concussions in youth athletes.

Consequently, based on the premise that assessing the youth athletes' knowledge, attitudes, intentions, and behaviors concerning concussions, will be invaluable in formulating interventions to prevent concussions in youth, the key constructs of Bandura's Social Cognitive Theory (SCT) (Bandura, 1986, 2004) will be selected as an additional framework in our target population. The intrapersonal and interpersonal levels of the CDC's SEM (Center for Disease Control and Prevention, 2015) together with the constructs of the SCT will be the framework for the concussion prevention intervention with the target population being middle school students. In line with the Healthy People 2020, IPV -2 objective: "Reduce fatal and nonfatal traumatic brain injuries in youth athletes," our interventions and activities will address three main behaviors: a) Increase recognition of concussion symptoms by middle school students, b) Increase reporting of concussion symptoms by middle school students and c) Increase response towards concussion symptoms by middle school students (by showing some evidence of self-efficacy and resilience such as asking to be removed from a game, sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion).

PURPOSE STATEMENT

Our understanding regarding factors associated with attitudes and behavior, gender differences, and concussion rates among various sporting events in high school and collegiate athletes will remain incomplete without addressing the gap in knowledge of such risk factors in younger athletes. Therefore, in order to extend the current literature beyond the focus of concussion in high school and collegiate sports, this study's overarching goals are: **first, to understand the social and behavioral factors** (selfefficacy; cultural values; gender variations; peer, coach and parenteral influences; knowledge, attitudes and behavior) **that affect the recognition & reporting of & response to youth sports concussions symptoms in middle school-aged children. Second, to develop and evaluate an interactive App-based intervention, using information about concussion risk and protective factors, to Increase Recognition** of, Reporting of, & Response to Concussions symptoms in Middle School-Aged Athletes in a South Eastern, U.S School.

INTERVENTION: "REPORT CONCUSSIONS, RESPOND NOW" ("RcRn")

Our approach will be to employ an interactive learning framework leveraging Web 2.0 social media tools, and other interactive visual and auditory cues, to enhance reporting and response to concussion symptoms targeting middle school students. An interactive concussion prevention app will be developed to assist in educating participants about concussions, informing them about their role in reporting concussion symptoms, and empowering them to report symptoms consistent with concussions, or behaviors they may observe in a teammate that may indicate a concussion. This app will appeal to middle school children because it will be interactive and similar to other apps used for games and educational purposes currently in use in many middle schools.

The app will be developed in collaboration with the Harvard Macy Institute, Georgia Tech, and the CDC, and made freely available to any school that might want to use it as part of their physical education curriculum. The App-based interactive tool created specifically for young athletes will focus on age appropriate and age-specific social and cognitive concussion risk and protective factors. The ultimate goal is to educate and empower youth athletes to recognize, report and respond to concussion symptoms, based on constructs of the social cognitive theory (Bandura, 2004) and the CDC's socioecological model (Center for Disease Control and Prevention, 2015). The App-based interactive intervention will be called '**Report concussions, Respond now'** and will be referred to henceforth as "RcRn" (Report concussions, Respond now).

Further details will be discussed in the methods section.

RESEARCH QUESTION

Grant Proposal Research questions:

To guide our pilot study, we will ask the following questions.

1. What are the social and behavioral factors that affect recognition of, reporting of, & response to symptoms consistent with youth sports concussions in middle school-aged students?

2. Are there gender differences in awareness, knowledge, attitude, behavior, perception, value, and self-efficacy pertaining to sports concussions in middle school- aged students?

3. What is the effect of a socio-behavioral framework based interactive concussion prevention program, on the recognition & reporting of, and response to youth sports concussion symptoms in middle school-aged students?

SIGNIFICANCE STATEMENT

The limited information about the knowledge, attitudes, and behavior concerning concussions among middle school students provides the opportunity to study this vulnerable population and has the potential to address a large gap in concussion literature concerning middle school-aged athletes. Therefore, the importance of this proposed study lies in its intent to 1) Increase knowledge regarding attitudes, behavior, and knowledge of concussion symptoms among middle school students. 2) Develop evidence and socio-behavioral framework based intervention programs that will help increase recognition of concussion symptoms by middle school students, increase reporting of concussion symptoms by middle school students, and increase response towards concussion symptoms by middle school students. 3) Increase adoption of concussion prevention programs among middle school students, and, 4) Lessons learned from this pilot study, will be helpful in developing larger scale studies targeted at preventing youth sports concussions. Ultimately, well-adopted concussion prevention programs would lead to the reduction of youth sports concussions, aligning well with the Healthy People 2020 goal of "reducing fatal and nonfatal traumatic brain injury."

DEFINITION OF TERMS

- Concussion or mild traumatic brain injury (TBI) is "a complex pathophysiological process affecting the brain". It is induced by biomechanical forces caused either by direct or indirect trauma to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the brain, resulting in a rapid onset of, and usually short-lived, impairment of neurological function (McCrory, Meeuwisse, & Aubry, 2013)
- 2. Behavior-the manner in which someone acts, functions, responds or reacts.
- 3. Protective health behavior- actions, responses, or reactions of an individual, group or system that prevents illness or injury to the individual(s).
- 4. Risky health behavior- actions, responses, or reactions of an individual, group or systems that has the potential to cause harm to the individual(s).
- 5. Attitude A learned predisposition to respond in a consistently favorable or unfavorable manner with respect to a given object (Fishbein & Ajzen, 1975).
- Middle School Athlete Player on the roster of school athletic teams such as, but not limited to - Boys' soccer, football, baseball, basketball; girls' volleyball, soccer, cheerleading, gymnastics; boys'/girls' swimming, mountain biking, etc.,
- Knowledge total Score-Total number of correct answers on questionnaire. A higher score is better.
- Attitude Total Score- Total Score on attitude questionnaire. A higher score is better.
- 9. Reporting of symptoms consistent with Concussions-Proportion of symptoms consistent with concussions reported by athletes.

10. Response to concussions- such as asking to be removed from a game, sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion (Score on response questionnaire: higher= better)

CHAPTER 2

Review of literature

Concussion Overview

Concussions are the most common form of brain injury for athletes. They can be associated with immediate symptoms of disorientation, amnesia, nausea, vomiting, confusion, visual disturbance, blank stare, slurred speech, vertigo, headache, loss of consciousness, or any alteration in consciousness. However, visual disturbance, pupil dilation, and/or loss of consciousness are not necessary for the diagnosis of concussions. Furthermore, any of these symptoms may last less than 15 minutes and still indicate a mild concussion. Symptoms may linger or disappear, so the key to identification is that there has been a change in mental status. Often, athletes refer to this phenomenon as a "ding" or "bell ringer." ("Practice Parameter: The management of concussion in sports (summary statement)", 1997). Concussions, which are characterized by immediate and transient alteration in the brain function, can result from: a direct mechanical force or trauma to any part of the body, that is then transmitted to the brain; by accelerationdeceleration movement of the brain, such as with whiplash; rotational injuries or axonal shearing as the brain moves around within the skull.

Compared with adults, younger persons are at increased risk for concussions with increased severity and prolonged recovery (McCrory P, Meeuwisse W, Johnston K, 2009). Increased susceptibility to concussions occurs while the brain is still undergoing maturation, making the brain much more vulnerable to catastrophic injury should a second, even mild, hit occur (Hovda, Prins, & Becker, 1999) Diffuse cerebral swelling, with delayed catastrophic deterioration, has been postulated to occur after repeated concussive brain injury in sports. This is called "second impact syndrome" (SIS) (McCrory & Berkovic, 1998). Severe consequences such as second impact syndrome may also be a concern for the young athlete when returning to activity while the brain is still in a vulnerable state (Buzzini et al., 2006). Moreover, there are case reports of the so-called "second impact syndrome" in which brainstem herniation occurs after potentially minor re-injury while a patient is still symptomatic from a previous concussion. These devastating injuries seem to occur primarily in child and adolescent athletes (Cantu, 1998; McCrory & Berkovic, 1998).

Even though many individuals recover rapidly after a mild concussion (Eisenberg, Meehan & Mannix, 2014), approximately one- third of children and adolescents with concussions will experience diverse patterns of physical, cognitive, or emotional symptoms beyond 1 month after injury, which can affect everyday functioning and quality of life. (Eisenberg, Meehan & Mannix, 2014; Zemak, Barrowman & Freedman, 2016).

There is also speculation that concussion in young athletes may produce more severe long-term developmental and cognitive problems than are seen in their older counterparts (Kirkwood et al., 2006). It has been noted that less force is needed to produce clinical symptoms of concussion in children compared to adults (Ommaya, Goldsmith, & Thibault, 2002).

Furthermore, experts hypothesize that brain systems that are responsible for skill acquisition are more susceptible to disruption from diffuse injury, such as is seen in concussion. Therefore, young children who are still developing their essential skills may be at increased risk for developmental delays (Sim, Terryberry-Spohr, & Wilson, 2008). Studies have also shown that younger athletes have prolonged cognitive disturbances (as measured by neuropsychological testing) after concussion compared with older athletes (Field, Collins, Lovell, & Maroon, 2003).

There is increasing evidence that youth are at a greater risk for concussions than the general population (Baillargeon, Lassonde, Leclerc, & Ellemberg, 2012). Also, youth tend to take longer than adults to physically and often psychologically recover following a concussion (Rajabali, Ibrahimova, Turcotte, & Babul, 2013). Post-concussion consequences have been shown to include physical and psychological stresses and decreased cognitive functioning, such as memory loss (Jayanthi, Dechert, Durazo, Dugas, & Luke, 2011). While the long-term impacts of multiple concussions and repetitive head injuries are not fully understood, "it remains unclear whether repetitive head impacts and multiple concussions sustained in youth lead to long-term neurodegenerative diseases, such as chronic traumatic encephalopathy–commonly known as CTE—and Alzheimer's disease." (Institute of Medicine of the National Academies, 2013).

This proposal does not seek to discredit the importance of sporting activities which serve to build strong community bonds, provide outlets for physical activity, and avenues for friendship and skill development. However, we do intend to stimulate discussions regarding the urgent need to strike a balance between sports and safety of the youth athlete, in an attempt to prevent concussions and their sequelae.

Epidemiology

More than 44 million youth participate in sports annually, and thus, understanding the frequency of sports-related concussions in children and adolescents is important on a population level (Centers for Disease Control and Prevention, 2011; National Council of Youth Sports, 2016).

It is estimated that 26.6 % to 30.2% of youth ages 6 to 12 years old and39.3 % to 42.7 % of 13-to-17 year olds were active to a healthy level through sports, organized or unstructured (Sports & Fitness Industry Association, 2015). The most robust data on sports participation and physical activity rates is generated from an annual household survey conducted by the Sports & Fitness Industry Association (SFIA). Results from their 2015 survey showed that among 13- to 17-year-olds, the rate of participation fell from 42.7% to 39.3%. However, there were still approximately 5.5 million basketball players, 5 million soccer players, 4.5 million baseball players and 1.3 million football players between the ages of 6-12 years old ("2015 U.S. Trends in Team Sports", 2016). The incidence of sports and recreation-related concussions (SRRCs) in the United States is unknown; however, most epidemiologic studies indicate that a large number of SRRCs occur each year (Selassie et al., 2013; Dompier et al., 2015; Marshall, Guskiewicz, Shankar, McCrea, & Cantu, 2015).

Compared to TBI data, precise data regarding youths' sports concussions is scarce. As of the 2013 report on youth sports-related concussions, the Institute of Medicine (IOM) noted that "The National Collegiate Athletic Association Injury Surveillance System and High School RIOTM (Reporting Information Online) data system were the only ongoing, comprehensive sources of sports-related injury data, including data on concussions, in young athletes." (Institute of Medicine of the National Academies, 2013). The IOM report further pointed out that there was no national data collection tool capturing equivalent sports injury information on athletes younger than high school age, or high school aged children participating in sports outside of the school setting (e.g., recreational leagues, summer leagues, travel teams, all-star tournaments, summer camps, etc.). The IOM stated that "this means that no one is currently capable of providing reliable data on concussion incidence, rates, or patterns among the many millions of U.S. children younger than high school age or high school aged athletes playing outside the school setting. This is simply unacceptable because the importance of such information is undeniable and invaluable in the attempts to stop the silent epidemic of sports related youth concussions" (Institute of Medicine of the National Academies, 2013).

Due to the paucity of data regarding concussions in younger athletes, much of the available concussion rates and trends are combined with TBI data which often includes information on mild, moderate and severe traumatic brain injury. Traumatic brain injuries (TBIs) from participation in sports and recreation activities have received increased public awareness, with many states and the federal government considering or implementing laws directing the response to suspected brain injury (Schatz & Moser, 2011; (Zhao, Han, & Steiner, 2008). To assess and characterize TBIs from sports and recreation activities among children and adolescents, the CDC in collaboration with the US Consumer Product Safety Commission, analyzed data from the National Electronic Injury Surveillance System--All Injury Program (NEISS-AIP) for the period 2001--2009. Results of that analysis indicated that an estimated 173,285 persons aged ≤19 years were treated in EDs annually for nonfatal TBIs related to sports and recreation activities. From

2001 to 2009, the number of annual TBI-related ED visits increased significantly, from 153,375 to 248,418, with the highest rates among males aged 10--19 years. Further analysis of the NEISS-AIP data revealed that from 2001--2009, the estimated number of sports and recreation-related TBI visits to EDs increased 62%, from 153,375 to 248,418, and the estimated rate of TBI visits increased 57%, from 190 per 100,000 population to 298 per 100,000 population (National Electronic Injury Surveillance System, 2012). During this same period, the estimated number of ED visits for TBIs that resulted in hospitalization ranged from 9,300 to 14,000 annually but did not show a significant trend over time.

Overall, the activities associated with the greatest estimated number of TBI-related ED visits were bicycling, football, playground activities, basketball, and soccer. Activities for which TBI accounted for >10% of the injury ED visits for that activity included horseback riding (15.3%), ice skating (11.4%), golfing (11.0%), all-terrain vehicle riding (10.6%), and tobogganing/sledding (10.2%). Activities associated with the greatest estimated number of sports and recreation-related TBI ED visits varied by age group and sex. For males and females aged ≤ 9 years, TBIs most commonly occurred during playground activities or when bicycling. For persons aged 10--19 years, males sustained TBIs most often while playing football or bicycling, whereas females sustained TBIs most often while playing soccer or basketball, or while bicycling (Centers for Disease Control and Prevention, 2011).

Furthermore, Bakhos et al., (2010) used data from the National Electronic Injury Surveillance System (1997–2007) and NEISS-AIP (2001–2005) to identify children and adolescents with a diagnosis of concussion. Concussion-related ED visits were analyzed for 8- to 13- and 14- to 19-year-old patients. Population data were obtained from the US Census Bureau and sport participation data were obtained from National Sporting Goods Association. Results from 2001 to 2005 showed that U.S children who were aged 8 to 19 years had an estimated 502, 000 ED visits for a concussion. The 8- to 13-year-old group accounted for 35% of these visits. Approximately half of all ED visits for concussion were sports related concussions (SRC). The 8- to 13-year-old group sustained 40% of these, which represented 58% of all concussions in this group. Approximately 25% of all SRC visits in the 8- to 13-year-old group occurred during organized team sport (OTS). During the study period, 4 in 1000 children aged 8 to 13 years and 6 in 1000 children aged 14 to 19 years had an ED visit for SRC, and 1 in 1000 children aged 8 to 13 years and 3 in 1000 children aged 14 to 19 years had an ED visit for concussion sustained during OTS. From 1997 to 2007, although participation had declined, ED visits for concussions in OTS in 8- to 13-year-old children had doubled and had increased by 200% in the 14- to 19-year-old group (Bakhos, Lockhart, Myers, &

Linakis, 2010). Additionally, recent studies by Bryan et al., (2016), indicated that most children with sports and recreation-related concussions (SRRCs), were not seen in health care settings. Of children with SRRCs seen in health care settings, most were seen as outpatients (Bryan, Rowhani-Rahbar, Comstock, & Rivara, 2016).

The trends indicate that a significant increase in concussion rates has occurred over time, (Lincoln et al., 2011) with a 4.2-fold increase (95% CI 3.4-5.2) over 11 years from 1997 to 2008 - a 15.5% annual increase. According to Sports Concussion Statistics, 3,800,000 concussions were reported in 2012, double what was reported in 2002 (Headcasecompany, 2012). Furthermore, the NEISS data showed that from 2002 to 2012, except 2007, concussion frequencies trended upward in nine principal youth sports (National Electronic Injury Surveillance System, 2012; Buzas, Jacobson, & Morawa, 2014) including football, soccer, ice hockey, lacrosse, basketball and wrestling. In 2011 alone, over 84,000 concussions were sustained in high school football and young soccer players (National Conference of State Legislatures, 2014). Additionally, a third of all sports concussions happen at practice, while 47% of all reported sports concussions occur during high school football (Headcasecompany, 2012).

The number and rising trends of youth sports concussions are further supported by the CDC's estimates of roughly 2.7 million children under 20 that were treated for "sports and recreation" injuries from 2001 to 2009. They also reported that head injuries were especially on the rise (Centers for Disease Control and Prevention, 2011). Others have estimated that between 1.1 and 1.9 million SRRCs occur annually in US children aged \leq 18 years. (Bryan, Rowhani-Rahbar, Comstock, & Rivara, 2016)

Thus, by increasing recognition & reporting of symptoms consistent with concussions by youth athletes, and by promptly responding to concussions such as, 'staying out a game,' accessibility to adequate medical care, strict removal from play and return to play policies, the incidence, prevalence, severity and long-term complications of sports related concussions can be decreased among children and adolescents.

Sporting activity

Although interest in sports-related concussions is usually focused on full-contact sports like football and ice hockey, concussions occur across a wide variety of high school sports. Concussion rates vary by sport, gender, and type of exposure. An understanding of concussion rates, patterns of injury, and risk factors can drive targeted preventive measures and help reduce the risk of concussion among high school athletes in all sports. (Marar, McIlvain, Fields, & Comstock, 2012).

During the 2010-2011 school year, more than 7.5 million students competed in high school sports (National Federation of State High School Associations., 2011). Prior research reports that high school athletes sustain more than 100,000 concussions yearly through sports participation, although this is generally considered an underestimate (Gessel, Fields, Collins, Dick, & Comstock, 2007).

Rosenthal et al., (2014) carried out a descriptive epidemiological study over a 7year period. They showed that High School Reporting Information Online (HS RIO) captured 4024 concussions with overall concussion diagnosis rates increasing significantly from 0.23 to 0.51 (P = .004). Concussion diagnosis rates increased for each of the nine sports studied, with five sports having statistically significant increases over this 7-year period. This analysis shows that, nationwide, concussion diagnosis rates have been increasing in high school sports, especially in recent years. In the HS RIO data, all sports showed an increasing trend in concussion rates between 2005-2006 and 2011-2012, with the overall rate and the rates in 5 of 9 sports increasing significantly (Rosenthal, Foraker, Collins, & Comstock, 2014).

Studies consistently report that football has the highest concussion rate (Gessel, Fields, Collins, Dick, & Comstock, 2007; Meehan, d'Hemecourt, Collins, & Comstock, 2011; Marar, McIlvain, Fields, & Comstock, 2012), in both competition and practice with other full contact sports (boys' ice hockey and lacrosse) also among the four sports with the highest rates. Many are surprised to learn girls' soccer has consistently had competition concussion rates as high as or higher than these boys' sports (Marar, McIlvain, Fields, & Comstock, 2012). Non-contact sports, such as track and field, volleyball, and swimming/diving, have the lowest (Gessel, Fields, Collins, Dick, & Comstock, 2007; Meehan, d'Hemecourt, Collins, & Comstock, 2011; Marar, McIlvain, Fields, & Comstock, 2012). Baseball has also been shown to be associated with concussion injuries in children (Lawson, Comstock, & Smith, 2009). In addition to the commonly mentioned sports of football, soccer, basketball and baseball the risk of concussions can easily be overlooked in sporting activities like cheerleading and gymnastics.

The National Federation of State High School Associations (NFHS) estimates approximately 400, 000 students participate in U.S high school cheerleading annually. The number of athletes participating in cheerleading is increasing as the sport becomes more popular (National Federation of State High School Associations, 2016). Currie et al., (2016) analyzed data from the longitudinal, National High School Sports-Related Injury Surveillance Study from 2009/2010 through 2013/2014. They found that injury rates in cheerleading ranked 18th of 22 sports, with an overall injury rate of 0.71 per 1000 athlete-exposures (AEs). Competition (0.85) and practice (0.76) injury rates were similar, whereas performance rates were lower (0.49). Although 96.8% of injured cheerleaders were girls, the overall injury rate was higher in boys (1.33 vs. 0.69, rate ratio [RR]: 1.93, 95% confidence interval [CI]: 1.30–2.88). Whereas concussions were the most common cheerleading injury (31.1% of injuries), concussion rates were significantly lower in cheerleading (2.21 per 10 000 athlete-exposures) than all other sports combined (3.78; RR: 0.58, 95% CI: 0.51–0.66) and all other girls' sports (2.70; RR: 0.82, 95% CI: 0.72– 0.93). Over half of all injuries occurred during stunts (53.2%) (Currie DW, Fields SK, Patterson MJ, et al. 2016). Others have shown that the number of cheerleading participants in the U.S has increased 18% since 1990 (Cantu & Mueller, 2009). In addition, due to the increasing popularity of cheerleading in children aged 6 and older, the risk of catastrophic head and spine injury, especially for the flier, is increasing (American Sports Data Inc, 2004; Cantu & Mueller, 2009). Cheerleading, despite its low competition/performance concussion rate relative to other sports, has the second highest practice concussion rate (Marar, McIlvain, Fields, & Comstock, 2012).

Gender differences

An estimated 21 % of sports-related concussions occur in high school athletes. (Gessel, Fields, Collins, Dick, & Comstock, 2007; Centers for Disease Control and Prevention., 2006). Although males continue to participate in contact sports such as football, lacrosse, and hockey at a higher rate than females, in 2008 3 Million or 41 % of high school athletes were female, up from 2.4 Million 10 years earlier (National Federation of State High School Association, 2006).

Several authors have suggested that there are gender differences in sports-related concussions. Alves et al., (2000) carried out a meta-analysis of 8 studies looking at post-concussion outcomes and gender differences. The results showed that females tended to fare worse than their male counterparts, with longer hospital stays, longer residual disabilities, and higher mortality rates. (Farace & Alves, 2000). Recently, other researchers (Brown, Elsass, Miller, Reed, & Reneker, 2015) performed a systematic review and meta-analysis of high school and collegiate athletes to find out whether

differences exist between males and females at baseline (pre-season/before concussion) or post-concussion for self-reporting of individual symptoms and total symptom scores. They found that the symptomatic presentation of males and females, most notably the prevalence of specific symptoms, was very divergent. Females had higher total symptom scores at baseline and post-concussion. They postulated that the differences could be explained by hormonal changes associated with the menstrual cycle.

An epidemiology study of 100 high schools, using data collected from the HS RIO, during the 2005-2006 and 2006-2007 school years was carried out on 610 males and 202 females by Frommer et al., (2011). These researchers also showed that male and female athletes presented with different types of symptoms; males reported more cognitive symptoms, while females reported more neurobehavioral and somatic symptoms (Frommer et al., 2011). However, other researchers have found the reverse, where concussions result in cognitive impairment in females more frequently than in males (Broshek et al., 2005).

Within a specific sport, causes of concussion differ between girls and boys. For example, in soccer, contact with the ground or with the ball has been shown to be a more frequent cause of concussion in girls than boys. While boys suffered concussions goaltending, more girls sustained concussions defending. Comparing baseball and softball, boys were more likely than girls to sustain a concussion after being hit by a pitch, a finding possibly attributable to the different pitching styles and balls. In basketball, more boys sustained concussions while rebounding and chasing loose balls, whereas more girls sustained concussions defending and ball handling (Gessel, Fields, Collins, Dick, & Comstock, 2007). Increased susceptibility to concussions in females has been attributed to differences in the style of play; biomechanical differences due to smaller head to ball ratios or weaker necks; and less total mass in their head and neck than males (Kirkwood & Yeates, 2012). A greater angular acceleration and displacement of the head and neck has been demonstrated in females. This movement was despite the earlier activity of the sternocleidomastoid muscle in females, which should have acted to stabilize and decrease acceleration and movement of the head (Tierney et al., 2005). Overall, current evidence suggests that within a given sport, females report higher rates of concussion than males and within comparable sports, female athletes may be at a greater risk of concussion than male athletes (Dick, 2009).

In the U.S, social factors may play a role in sports related concussions in young athletes, such as boys suffering from head injuries and not reporting their symptoms for fear of being removed from play. Specifically, reluctance to report injury was demonstrated in high school football players (Lovell et al., 2002), where only 47.3% of players claiming to have suffered a concussion reported their injury. Cognitive factors such as underestimating the seriousness of the injury, not wanting to be withdrawn from competition, and not being aware of having suffered a concussion, have been cited as reasons for underreporting concussion injury (McCrea, Hammeke, Olsen, Leo, & Guskiewicz, 2004).

In spite of what is known regarding factors associated with gender differences in concussion rates among various sporting events, there is still a gap in knowledge regarding the gender differences in reporting and responding to concussions in athletes younger than high school. We also are not fully aware of the role played by physiological, hormonal, and psychosocial risk factors in young adolescent children. These factors, if not well understood, may add to the challenge of preventing sportsrelated concussions in youth athletes.

Sports culture

The anthropologist, Christie Kiefer (2007), defined culture as a complex integrated system of thought, and behavior, shared by members of a group- a system whose whole pattern allows us to understand the meanings that people attach to specific facts and observations. Culture, therefore, shapes how individuals, and their communities, interact and engage in relationships. Since culture shapes community engagement, effective engagement requires an understanding of culture (Blumenthal & DiClemente, 2004; Devieux, 2005; Silka, Cleghorn, Grullón, & Tellez, 2008).

Content analysis of Sports Illustrated articles, from March 1969 through April 1991 (Nixon, 1993), suggested that athletes are exposed to a set of mediated beliefs about structural role constraints, structural inducements, general cultural values, processes of institutional rationalization and athletic socialization. These beliefs collectively convey the message that they ought to accept the risks, pain, and injuries of sport. Widespread acceptance of risk, pain, and injuryby athletes makes pain and injury statistically normal in sport, and at the same time, widespread acceptance of what has been called here "the culture of risk" normalizes their pain and injury experiences (Curry, 1991;

Curry & Strauss, 1988). Furthermore, the evidence evaluated in Nixon's study suggests that this culture of risk can foster guilt, shame, uncertainty, job insecurity, and frustration, among those who complain about pain and injuries, and even depression among those with disabling injuries. In general, Nixon's study showed that athletes are exposed to mediated and more direct messages that tell them they must play as long as possible with pain and injuries and must try to come back as soon as possible after serious injuries.

Socio-behavioral factors

Current culture surrounding concussions

Research suggests that too many young athletes still do not report their concussion symptoms (Chrisman, Quitiquit, & Rivara, 2013; Rivara et al., 2014), are not removed from play, and continue to play with symptoms, or return to play too soon. (Register-Mihalik et al., 2013; (O'Kane et al., 2014; Hwang, Trickey, Lormel, & Bradford, 2014).

In one study, researchers interviewed a group of close to 800 high school athletes during a season. They found that sixty-nine percent of athletes with a possible concussion played with concussion symptoms, while forty percent of those athletes said that their coaches were not aware that they had a possible concussion (Rivara et al., 2014). In a different study, 50 female and male high school athletes were asked what they would do if they thought they had a concussion: They most commonly answered, "I would keep playing and see how I felt" or "I would take a little break and return to play (6/9 groups)." None said that they would stop playing entirely if they experienced concussion symptoms (Chrisman, Quitiquit, & Rivara, 2013). In another study of 150 young patients seen in an emergency department for a concussion, many did not take the time to heal fully before returning to their usual activities. Thirty-nine percent reported returning to play on the same day of their concussion, and more than half (58 percent) returned to play without medical clearance (Hwang, Trickey, Lormel, & Bradford, 2014).

Young athletes depend on their coaches for guidance and need to feel comfortable to report their symptoms to their coaches, athletic trainers, teammates, and parents (Chrisman, Quitiquit, & Rivara, 2013; Harmon, Drezner, & Gammons, 2013). In fact, young athletes' beliefs about their coaches' expectations on reporting may trump their knowledge or intention to report a possible concussion (Chrisman, Quitiquit, & Rivara, 2013; Register-Mihalik et al., 2013). The way coaches talk about concussion affects young athletes' behaviors around reporting symptoms. Young athletes who receive negative messages from their coaches, or who are insulted by their coaches for reporting an injury, may feel pressured to keep playing with concussion symptoms. On the other hand, young athletes who receive positive messages from their coach and are praised for symptom reporting are more likely to report their concussion symptoms (Chrisman, Quitiquit, & Rivara, 2013).

The IOM report concurred with earlier observations of the culture of risk in sports. Specifically, "the culture of sports negatively influences athletes' self-reporting of concussion symptoms, and their adherence to return-to-play guidance. Athletes, their teammates, and in some cases, coaches and parents may not fully appreciate the health threats posed by concussions. If the youth sports community can adopt the belief that concussions are serious injuries, and emphasize care for players with concussions until they are fully recovered, then the culture in which these athletes perform and compete, will become much safer." (Institute of Medicine, 2013). Therefore, since a young athlete's views and actions on the sports field are influenced by those of their parents, coaches, teammates, and even spectators (Shields, Flavio, Bredemeier, & Power, 2007; LaVoi & Stellino, 2008; Shields, Bredemeier, LaVoi, & Power, 2005; Omli & Wiese-Bjornstal, 2011), collectively, these groups shape the culture of sports and influence reporting of, and response to, concussions.

The current state of knowledge, attitudes and behaviors surrounding concussions.

Several studies have been carried out by researchers, in an attempt to better understand the social and behavioral factors such as knowledge, attitudes, and behaviors surrounding youth sports concussion. While we have some information regarding such factors, there are still many unknowns surrounding youth concussion behavior.

Currently, some researchers have found that knowledge of concussion signs and symptoms has been found to be deficient in some surveys of youth athletes (Bloodgood et al., 2013; Kaut, DePompei, Kerr, & Congeni, 2003; Kroshus, Daneshvar, Baugh, Nowinski, & Cantu, 2013). However, an interesting finding based on an online survey of youth athletes (n=252) showed that younger youth (ages 10 to 13), were significantly more likely to view concussions as a "critical issue" than were older youth (ages 16 to 18 years) (Bloodgood et al., 2013), perhaps indicating that existing concussion educational efforts were reaching younger youth more effectively than older youth. Another possibility may be that teenagers' attitudes differ towards risk.

Reporting and Responding to Concussions.

Reporting a possible concussion is the most important action young athletes can take to bring their injury to light. Reporting symptoms will facilitate an athlete being properly assessed, monitored, treated and given needed time to heal (Centers for Disease Control and Prevention, 2015). However, too many athletes do not take this critical first step. (Chrisman, et al., 2013; Rivara et al., 2014). Some studies suggest that high school athletes have limited knowledge of signs and symptoms of concussion, which may play a role in reporting of the injury. (McCrea, Hammeke, Olsen, Leo & Guskiewicz, 2004).

When it comes to championship games, youth athletes are more reluctant to report concussions. In a study, where the scenario presented to 58 young athletes involved a championship game, only 36 % of them said they would sometimes tell their coach or athletic trainer about a possible concussion (Bramley, Patrick, Lehman, & Silvis, 2011).

McCrea et al., (2004), reported three of the most common reasons for not reporting concussion as not thinking the injury was serious enough to report; motivation to not be withheld from competition; and lack of awareness of probable concussion. However, this study was limited by reporting bias; measurement issues related to reporting; and the inclusion of only high school football athletes. Other researchers (Chrisman, Quitiquit, & Rivara, 2013; Register-Mihalik et al., 2013) found similar reasons for low reporting rates among young athletes, with additional evidence that showed that young athletes may feel the pressure to hide their concussions because they did not want to jeopardize their future sports career, or let their coaches or teammates down. Although these studies attempted to understand reasons behind under-reporting, little is known about the influence of knowledge level, attitudes, and intentions on the behavior of reporting a possible concussion specifically in youths that are not yet in high school. Our proposed study will expand on these findings, to

include a more specific examination of factors influencing reporting of concussion in middle school-aged children and adolescents.

The current culture of sports may discourage athletes from reporting their concussion symptoms and removing themselves from play (Kroshus, Kubzansky, Goldman, & Austin, 2014; Torres et al., 2013). A recent study of high school athletes' $(n=167, age=15.7 \pm 1.4)$ intentions to report sports-related concussions showed that intention to report was associated with perceptions about concussion reporting, perception of important social referents' beliefs about concussion reporting, and perceived control over concussion reporting. Although reporting intention may not always be an indicator of what an individual's actual concussion reporting behaviors will be, these findings suggest that future concussions among athletes, coaches, and parents (Register-Mihalik et al., 2013b). Importantly, greater athlete knowledge about concussions and more favorable attitude toward reporting possible concussion was also associated with increased reporting of concussion and "bell-ringer" events in these youth (Register-Mihalik et al., 2013a).

To summarize what is known about youth sports concussions at various ecological levels:

Athletes

Most older athletes have heard about concussion ((Bloodgood et al., 2013). However, young athletes may be unable to identify if their symptoms are caused by a concussion or another condition (Register-Mihalik et al., 2013; Chrisman, Quitiquit, & Rivara, 2013). Athletes are more likely to report a concussion in practice. Over 50% of athlete's report that their coach did not know they had a concussion (Chrisman, Quitiquit, & Rivara, 2013). Few athletes stop playing entirely if they experience concussion symptoms (Rivara et al., 2014; O'Kane et al., 2014).

Participation in concussion education may support increased symptom reporting by athletes (Register-Mihalik et al., 2013; Bramley, Patrick, Lehman, & Silvis, 2011). A survey of almost 170 high school athletes in six sports found that young athletes who were more knowledgeable about concussion were more likely to report a concussion during practice (Register-Mihalik et al., 2013). Another study of high school athletes who received concussion education from any source showed that they were more likely to report concussion symptoms to a coach or athletic trainer compared to athletes with no education. Specifically, seventy-two percent of athletes who had received concussion education indicated that they would always notify their coach of concussion symptoms. Only 12 percent of athletes who had no history of concussion education stated they would always report their concussion symptoms to their coach (Bramley, Patrick, Lehman, & Silvis, 2011)

Coaches

Coaches feel it is their responsibility to recognize a possible concussion and remove an athlete from play (Faure & Pemberton, 2011). Coaches may have difficulty identifying some concussion signs and symptoms, such as vision problems and sensitivity to light and noise (Naftel, Yust, Nichols, King, & Davis, 2014; Valovich McLeod, Schwartz, & Bay, 2007). Athletes who receive positive messages from their coach and are praised for symptom reporting are more likely to report their concussion symptoms (Bramley, Kroft, Polk, Newberry, & Silvis, 2011). Coaches are less likely to remove a young athlete from play when it is a championship game (Zonfrillo et al., 2012).

Similar to athletes, coaches who receive coaching education are more likely to correctly recognize concussion signs and symptoms and feel comfortable deciding whether an athlete needs to be evaluated for a possible concussion (Valovich McLeod, Schwartz, & Bay, 2007; Saunders, Burdette, Metzler, Joyner, & Buckley, 2012; Chrisman, Schiff, Chung, Herring, & Rivara, 2014).

Parents

Parents do not always recognize symptoms consistent with concussions in their children when they appear (Carl & Kinsella, 2014). Mothers are more likely than fathers to strongly agree that concussions are a critical issue ((Bloodgood et al., 2013). Parents play a key role in influencing their children's behavior – including concussion reporting (Stevens, Penprase, Kepros, & Dunneback, 2010). Parents serve as role models for safety behaviors – including helmet wearing (Provance, Engelman, & Carry, 2012).

Health Care providers

Health care providers do not feel they have adequate knowledge or training of concussion management - such as return to play (RTP) protocols ((Zonfrillo et al., 2012; Carl & Kinsella, 2014). Although guidelines exist, knowledge of, and adherence to them is low among some specialties (Carl & Kinsella, 2014; Covassin, Elbin, & Stiller-Ostrowski, 2009). Current medical education often does not include an evidence-based curriculum on concussions, and few health care providers receive continuing medical education about it (Kaye, Gallagher, Callahan, & Nance, 2010; (Morton & Korley, 2012).

Educational efforts should, therefore, be tailored to meet the needs of, and address the main concerns reported by athletes, coaches, parents, schools and medical providers (Kroshus, Kubzansky, Goldman, & Austin, 2014). Among high school athletes, standardized protocols for schools and medical providers, education, and training, and coordination among the key stakeholders led to an increase in the number of concussions identified, reported, and treated (Hotz et al., 2014).

However, despite all that is known, there are still a lot of unanswered questions regarding sports-related concussions in youths. Questions such as the factors that influence youth athletes' reporting of concussions, reliability of self-reporting of concussions, and variance by gender, age, and type of sports. We also need to improve accurate concussion reporting among athletes, peers and caregivers. Additionally, novel approaches to accurately and reliably improve information regarding concussions and how to optimally use such behavioral-based intervention strategies, need to be developed and tested. Furthermore, we need to investigate if these programs and strategies will improve the current state of reporting and response to concussions in youth athletes. (Centers for Disease Control and Prevention, 2015)

Our study aims to understand the social and behavioral risk and protective factors among youth athletes in middle school. Also, we will study the gender variations of these risk factors as it pertains to concussion-related behavior and then develop and use an innovative and interactive App-based, concussion prevention program targeted to this subpopulation. The new information gained will add to the current knowledge and help to answer some of the unknowns regarding concussions in youth athletes.

Theoretical Framework

Theories are a set of interrelated concepts, definitions, and propositions that aid in explaining or predicting events or situations by specifying relations among variables (Glanz, Rimer, & Lewis, 2002). Together with data and trends, explanatory and change theories are invaluable in understanding the social determinants of why some athletes are healthy and others unhealthy from the standpoint of concussions.

The main objective of this study is to use information from concussions related data and trends, as well as theories and frameworks, to address key behaviors and determinants, which can be used to formulate interventions to address the issue of Youth Sports Concussion at multiple socioecological levels. The first phase of our pilot study will address the public health concern of Youth Sports Concussion, using the Social Cognitive Theory (SCT) to target the individual and interpersonal socio-ecological levels.

The Social Cognitive Theory is relevant to public health interventions because the SCT deals with cognitive, emotional, and other aspects of behavior that are important for understanding behavioral change. It also provides a firm theoretical background, new insights, and understanding for new behavioral research, and related public health interventions. Therefore, since the SCT explains how people acquire and maintain certain behavioral patterns, while also providing the basis for intervention strategies (Bandura, 1997), this study will rely heavily on the SCT.

The SCT also asserts that the social environment, the personal characteristics of the individual, and their behavior interact and influence each other. This triadic relationship influences an individual's decision to adopt health behaviors (Bandura, 1986; Bandura, 2004). Therefore, understanding the determinants of behavioral change at various socio-ecological levels, and the way in which they interact, is invaluable in designing, implementing, and evaluating programs related to youth sports concussion prevention.

Furthermore, the key constructs and concepts of the SCT which are: (1) knowledge, (2) perceived self-efficacy, (3) outcome expectations, (4) goal formation, and (5) socio-structural factors (DiClemente, Salazar, & Crosby, 2013), become indispensable when assessing the knowledge, attitudes, intentions, and behaviors concerning concussions.

Knowledge is a precondition for behavior change and serves as a "gateway" that must be passed before more complex, personal, and social issues come into play. It is important to note that knowledge is a fundamental starting point, but not sufficient for behavioral change. However, for knowledge to be complete, it requires not just content knowledge about concussions but procedural knowledge as well. A good understanding of concussion concepts will help the young athlete know how to recognize concussion symptoms, and also, what to do after recognizing a possible concussion (reporting and responding).

Self-efficacy refers to the individual's perception of confidence or ability to adopt the given health-protective behavior. Outcome expectation refers to the anticipated consequences of a person's behavior; therefore, these expectations can lead to behavior change if a person believes the consequence leads to a positive behavior and/or can avoid a negative outcome.

According to the SCT, behavior change is further achieved through *Goal Formation*, which is the breaking down of goals into a progressive series of easy-tomeasure sub-goals. (Bandura, 2004). The *socio-structural factors* refer to the suggestion that the world people live in enables and limits their ability to effectively engage in goaldirected behavior (DiClemente, Salazar, & Crosby, 2013). For example, athletes who become aware that concussions can be life altering or even be fatal in cases of second impact syndrome will have a foundation for behavior change in reporting concussion symptoms. Conversely, many athletes recover relatively quickly and may not have longterm consequences, and this may lead to these athletes choosing to keep silent about their symptoms, instead of reporting their symptoms.

In addition, potentially due to a lack of resilient self-efficacy (i.e., the ability to report in adverse circumstances) with the outcome expectations (i.e., being removed from the game) and the possible socio-structural factors (i.e., the lack of high-performing second-string players, or the lack of trained coaches to accurately evaluate concussions), the athletes may disregard the need to report their injury. With the multiple variants at play and the numerous considerations needed, the overarching task of behavior change becomes challenging.

Reciprocal Triadic Causation

The concept of the Reciprocal Triadic Causation (RTC) in SCT explains much of the behavior seen in today's sports. At the collective level, SCT suggests that people

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shape the environment, which in turn shapes the people. Thus, depending on the context, the environment can either promote healthy behavior, through the availability of resources and social norms, or it could hamper such efforts (DiClemente, Salazar, & Crosby, 2013). The person and their behavior have a reciprocal effect as well, so there are limitations to only focusing on the environment. This single pathway means that people's cognitions can also dictate their behavior.

In addition, the social norm for an athlete is to be strong. These social norms exist at the interpersonal level and the community level. Nike's "Just do it" slogan is a good example. Although Nike isn't promoting injury, they are promoting a behavior of pushing through pain and exceeding one's limit as an athlete. This social norm of being "tough" is a risk factor as it leads to another psychologically related determinant; **stigma associated with reporting injury as an athlete.** These social norms can be broken down through vicarious learning and observational modeling (DiClemente, Salazar, & Crosby, 2013).

Key Determinants

The key determinants at the personal and interpersonal level that hinder responding and reporting of concussion symptoms in youth athletes must be addressed first. Addressing these key determinants will increase recognition and reporting of, & response to possible concussions among middle-school aged athletes, thereby, aligning with the overarching health goal of preventing concussions in youth athletes and reducing the risk of fatal or non-fatal concussions among young athletes. This interrelated pathway is shown in the behavior, determinant and intervention model (Logic BDI- appendix **D1**)

Application of Theories

The theoretical construct will be explained first (a), followed by specific applications based on the determinants of behavior change (b).

1a) **Knowledge** is defined as facts, information, and skills acquired by a person through experience or education or, the theoretical or practical understanding of a subject. According to Bandura (2004), knowledge is a precondition for behavior change. Content knowledge about concussions, how concussions are sustained, what behaviors lead to increased risk of concussions, signs, symptoms and consequences of concussions must be emphasized. Furthermore, precise procedural knowledge would be provided, explaining how to avoid unhealthy sporting behavior, and rather engage in healthy behavior specific to the type of sporting activity, as well as, how to promptly report and seek help after a concussion.

1b) Knowledge-Protective factors: 1) Increased awareness of concussions, 2) Increased knowledge of impact of concussions, 3) Increased knowledge of safe practices in sports,
4) Increased knowledge of concussion symptoms and signs, 5) Increased content & prevention knowledge of concussions, 6) Risk of concussions in different sports, 7) Decreased participation in sports-related risky behavior.

Risk factors of 8) decreased knowledge of concussions 9) increased participation in high impact sports.

2a) **Self-efficacy** is a person's perception of his or her ability to perform a specific behavior, specifically one's belief in one's ability to succeed in specific situations or accomplish a task. (Bandura, 2004). In this case, the athlete's ability and confidence to

adopt healthy protective sporting behavior is crucial. Self-efficacy is therefore an extremely relevant construct for successful prevention of concussion, because the athletes must first believe that they can make the necessary changes specific to their sports, despite difficult circumstances like the culture of not speaking up about injuries for fear of "failure, or loss of position or even potential income (physiological state). Verbal persuasion, vicarious experience, and enactive attainment are useful techniques to increase self-efficacy, resilience and reach positive behavioral capacity. (Bandura, 1986) 2b) **Self-Efficacy-Protective factors**: 1) Increased self-efficacy in recognizing signs & symptoms of concussions, 2) Increased comfort verbalizing signs and symptoms & seeking appropriate help for concussions, 3) Increased resilience, 4) Increased self-motivation for care, 5) Increased prevention & management skills.

Risk factors: 6) Low self-esteem and fear.

2b) **Perception-** is defined as the process of recognizing and interpreting sensory stimuli (DiClemente, Salazar, & Crosby, 2013). In the case of sports-related concussions, athletes may or may not perceive the risk of sustaining a concussion, and some athletes may even perceive the risk of concussions as so low that they may think concussions cannot happen to them.

Protective factors: 1) Increased perceived susceptibility of concussions, 2) Increased perceived importance of avoiding concussions, 3) Increased perceived risk of concussions, 4) Increased perception of peer support, 5) Perceived benefit of reporting and responding to concussions.

Risk factors: 6) Perceived barriers to reporting and responding to concussionsretaliation/negative consequences from peers and adults, 7) Erroneous perception that "concussions cannot happen to me," 8) Perception that concussions are minor problems and not something to worry about because they are 'just bell ringers.'

3a) **Outcome expectancy**- is defined as a belief about the likelihood of the behavior leading to a specific outcome (Bandura, 1986), i.e., the anticipated positive outcomes that stem from engaging in the specific behavior.

For there to be any meaningful change in behavior, there must be an overwhelming belief by the individual that the risk of change is outweighed by the benefits of staying the same. The term "Pay off" or net gain becomes applicable (Bandura, 1986). Convincing athletes to engage in healthy sporting behavior that may only pay off later in life- by the absence of complications that may never be seen - is challenging. (The conundrum of prevention). Therefore, a reinforcement which may be intrinsic to the athlete, or extrinsic (socially structured) becomes relevant. Furthermore, adding or subtracting rewards and privileges usually produces immediate results, leading to a higher motivation to practice desired beneficial health behavior or the corollary. 3b) **Clarity of values**- this construct is associated with defining one's purpose and core values of what is judged as important or worthy of life. In the case of the athlete, popularity or income may be deemed more important than preventing concussions, and thus, this construct can be used to craft concussion prevention interventions that focus on protective values.

Protective values: 1) Increased clarity of values about sports, 2) Decreased peer pressure influence, 3) Increased outcome expectation, 4) Increased goal formation.Risky values: 5) Emphasis on financial gain or future scholarships.

4) Goal formation- According to the principles of SCT, behavior change is best achieved by breaking down goals into a progressive series of sub-goals (Bandura, 1986). This idea of bite size goals infused with cues to action is imperative for our young and maturing athletes, especially if the sub-goals are well defined, easy to measure behaviors, reproducible and sustained in a nurturing and stable socio structure that encourages the new behaviors to become habitual. An example would be a sub-goal of raising selfawareness, self-reporting, and early intervention in an athlete. This can lead to a mediumterm sub-goal, of making every student-athlete aware of the CDC slogan, "It's better to miss one game, than the whole season." (Centers for Disease Control and Prevention, 2015). The achievement of such a goal can serve to increase self-efficacy and expectancies (benefits), thereby motivating the continued protective behavior during contact sports.

5) **Socio- structural factors**- "Goal attainment through motivated behavior (positive outcome expectancies combined with sufficient levels of perceived self-efficacy) is a function of the supporting factors, as well as the impeding factors, of a person's environment, i.e., to say, the world people live in enables and limits their ability to effectively engage in goal-directed behavior" (DiClemente, Salazar, & Crosby, 2013). Socio-cultural factors such as customs, lifestyle, and values that characterize a society (religion, attitudes, economic status, class, culture, language, politics and law) can affect the quality of life and health of its citizens including the risk of concussions in youth athletes. Since individual behaviors are often within the confines of societal norms and hierarchical organizations, the same is true for the "World of Sports." Undoubtedly, a change in the culture of sports is urgently needed. However, this is beyond the scope of

this project. Finally, we dare not overlook the concept of interdependence as described in Bandura's Reciprocal Triadic Causation, as one of the key concepts of SCT (Bandura, 1986). The individual (cognition, affection, and biology), behavior and the environment (sports environment, sporting network influence, parents, coaches, and teammates), operate as a whole with neither operating as an independent part.

6) Psychology of injury- psychology is defined as the study of behavior and mind; it embraces all aspects of conscious and unconscious experience as well as thought (DiClemente, Salazar, & Crosby, 2013).

Risk factors in reporting of concussions and continuing to play with a possible concussive injury, include: 1) personality, 2) history of stressors, 3) coping resources, 4) the previous history of concussion, 5) time lost to the injury, 6) effect of the injury on athletic performance (Grove, Hanrahan, & Stewart, 1990; Petrie, 1992), 7) athletic identity, 8) self-esteem and body image (Wiese-bjornstal, Smith, Shaffer, & Morrey, 1998).

Behavior Determinants Interventions Logic Model

Logic models are graphic depictions that show clearly and concisely the causal mechanisms through which specific interventions can affect behavior and thereby achieve a health goal. These causal pathways between programs and behavior paved by best available data and theories, lead the way to successful interventions (Kirby, 2002).

The process of creating a logic model first involves identifying the main **health goal**, which guides each step of preceding action; secondly, identifying and selecting all important **behaviors** that affect the health goal; and thirdly, identifying and selecting

potentially important **determinants** (including risk and protective factors) to be targeted using **interventions and activities** to promote public health.

In line with Healthy People 2020, IPV -2 objective: We will choose our main health goal to be "Reduce fatal and nonfatal traumatic brain injuries in youth athletes" (Healthy People 2020, 2015), specifically Youth Sports Concussions. Also, our intermediate goal focuses on secondary prevention and improved outcomes. Therefore, we have identified and selected three main behaviors to address: A) Increased recognition of symptoms consistent with concussions in middle school athletes, B) Increased reporting of symptoms consistent with concussions (by middle school athletes) and C) Increased response after a concussion (by middle school athletes), such as asking to be removed from play, sitting out a game, supporting a teammate with a concussion or adhering to concussion and return to play protocols.

SOCIAL-ECOLOGICAL FRAMEWORK

The strengths of the social-ecological framework lie in its intentional study of the different layers of ecological interaction, between the individual, family, peers, community, environment, organizational and policy levels. The ultimate goal of this framework is to remove barriers associated with developing, implementing, evaluating public health and health promotion interventions.

The staggering data on sports concussions and an ever-changing socioenvironmental context of youth sports, warrant interventions to address *the public health* *problem of youth sports concussion*. Using the social, ecological framework with an emphasis on the **individual**, **and interpersonal levels**, our aim is to provide a framework of behaviors, determinants, and interventions that address this problem using a Behavior Determinant Intervention (BDI) logic model. The process of creating a logic model starts with identifying the main **health goal**, which is followed by identifying and selecting all important **behaviors and determinants** that affect the health goal (including risk and protective factors), these behaviors and determinants are then targeted using **interventions and activities** to promote public health.

The charge of public health for "…prevention of early mortality, morbidity, and associated negative health outcomes" is a complex mission that utilizes multiple socioecological layers, or levels, of health intervention (DiClemente, Salazar, & Crosby, 2013). To meet the challenge of this complexity, the systems-based model of the *Social Ecological Framework* will be applied to the selection of the design of the concussion prevention programs. This framework, also referred to as the Social Ecological Model (SEM), offers a structure to plan for interventions associated with each level of factors that influence health behavior and outcomes. The framework was originally rooted in understanding that disease is situated in a social ecology or that "the underlying cause of the disease lies in the sociocultural environment" (DiClemente, Salazar, & Crosby, 2013).

Multiple ascending bands of influence represent this social ecology: *individual*, *interpersonal* (relationship); *organizational*; *community*; and *policy* (Mercy & Vivolo-Kantor, 2016). Using the model to plan a comprehensive health intervention, public

health practitioners define risk factors and then determine the associated interventions at each level. Additionally, within this model, public health practitioners can determine alignment and find synergies targeted across a comprehensive set of factors so as to effectively outline and direct their efforts. As a theory, the framework can "help health educators [and the public health community at large] better understand what influences health, relevant to individual, group, and institutional behaviors and to thereupon plan effective interventions directed at health-beneficial results" (Hochbaum, Sorenson, & Lorig, 1992).

The CDC uses a four-level social-ecological model to better understand diseases, injuries, violence (Mercy & Vivolo-Kantor, 2016) and the effect of potential prevention strategies ("The Social-Ecological Model: A Framework for Prevention|Violence Prevention|Injury Center|CDC," 2016). This model considers the complex interplay between individual, relationship, community, and societal factors. It allows us to understand the range of factors that put people at risk for violence or protect them from experiencing or perpetrating violence ("The Social-Ecological Model: A Framework for Prevention|Violence Prevention|Injury Center|CDC," 2016). The overlapping rings in the model illustrated in Figure 1 show how factors at one level influence factors at another level. We plan to use this same model to better understand unintentional injuryconcussions in youth and the effect of potential prevention strategies.

The following discussion shows how the CDC's SEM model can be used as a framework for understanding and increasing recognition and response to concussions among youth athletes.

Individual

The first level targeting the individual athlete will help to identify biological and personal history factors that increase the likelihood of sustaining concussions. Some of these factors are age, education, income, substance use, or history of abuse. Prevention strategies at this level will be designed to promote attitudes, beliefs, and behaviors that ultimately prevent injury. Specific approaches will include education and life skills training.

Relationship

The second level will examine close relationships that may increase the risk of experiencing concussions. A young athletes' closest social circle-peers and family members influence their behavior and contribute to their range of experience. Prevention strategies at this level may include parenting or family-focused prevention programs, mentoring and peer programs designed to reduce conflict, foster problem-solving skills, and promote healthy relationships.

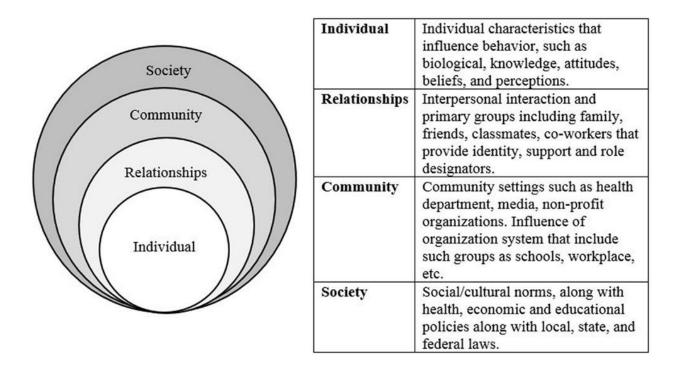
Community

The third level can be used to explore the settings, such as schools, and neighborhoods, in which social relationships occur and seek to identify the characteristics of these settings that are associated with an increased risk of concussions. Prevention strategies at this level are typically designed to impact the social and physical environment – for example, by creating concussions protocols for coaches and Athletic Trainers. Also, ensuring the availability of health care, reducing social isolation, improving economic and housing opportunities in neighborhoods may lead to better school funding and availability of sports protective gear for young athletes. Additionally, improving the sports climate, processes, and policies within the school, increasing buy-in of concussion prevention strategies by all staff of the school including the head of the school will be very helpful.

Societal

The fourth level looks at the broad societal factors that help create a climate in which unintentional injury such as concussions in youth athletes is discouraged or inhibited. These factors include social and cultural norms such as the notion of "playing through pain." Other large societal factors include the health, economic, educational and social policies that help to maintain economic or social inequalities between groups in society. Emphasis must also be placed on creating environments conducive to change, making it easier to adopt healthy behavior such as laws and policies of "return to play" and "return to learn."

The strength of the socio-ecological framework is that it focuses on the different layers of ecological interaction, from the challenges faced by the individual athlete, to how they interact with the proximal (family, peers, coaches and community) and distal influences (environment, organizational, policy). The **individual** or intrapersonal and the **relationship** or interpersonal levels will be the focus of the first phase of our concussion prevention intervention, with the **target population** being **middle school aged youth athletes.** Figure 1.



Adapted from the CDC SEM framework for Violence

Center for Disease Control and Prevention. The Social-Ecological Model: A Framework

for Violence Prevention. Available from: http://www.cdc.gov/

ViolencePrevention/pub/SEM_framework.htm

Concussion Education

Existing Programs

Athletes, Coaches, and Parents

There have been initiatives centered on toolkits developed for concussion education, involving collaboration with several health, sports, and national organizations such as the CDC's "Heads Up: Concussion in Youth Sports" initiative in 2007. This CDC toolkit includes fact sheets tailored for coaches, parents, and athletes; a clipboard; a magnet; and a quiz to test concussion knowledge. An online concussion training module for coaches is also available via the campaign's website (Center for Disease Control and Prevention, 2010; Centers for Disease Control and Prevention, 2012; Centers for Disease Control and Prevention, 2015).

Despite these toolkits, research has shown that coaches may not be able to identify subtle concussion symptoms, and may not be aware of the importance of managing cognitive activities following a concussion (Faure & Pemberton, 2011; Chrisman, Quitiquit, & Rivara, 2013; Naftel, Yust, Nichols, King, & Davis, 2014). Also, parents are not familiar with state concussion laws, or school, or league protocols, regarding concussions (Shenouda, Hendrickson, Davenport, Barber, & Bell, 2012; C. S Mott Children's Hospital, 2010).

Health Professionals

The literature on concussion education in medical schools is sparse. In a Canadian survey of medical schools, only 4 of the 14 schools that responded to the survey (out of a total of 17 medical schools), indicated that concussion education was included in the curriculum for medical students (Burke, Chundamala, & Tator, 2012). Notably, some health care providers do not feel they have adequate training on concussions, and the use of evidence-based, and standardized assessment tools and guidelines is limited (Kaye, Gallagher, Callahan, & Nance, 2010; Giebel, Kothari, Koestner, Mohney, & Baker, 2011; Zonfrillo et al., 2012; Broshek, Samples, Beard, & Goodkin, 2012; Carl & Kinsella, 2014).

Social media as an education tool

Content analyses of social media sites such as Facebook and Twitter, show that people use these sites not only to share and discuss news stories about concussions, but also to share personal experiences, and to seek, and offer advice. These content analysis studies highlight the capacity of social media to serve as a broadcast medium for sports concussion information and education (Ahmed, Sullivan, Schneiders, & Mccrory, 2010; Finch, McCrory, Ewing, & Sullivan, 2012).

Other tools, such as text messaging, have been used as a method for injury registration in sports, such as in elite female football (Soccer) (Nilstad, Bahr, & Andersen, 2012). Also, current literature suggests that there is some evidence supporting the use of interactive computer programs, such as e-modules, for concussion education

purposes. Such interactive learning platforms have been used successfully in Canada with the Hockey Concussion Education Project (Echlin et al., 2014).

Finally, even though some studies have shown that concussion knowledge in youth can be improved by educational interventions, such as; workshops and lectures, videos, and other programs, (Cook, Cusimano, Tator, & Chipman, 2003; Bramley, Patrick, Lehman, & Silvis, 2011; Bagley et al., 2012; Cusimano, Chipman, Donnelly, & Hutchison, 2013; Miyashita, Timpson, Frye, & Gloeckner, 2013; Echlin et al., 2014), there is insufficient information concerning the effect of these interventions on behavior. This gap in knowledge provides an opportunity for evaluation of concussion education programs.

We also know that knowledge, although essential for behavior change, does not necessarily translate into changes in behavior. Therefore, there is the need to discover other modifying factors, and determinants, that influence whether, and how, individuals respond to information including social, attitudinal, and emotional forces. Additionally, despite what is known regarding factors associated with gender differences in concussion rates among various sporting events, there is a paucity of data regarding the gender differences in the physiological, hormonal, psychosocial, normative, and cultural risk factors. These factors are worth studying because, they may add to the challenges of preventing concussions in young maturing middle school aged athletes, who eventually grow up to be high school and collegiate athletes.

Sports-related concussions in youth have been a focus of the Institute of Medicine (IOM) of the National Academies. The IOM, released a report in 2013, titled, "Sport-Related Concussions in Youth: Improving the Science: Changing the Culture" (Institute of Medicine, 2013), encouraging research and focus on youth sports concussions. Also, youth sports concussion has long been a focus of the Injury Prevention Center of CDC and aligns well with the Healthy people 2020 goal to "Prevent unintentional injuries and violence, and reduce their consequences" (Healthy People 2020).

This study will strive to add to the existing information about youth sports concussion. By using theory-based frameworks and interventions to address the determinants of concussions in middle school athletes, we hypothesize that interventions created specifically for this young population will lead to increased recognition, response, and reporting of concussions.

Novel Concussion Prevention Intervention Program

Intervention based on Applying theories and frameworks

The intervention for our proposed study will be called: <u>"Report concussions, Respond</u> <u>now" (RcRn).</u> We would use a novel, App-based intervention, underpinned by the social cognitive theory and socioecological model, targeted towards younger athletes, specifically, middle school aged children. The RcRn App based intervention will be fully discussed in the methods section.

Review of literature regarding methods

Methods

Studies have focused on the value of mixed-methods approaches for researching questions about social experiences and lived realities; these studies stress the importance of qualitative data in addition to quantitative data (Mason, 2006). This pilot study will, therefore, employ a mixed-methods approach where quantitative data via surveys and qualitative data via focus groups would be employed. Our focus group methodology would follow evidence-based principles of using focus groups in children, including keeping age ranges narrow and conducting focus groups in a non-classroom setting as research suggests that this informal setting can lead to more participation by the students (Gibson, 2012).

CHAPTER 3

METHODOLOGY

Request for Application (RFA)

This grant proposal is in response to the request for application (RFA) by the CDC-Funding Opportunity Announcement Number: RFA-CE-17-002. Opportunity Title: Development and Evaluation of Sports Concussion Prevention Strategies.

Our grant proposal aligns perfectly with the description of the RFA above announced by the CDC which is to: "either (a) develop and pilot test a new intervention OR (b) rigorously evaluate an existing intervention that targets young athletes participating in sports programs."

According to the CDC, "interventions should be social and behavioral in nature and should represent either primary prevention or secondary prevention of sports-related concussion. Primary prevention interventions aim to prevent sports-related concussions before they occur, while secondary prevention interventions aim to reduce the impact of concussions that have already occurred. Information gleaned from this research can inform mechanisms of change in the culture of youth sports and support multi-stakeholder approaches to promoting a positive (preventive) culture of sport to mitigate negative norms, beliefs, attitudes, and policies that may increase risks of concussion

among young athletes."

(http://www.grants.gov/searchgrants.html?fundingCategories%3DHL%7CHealth) Our study proposes to fill the identified gap in knowledge about the determinants of concussions in middle school-aged students by using social-behavioral frameworks and interventions to improve our understanding of the determinants of concussions in youths and subsequently facilitate the creation and implementation of an intervention that will increase recognition, reporting, and response to concussions.

This project will use an innovative and interactive App-based program called "RcRn" (Report concussions, Respond now). It will be based on constructs of the Social Cognitive Theory (SCT) (Bandura 2004) and the Center for Disease control and Prevention (CDC) social ecological model (Center for Disease Control and Prevention, 2015). "RcRn" will be created specifically for middle school-aged participants but made easily adaptable for use by older children. The goal of the intervention will be to educate and empower youth athletes to recognize, report and respond to concussions. Evaluation of the process and impact of the intervention will be an integral part of this proposal.

Our proposal aligns well with the funding opportunity call for proposal to develop and evaluate sports concussion prevention strategies that are social and behavioral in nature by developing and pilot testing a new intervention.

To achieve our health goal of preventing sports related concussions in youth, our interventions and activities will target middle school-aged children and address three main behaviors: a) Increase recognition of concussion symptoms, b) Increase reporting of

concussion symptoms and c) Increase response towards concussion symptoms (by showing evidence of self-efficacy and resilience such as: asking to be removed from a game, sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion).

Grantor Request

We are requesting sponsorship from the Centers for Disease Control and Prevention (CDC) for this research project because they have an extensive experience in the field of unintentional injury and specifically youth concussions. They have access to many resources and various organizations whose sole purpose is to bring awareness to concussions in youth sports.

The CDC has partnered with experts and organizations to establish and develop programs such as the "Heads Up Concussion in Youth Sports Initiative." This initiative serves as a tool to help parents, youth athletes, health care providers and coaches, recognize and minimize the risk and amount of concussions among children and teens (Centers for Disease Control and Prevention, 2015). The CDC has recognized the importance of concussion prevention in youth and has been at the forefront of research and program formation targeted at concussion prevention.

They have successfully partnered with over 85 organizations to reduce concussions in youth athletes. With these efforts, over 3 million coaches in youth sports have successfully completed the Heads Up training, over 50 different products to train people on youth concussion issues have been developed, more than 6 million copies of Heads-Up Material have been distributed, contact with about 40 million Americans on social media has been made and over 215 million media representations through print and TV have been made. As of January 2013, the CDC and the Heads-Up program had reached over 65 million people.

The impact of the CDC has been monumental in the fight against the silent epidemic of sports related youth concussions, therefore, partnering with them will align our common goals to reduce childhood injury from concussions and preserve the mental and physical status of our youth.

Specifically, we would like to partner with the CDC to find ways to understand youth specific concussion behavior, develop targeted concussion prevention interventions, aimed at youth athletes and finally evaluate concussion prevention programs with an ultimate goal of decreasing sports related concussions and preventing unintentional injury from concussions, specifically in at-risk groups such as younger athletes. Heretofore, the focus has been on athletes engaged in high school and collegiate sports.

Grant Review Process

The selected grant proposal reviewers had no conflict of interest with this specific grant proposal thesis. The grant proposal plan and external review template were sent to them via email. They had approximately four weeks to review the proposal, fill out the external review template and return the template to the student.

Each grant reviewer provided a written critique using the template provided, based on review criteria and judgment of merit. The reviewers had the opportunity to provide feedback regarding recommendations concerning the scientific and technical merit of the proposal, via the review template to the student. The reviewers independently returned the review template via email to the student. The student analyzed, interpreted and answered all questions and comments, as shown in Chapter 4 of the Grant Proposal Thesis. The Grant Proposal Plan was then amended accordingly and presented in Chapter 5 of the Grant Proposal Thesis.

The review criteria as shown on the template considered the significance, innovation, environment, approach of the proposal and the investigator's experience. Adapted from the https://grants.nih.gov/grants/peer_review_process.htm#Summary See Appendix K for external review template.

Grant Proposal Reviewers

Grant Reviewer 1

Dr. David Westfall M.D., M.P.H., C.P.E.,

District Public Health Director for District 2 at the State of Georgia's Department of Public Health.

Adjunct faculty at Rollins School of Public Health, Executive MPH

Dr. Westfall earned his medical degree from the University of Florida, College of Medicine and completed his Family Medicine residency at Riverside Hospital in Newport News, Virginia, where he was Chief Resident. He has been board certified in Family Medicine since 1972 and served three years in the U.S. Navy at the Navy Aerospace and Regional Medical Center in Pensacola, Florida as a faculty member of the Family Medicine Residency. In 1978 he opened a private practice in Gainesville, Georgia.

Dr. Westfall graduated from the Rollins School of Public Health in 2009 and currently serves as the District Public Health Director for District 2 at the State of Georgia's Department of Public Health. Dr. Westfall began his tenure with the Georgia Department of Public Health in 2006. In his current role, he oversees 13 county health departments that serve a population of approximately 650,000 residents. He also serves as Chief Executive Officer for the 13 county boards of health. In this role, he is responsible for promoting and improving public health in 13 county areas in North Georgia. Some of his notable accomplishments in his role as District Health Director include increasing primary care services for HIV patients in the district's Ryan White Clinic, improving access to health care, and improving employee development for district staff.

He holds numerous board leadership positions for organizations that help the uninsured, medically underserved areas, children who are victims of sexual or severe physical abuse, and emergency preparedness. He helped start the Good News Clinics (GNC), which provides medical and dental care at no cost to low-income, uninsured residents of Hall County. Dr. Westfall currently serves as a volunteer physician and advisory board member for GNC, which in 2011 provided approximately \$22 million in services to uninsured residents of Hall County. In addition, he remains very engaged with the EMPH program at Rollins through teaching and serving on thesis committees. As an adjunct professor in the EMPH program, he teaches a course in Planning and performance measures of non-profits.

The principle investigator selected Dr. Westfall as a reviewer because of his experience in the medical field and his experience with grant proposal applications and processes.

Grant Reviewer 2

Johanna Hinman, MPH, MCHES

Adjunct faculty at Rollins School of Public Health, Executive MPH

Johanna M. Hinman is Associate Director of Education for the Department of Surgery at Emory University's School of Medicine. Johanna has 18 years of experience in public health education, health communication, program planning and project management. A graduate of Emory's Rollins School of Public Health (RSPH) and a Master Certified Health Education Specialist, Johanna has worked for the CDC and the Arthritis Foundation National Office. She spent ten years at the RSPH, working in tobacco control and environmental health, then the Emory Prevention Research Center (EPRC). Johanna oversaw EPRC administration, managed supplemental funding applications, led communication and dissemination efforts, supervised project staff, and coordinated partnership activities. In 2012, she joined the Department of Surgery, where she oversees programs and initiatives for education and training of medical students, surgery residents, fellows and faculty members. She also administers the Center for Surgical Anatomy and Technique (CSAT), which engages innovative teaching and simulation practices for the training of surgeons.

Johanna is active in the Georgia Public Health Association (GPHA) and the American Public Health Association (APHA). She is a Past Chair of APHA's Public Health Education and Health Promotion Section and the GPHA Health Education and Health Promotion Section, and a past President of the RSPH Alumni Association. She is the Immediate Past President of GPHA. Johanna also teaches in the Executive MPH Program at RSPH. She teaches the Grant Proposal and research methods class in the EMPH program at Emory.

The principle investigator selected Ms. Hinman to be a reviewer for this grant proposal due to her expertise in grant writing and research methodologies as well as her interest in health promotion and community-based research.

Grant Proposal Reviewer 3

Lisa M. Carlson, MPH, MCHES

Director of Management and Operations, CHAMPS

Adjunct faculty at Rollins School of Public Health

Lisa M. Carlson joined the Emory Global Health Institute in April 2015 to provide administrative leadership for the rapid start-up and implementation of the CHAMPS Network. She has served at Emory since 2002, primarily as the first principle Director of the academic programs of the Emory Transplant Center (ETC).

From 2004 to 2010, Carlson facilitated academic program growth by more than 350 percent. Over time, the role grew to encompass the administration of the basic science, translational and clinical research programs of the ETC, Surgery, Urology, Otolaryngology, and more recently, the Brain Health Initiative. Prior to joining the ETC, Carlson served as Director of Operations for the Tobacco Technical Assistance Consortium at the Rollins School of Public Health, Vice-President for Population Health with the Arthritis Foundation National Office, and a team leader with the Georgia Medical Care Foundation.

She is a Master Certified Health Education Specialist and a graduate of Yale University and the Rollins School of Public Health (RSPH), where she is a past president of the RSPH Alumni Board. Ms. Carlson is on the adjunct faculty at RSPH, teaching public health ethics and qualitative methods in the distance-based Executive MPH program, for which she received the Outstanding Teaching and Mentoring Adjunct Faculty Award in 2015.

Ms. Carlson was selected as a reviewer because of her expertise in research and qualitative methodology.

Study Personnel Justification

Unini Odama, M.D., Physician/Nephrologist (PI, effort = 12 calendar months). Dr. Odama is a physician whose specialty is in nephrology and hypertension, general internal medicine and clinical research. She has worked in this field since 2003 and has served as Co-PI on several research studies.

Dr. Odama is also earning her Master of Public Health degree with a focus in prevention science, which will be completed in November 2016. Her MPH program has given her hands-on experience with social, behavioral theories, needs assessment and evaluation of programs. She has also gained skills in collaborative research using both qualitative and quantitative methods in her work. Her contributions as a physician span over a decade with many publications. Some of Dr. Odama's contributions in the medical field include numerous collaborations, books, and publications more recently as a global clinical research scholar at the Harvard Medical School.

She has been invited to speak about many public health concerns such as the issue of youth sports concussions at various settings including; Rollins School of Public Health, end of semester presentation and guest speaker on podcasts such as (http://adventuresinbraininjury.com/podcast-8/) about the concussion crisis in youth athletes. Dr. Odama has been the keynote speaker at the *International Symposium of Clinical Neuroscience* where she discussed the *Epidemiology of Youth Sports Concussions*.

As a Harvard Macy Institute Scholar since 2014, she has continued to gain expertise in medical education teaching skills, and specifically, she is in the process of learning and creating innovative and interactive App based and web 2.0-based prevention curriculums targeted at preventing youth sports concussions. Her current Thesis supervisor is the Director of the Center for Unintentional Injury Prevention at the Center for Disease Control and Prevention (CDC). Dr. Odama will coordinate and provide ongoing guidance and careful review of the work that will be carried out in her group by collaborators, Ms. S (graduate student) and Ms. Bell (MPH). She will be solely responsible for all aspects of this research from the implementation of the proposed research plan, analysis of data and publication.

Ms. S, M.B.B.S., MPH (Analyst, Co-PI, effort = 6 calendar months). Ms. S is a second-year graduate student currently earning a Master of Public Health degree at Rollins School of Public Health with a focus on prevention science and will graduate in the spring of 2017. She trained as a Physician overseas where she worked in a rural area Cardiology Hospital. She has been a presenter in many Preventive Cardiology workshops throughout her career. She is currently working with "Innovative Solutions for Disadvantage and Disability" (ISDD), to develop a Mental Health Literacy Curriculum for Veteran parents with a focus on PTSD. Her work for this project will be overseen by the Principal Investigator, Dr. Odama, who has experience regarding concussions in youth.

Ms. B, MPH (Analyst, Co-PI, effort = 6 calendar months). Ms. B earned her Master of Public Health degree at Rollins School of Public Health in May 2016. She has worked in the area of cardiovascular disease and plant based diet. She also worked with the Georgia Department of Health as a volunteer on their Chronic Disease and Prevention team for a year assisting with analyzing school wellness policies, wellness program evaluations, and grant-funded school programs for over 100 counties in the state of Georgia, and making recommendations to improve those policies. Her work for this project will be overseen by Dr. Odama who has direct experience with research as it pertains to concussions in youth.

Protection of Human Subjects

All grant proposals are exempt from IRB review; therefore, we did not need to submit this proposal to the Emory IRB. However, because this proposal includes human subjects, a description of how human subjects will be protected if the proposal is funded will be addressed.

Research on school children is subject to the funder's, participating IRB, state and federal guidelines. Therefore these will be followed.

The Pilot Study Protocol and research instrument will be submitted to the Human Investigations Committee of Emory University, Institutional Review Board (IRB) for clearance. IRB clearance will be necessary because this study will include human subjects. Importantly, this study will assure the preservation of the anonymity of the participants by using aggregate data and maintaining the confidentiality of the collected data.

Privacy Issues

The participants will not provide identifying information, therefore protecting the identity and privacy of the participant. Only anonymous aggregated information will be used. Adequate data collection and storage methods will be employed to ensure privacy

compliance. An evaluation plan will be put in place to monitor both the process and the study outcomes. Information from this pilot study will be carefully and accurately disseminated to all stakeholders to be used in creating health promoting interventions and programs geared towards preventing concussions in youth sports.

Research in Children:

In the S.E United States, the age of majority is 18, except in Alabama, where the age of majority is 19, hence based on concerns for the welfare of children as research subjects, protections for children that exceed those for adults are often incorporated into the federal regulations for protecting research subjects. At the same time, regulators recognize that some research presents no more than minimal risk to children and allow for flexibility in the parental permission and child assent processes (General Education Provisions Act, 20 USC § 1221 (2012).Since this study involves interviews, surveys, and observations, in which the researcher participates in the activities being observed, the IRB will determine if the Subpart D, U.S. Department of Health and Human Services (HHS) regulations should apply (U.S. Department of Health and Human Services (HHS) Office for Human Research subjects known as the Common Rule: U.S. Department of Health and Human Services (HHS) Regulations, Subpart A will be adhered to (Protection of Human Subjects, 45 CFR § 46 (2009).

Consent/confidentiality

After obtaining IRB and Ethics approval, informed consent would be obtained from parents and assent from middle school children below the age of 19. Also, agreements will be obtained from the school headmaster and athletic director. If required, agreements will also be obtained from the school district administration.

Consent Process and Enrollment

The principle of respect for persons requires that subjects give informed consent to participate in the research project (Hulley, 2007). As investigators, we must disclose information that will be relevant to the subject's decision to participate or not. In the written informed consent document, such information will include: the nature of the research project, the procedures of the study, the potential risks and benefits of the study, assurances that participation in the research is voluntary, protection of confidentiality and answers to any questions about the study that they may have. After the participants' questions have been answered to their satisfaction, they may sign the consent form and begin participating in the study. Once the participant signs the consent form, they will automatically be enrolled in the study. Each participant will receive a subject ID number to protect their confidentiality and to remove protected health information and/or identifiers.

Participant recruitment & Sample Size

A primary survey of middle school students in grades 6-8 in an identified pilot school will be carried out. The pilot school will be selected by convenience sampling and located in the southeastern U.S since all the investigators are located in this region. An estimate of the number of participants needed for the study, calculated based on an expected participant rate of 80 %, power of 80 % (B= 0.20) and a 95 % confidence level is 384. However, the final sample size will depend on participant recruitment based on parental consent. Attempts will be made to optimize the sample size from a single school due to feasibility and funding considerations. This will be achieved by conveniently selecting a school that has at least 500 middle school students. We will also focus on achieving buy-in by the School headmaster and Athletic Director and other stakeholders prior to the initiation of the study via meetings and site visits.

In the event that the recruited participants from the 6-8th grades are not sufficient from the first school, additional participants will be recruited from a second school in the same south-eastern region. Care will be taken to match participants according to demographics and other variables such as socioeconomic status, grade, gender, and sporting activity.

Justification for subject population

The rationale for selecting middle school children are: A) Timing of our concussion intervention to a period just before youth athletes enroll in high impact competitive sports, like high school football, soccer, lacrosse, etc., B) Selecting middle school-aged children is also in response to the call by the IOM to address the silent epidemic of concussions in those athletes younger than high school. C) Middle school students often explore various sporting activities before enrolling in high school sports and therefore, it is invaluable to increase their awareness, recognition, and responsibility of reporting concussions. This would prepare them to be part of the first line of response, by early recognition and reporting of concussions. D) This age group will help to 'catch them young' before they buy into the known sports culture of high school and college sports of "keeping silent" and "playing through the pain." Intervening early is particularly important because studies have suggested that to change the behavior of athletes, you need to intervene earlier than high school with theory-based interventions that increase awareness and knowledge of concussions, change harmful perceptions, and modify peer influence by increasing self-efficacy and positive reinforcement (Bloodgood et al., 2013). E) The ultimate goal is to develop targeted interventions to prevent concussions in youth athletes at the various socio-ecological levels, beginning with the young athlete.

Even though targeting middle school athletes is vital for concussion-prevention strategies, it will be important to assess when values about sports begin and the ideal time to start intervening. Furthermore, since many children are already in youth sports leagues such as pee wee football and youth soccer, it will also be important to determine whether concussion prevention intervention needs to begin earlier than middle school. These substantial questions are, however, beyond the scope of this project.

Introduction to methodology

Previous studies have focused on high school and collegiate sports concussions and very little on those younger than high school (Institute of Medicine, 2013). This project will, therefore, focus on understanding the factors associated with the recognition of, reporting of and response to symptoms consistent with concussions among children and adolescents in middle school.

Furthermore, we will use App-based interactive interventions to successfully reduce youth sports concussions among middle school-aged students. To achieve these goals, we propose the following Specific Aims.

Aim 1. Understand the behavior. Understand the socio-behavioral concussion risk factors among youth athletes in middle school and understand the gender variations of these risk factors as it pertains to concussion risk.

Aim 2. Interactive Intervention. Increase recognition and reporting of, and response to concussions symptoms among middle school children, through the use of an innovative theory-based, App-based, interactive, concussion prevention intervention.

Aim 3. Develop more programs and provide additional literature. Use the information gathered from this study, intervention and evaluation to further develop youth sports concussion programs for middle school students and also provide additional literature that is relevant to the subject.

Time and Task Chart

To guide our study, we will follow a time and task chart which will be summarized here but shown in details in **Appendix A**.

- a) Our proposed study will be completed within 22 months, including six months for the development and testing of the interactive concussion prevention app ("RcRn"); 10 months for the intervention and data collection and the last six months for analysis, evaluation and dissemination of the results. This estimate is also based on the anticipated adequate number of enrolled participants. To achieve the objectives of this study, the research will be divided into phases.
- b) Phase 1: A detailed protocol will be submitted to the Institutional Review Committee/Ethics Committee for approval, a thorough consent process will be put in place as well as a process for accumulating and protecting data. IRB and Ethics approval will be obtained from Emory University/CDC
- c) Secure funding from CDC.
- d) Phase 2: Enlist collaborating sites, obtain signed consents from parents and agreements from the Head of School, Athletic Director, other stakeholders. Training of volunteers to follow protocol and guides, especially regarding research involving children.
- e) Phase 3: Continue the consent and assent process, screening and enrollment, data and sample collection, data storage and warehousing, data lock/study closeout process and statistical analysis.

 f) Phase 4: Evaluation and preparation of manuscript for the dissemination of results in national and international journals and conferences.

The aforementioned task chart will be followed diligently, and the study will proceed as described in the rest of this section. **See Appendix A for Timeline and Task Chart.**

Research design

This study will be a pilot study carried out among middle school aged students. We will utilize a mixed-methods approach for researching questions about the social and behavioral factors that affect recognition and reporting of, & response to symptoms consistent with concussions; gender differences in awareness, knowledge, attitude, behavior, perception, value, self-efficacy pertaining to youth sports concussions; and, the effect of an interactive theory based, App-based concussion prevention intervention on the aforementioned attitudes and behaviors towards concussions.

Objectives:

The objectives of this study are as follows:

A) Increase recognition of symptoms consistent with concussions by middle school students, by 75 %, in one year.

B) Increase reporting of symptoms consistent with concussions by middle school students, by 50 %, in one year.

C) Increase response towards concussions by middle school students, by 50 %, in one year. (Increase response by middle school students would be defined as showing some evidence of self-efficacy and resilience such as: asking to be removed from a game,

sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion).

Outcome and Outcome measures:

Over the course of one year, we anticipate that 75 % of the participants in this pilot study will have an increased recognition of symptoms consistent with concussions; and 50 % increased reporting of, and response towards concussion symptoms. Furthermore, we hope to replicate this model in larger studies that focus on school-based concussion prevention programs.

The anticipated increase in prevention of concussions in youth sports and prevention of unintentional injuries and their consequences align well with the CDC's Healthy People 2020 objectives (Healthy People 2020, 2015) as well as The Institute of Medicine (IOM) of the National Academies' focus on youth sports concussions as discussed in their report, "Sport-Related Concussions in Youth: Improving the Science: Changing the Culture" (Institute of Medicine of the National Academies, 2013).

We expect to answer our aforementioned research questions using quantitative and qualitative data obtained from middle school participants. Firstly, the influence of sociobehavioral factors on youth sports concussions, gender variations and influence of sports culture will be measured by behavioral and attitudinal surveys and focus groups regarding awareness, knowledge, perceptions, recognition, reporting, response, selfefficacy, peer influence and psychology. Secondly, our intermediate objective, the changes in behavior that result from changes in knowledge, attitudes, and efficacy will be measured by Pre- and Post-intervention surveys and focus group interviews of middle schoolers. This will determine the change in recognition and reporting of, and response to concussion symptoms.

Evaluation of the intervention and outcomes will be based on results from Pre-and Post-intervention surveys and focus group interviews of participants. It is expected that the answers to these questions in conjunction with what is known about the protective and risk determinants of concussions will be useful towards the development of future programs targeted at preventing concussions in young athletes. The ultimate outcome of this study which is to prevent concussions in youth sports will be measured via 5-year longitudinal annual follow-up surveys of the cohort of middle school participants selected for this study.

Qualitative data will be gathered via focus group interviews of middle school participants to investigate determinants of concussions in middle school aged children. We would collect quantitative data using a survey instrument to capture data on middle school participants' knowledge, attitudes, and beliefs regarding concussions. The survey will also ask all participants if they have ever had concussions and if yes, to recall previous concussions and concussion-like events. They will also be asked to indicate whether they reported the concussion symptoms to a coach or a medical professional.

Delimitations

- 1. All participants will be middle school students, Grades 6, 7 and 8.
- 2. All middle school students will be eligible to participate regardless of their participation in sports, or, what type of sports they participate in.
- 3. The selection of the pilot school will be done based on a convenient sample.
- 4. All recruitment meetings will be conducted by the principal investigator or assigned study contact.

Assumptions

- 1. The students will answer the questions truthfully and with maximal effort.
- 2. The questionnaires will be valid and reliable.
- 3. The students will not receive help from other sources on the questionnaires.

4. Each participant will complete the questionnaire according to the directions in the instructions.

5. All participants will be honest about their concussion history and reporting of these concussions.

6. The questionnaire will be completed in a similar environment by all participants.

Methodology-Focus Groups

Guidelines for determining non-probabilistic sample sizes are virtually nonexistent.

Though there are no rules for sample size in qualitative inquiry; purposive samples are

the most commonly used form of non-probabilistic sampling. Their size typically relies on the concept of "saturation," or the point at which no new information or themes are observed in the data (Patton, 2002). Although the idea of saturation is helpful at the conceptual level, it provides little practical guidance for estimating sample sizes, prior to data collection, necessary for conducting quality research (Guest, Bunce, & Johnson, 2006; Patton, 2002).

Guest et al., reviewed twenty-four research methods books and seven databases, and found that very little headway had been made regarding sample size guidelines. Morse's (1995) comments succinctly summed up the situation. She observed that "saturation is the key to excellent qualitative work," but at the same time noted that "there were no published guidelines or tests of adequacy for estimating the sample size required to reach saturation.

However, several studies have shown that when the aim of a study is to understand common perceptions and experiences among a homogeneous group, twelve interviews should suffice (Guest, Bunce, & Johnson, 2006). Since we aim to understand the perceptions and experiences that drive behavior regarding concussions in a middle school population in a single pilot school, we will randomly select participants to participate in 12 focus group interviews. This number is consistent with previously mentioned studies shown by Guest et al., (2006). However, as Morse (1995) pointed out, saturation can be an "elastic" concept and therefore "there must be flexibility built in regarding sample size of focus groups especially in field work, and sample size must be judged in context." (Patton, 2014) "Focus group interviews are typically homogenous and involve open-ended questions with groups of five to eight people on specially targeted or focused issues" (Patton, 2014), therefore, for the purpose of the focus groups interviews, two groups of six children each will be selected randomly from each grade for same-sex focus group discussions at the beginning and end of the study. There will be a total of six focus groups at the beginning and six at the end of the study. The same groups will participate in the pre-and post-focus groups for comparative ease and to improve internal validity. These sessions will last no longer than 45 minutes and would be headed by an experienced moderator (PI) and a trained assistant moderator (CoPI).

Research suggests that focus groups with children and youth work best when the age ranges are kept narrow (Gibson, 2012). Therefore we will randomly select children from the same grade for the focus groups while all students willing to take part in the study will fill out the questionnaire.

The study period will be 22 months in total. It will consist of three main parts; the first six months will be used to design the RcRn App intervention. The next ten months including, months corresponding to a school calendar year, September 2017-April 2018 will focus on the qualitative and quantitative data collection, as well as the intervention phase. The final six months of the study will focus on analysis, evaluation of the study process and outcomes as well as dissemination of results.

See Appendix A for Timeline and Task Chart.

Quantitative component

A survey questionnaire will serve as the instrument for the quantitative part of the study. This instrument will be pretested for face validity by three questionnaire experts at the Rollins School of Public Health, Emory University. This validated attitudinal and behavioral questionnaire will be tailored to middle school-aged participants. The survey will be administered electronically to students whose parents have consented and who have assented to participate in this study. An alternate option of administering the questionnaire will include a paper-based questionnaire prepared by EPI-info for the 6-8th-grade participants. This questionnaire regardless of the format will be administered at the same time during a school physical education period.

The questionnaire would be more acceptable via an electronic form, and it will cause minimal disruption to the students because the students in the pilot school would already be using IPADs or computers for daily school activities and every student will have access to an IPAD or computer with them daily for school use. The short (15-20 minute) questionnaire will be administered during normal class hours during a physical education period after obtaining consent from parents, assents from participants and agreements from the Athletic Director and Principal of the School.

Survey Instruments

Quantitative component

The survey questionnaire will consist of 24 multiple choice questions, made up of closed-ended questions, categorical questions, Likert-scale questions, and a few options for open-ended responses.

Questionnaire Topics:

The questionnaire topics were developed in an attempt to address specific research questions posed in the study as stated below.

- What are the effects of social and behavioral factors such as knowledge, attitudes, and behavior on recognition and reporting of, & response to sports concussion symptoms?
- 2. Are there gender differences in awareness, knowledge, attitude, perception, value, and reporting behavior pertaining to sports concussion symptoms among middle school athletes?
- 3. What is the effect of a theory-based intervention on recognition, reporting of and response to sports concussion symptoms in youth?

The Questionnaire will be divided into five main sections:

 Demographics – Question 1-4: will address the objectives pertaining to identifying gender and age differences in reporting concussion symptoms and response differences based on demographic characters. No names would be collected to protect the privacy of the participant.

- 2. **Sporting Behavior** Q 5-6: will address the type of sporting activities of participants and associated protective or risky sporting behavior.
- Knowledge Q 7-14: This section will attempt to address their content knowledge of concussion symptoms and their knowledge regarding what they need to do if they experience symptoms consistent with a concussion.
- 4. **Perceptions-** Q 15-17: The rationale for these questions is to assess the perception of risk of concussions among middle school participants.
- Attitudes-Q 18-24: This section seeks to understand the attitudes towards concussions and the determinants of reporting sports related concussion symptoms among middle school participants.

See Appendix B for Questionnaire

Qualitative Component

A focus group guide will be developed based on the constructs of the social cognitive theory. The guide will start with a standard introduction and opening question, followed by discussion topics, and probes. The focus group discussions will have questions about the knowledge of concussions, beliefs about concussions, views and values of sports, the perception of concussion risk and recognition and reporting behavior. This instrument will be pretested for face validity by three focus group experts at the Rollins School of Public Health, Emory University. The focus group guide will be developed and tailored to middle school-aged participants.

Qualitative data focusing on questions regarding youth sports concussions will be obtained via focus group sessions at the beginning of the study and at the end of the study period. The focus group interview schedule will begin in September- the second month of a new school year to allow the students and staff settle into the school routine in August (1st month), and the final data collection will be scheduled for April (8th month) before the end of the school year in May. The qualitative data is expected to add depth and character to the final results.

The focus groups will consist of six students at a time, each session lasting no more than 45 mins to fit into the student's usual school physical education period scheduled time. Care will be taken to engage participants by the use of fun activities (making own name tags, ice breakers, etc.) To maximize student participation, each session will provide a small incentive of \$5.00 attached to a thank you card. Also, school physical education credit will be given to every participant at the end of the study.

Focus group procedure

The focus groups will be conducted in a non-classroom setting as research suggests that this informal setting can lead to enhanced participation by the students (Gibson, 2012). For the convenience of students and parents and to ensure maximum attendance and security, the gym area in the school or a picnic area on the school lawn will be utilized during a school PE assigned period. Each discussion will be facilitated by professionals with training and experience conducting focus groups. The main facilitator, Dr. Unini Odama (PI) and her assistant (CoPI) will leverage their public health knowledge, experience in conducting previous focus groups and knowledge about concussions to lead the discussions. The focus group session will be recorded after previously obtaining consent from all participants and their parents.

Facilitators will follow a focus group guide with standard introduction and opening questions, discussion topics, and probes. Focus group discussions will have questions about the knowledge of concussions, beliefs about concussions, views and values of sports, the perception of concussion risk, recognition and reporting behavior. Each focus group will be audio recorded and a second facilitator will take notes on key issues during the discussion. Participants will be offered a brief break with light refreshments approximately half way through the discussion. Each focus group will be subsequently transcribed verbatim.

After each focus group, participants will complete a brief questionnaire that measures awareness, knowledge, attitudes and beliefs surrounding concussions as well as response and reporting behavior. Due to the importance of hearing directly from the participants without contamination in any way, we will complete the surveys after each focus group to maintain the integrity of the qualitative data and to minimize the threat of the survey questions influencing the discussion during the focus groups

Focus group discussion topics

The focus group discussion topics will follow the main themes found in the survey questionnaire but will attempt to collect in-depth information about youth sports concussion behavior and also give a chance for the participants to share some stories from the field regarding sports-related concussions and their reporting and response behavior. These same-sex group discussions will also allow us to explore variations among gender, grade level, and concussion risk behavior. Participants will report age and gender, and the type of sports played. The socioeconomic status will be estimated using publicly available data regarding the proportion of students who receive free lunch at the school. The same standardized script will be used to facilitate all focus group sessions involving the middle school participants at the initiation and termination of the study. (Pre-and Post-Intervention)

See Appendix C-Focus Group Guide

Intervention phase:

Novel Program "Report concussions, Respond now" ("RcRn")

This Novel App to enhance reporting and response to concussions will be called "**RcRn**," and it will used weekly during a normal physical education period for 6-8th graders throughout the study period. The "**RcRn**" app will provide specific content knowledge about concussions and precise procedural knowledge, on how to avoid unhealthy sporting behavior (risky behavior) and rather engage in healthy sporting behavior (protective behavior) including reporting and responding to concussions. The detailed description of this app in a Logic BDI model can be found in **Appendix D**.

Phase 1- Educate- The *Proposed Pilot Study will focus on education via an interactive* App- based intervention

To address the threat of feasibility, our study will be divided into phases. This pilot study will focus on phase 1 of the study. However, the overarching goal is for sustainability of the concussion prevention program and implementation in middle schools across the country. Therefore future studies will be planned to include more schools in a randomized cluster design. This will also enhance the usability of the program, since the education and empowerment components can be used together in a comprehensive package or piecemeal depending on the needs of the school.

"RcRn" will be targeted at youths in 6th grade to 8th grade. The App-based interactive curriculum will be flexible and adaptable for all levels of the socioecological framework and all ages. The **"RcRn" Education App** will initially focus on the individual and interpersonal levels of the socioecological model.

Our approach will be based on strategies used in effective teaching principles of "Spacing and Testing." The first principle is the spacing effect—As described by Dr. Kerfoot, the inventor of this teaching methodology (Kerfoot et al., 2006; Kerfoot, 2010; Long, Kerfoot, Chopra, & Shaw, 2010). "When you present and repeat information over intervals of time [as opposed to "binges"], you can increase the uptake of knowledge," he explains. "And it's encoded in ways that cause it to be preferentially retained." The second principle is the testing effect: "When you present information in a 'test' format, rather than just reading it, long-term retention is dramatically improved." This method is more like grazing: "spaced education." More than ten rigorous studies on medical students and residents using randomized trials have shown its efficacy: it can increase knowledge by up to 50 percent, and strengthen retention for up to two years (Kerfoot et al., 2006). Furthermore, students report enjoying spaced education; its website (www.spaceded.com) even calls it "addictive."

The 'testing effect' refers to the psychology research finding that testing of information generates stronger retention of learning compared to the standard studying of

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content. This process is often termed 'retrieval practice' in the psychology literature or 'test-enhanced learning' or in the education literature as 'practice testing' (Dunlosky, Rawson, Marsh, Nathan, & Willingham, 2013). Furthermore, practice testing and distributed testing have been demonstrated across an impressive range of practice tests formats, kinds of material, learner ages, outcome measures and retention intervals. Thus, practice testing has broad applicability. It is not particularly time intensive relative to other techniques, and it can be implemented with minimal training. Several studies have provided evidence for the efficacy and success of these approaches across students of different ages, with a wide variety of materials, on the majority of standard laboratory measures, and over long delays. (Dunlosky, Rawson, Marsh, Nathan, & Willingham, 2013; Roediger & Karpicke, 2006; Karpicke & Roediger, 2007; Kerfoot et al., 2006).

We will, therefore, incorporate these effective learning techniques into our interactive App-based concussion intervention to increase retention of concussion knowledge as these techniques have been shown to be more effective than highlighting, key work mnemonic, summarization and elaborate interrogation (Dunlosky, Rawson, Marsh, Nathan, & Willingham, 2013). Underpinned by these effective techniques, our interactive "**RcRn**" app will provide content and procedural information about the causes, symptoms, signs, consequences of concussion, as well as how to recognize and promptly report and respond to concussions. These techniques will enhance the uptake of information, the long-term retention and the retrieval of the concussion-related information presented to the participants during the "spaced" six-month long sessions.

"RcRn" App intervention-Goals

- 1. Foster protective sporting behavior- reporting and responding to concussions.
- 2. Influence attitudes and clarify values- such as sports is not the only way to success or choosing nonimpact sports.
- 3. Teach and help children and adolescents learn new skills and apply themcommunicating or reporting concussion symptoms, dealing with peer pressure.
- 4. Impart knowledge about concussions and what to do, if they experience symptoms consistent with concussions.
- 5. Improve retention and retrieval of concussion-related knowledge.
- 6. Enhance learning about concussions in children and adolescents.
- 7. Sustainability of the concussion prevention App.

"RcRn" App intervention-Structure

The app will be designed and structured in collaboration with an instructional designer from Georgia Tech. We will use the following design rubric to ensure that the App is usable, aligns with proposal goals and created in a way to engage the learner and increase knowledge retention.

"RcRn" App-Design rubric

- 1. Accessibility.
- 2. Enagement of App user.
- 3. Knowledge assessment component.
- 4. Teaching to the goals and objectives of the proposal.
- 5. Alignment with goals and objectives of the proposal.

- 6. Supports individual and personalized learning.
- 7. Allows for specific feedback to App user.
- 8. Allows specific feedback to App developers.
- 9. Aesthetically pleasing (fonts, colors, layout, flow of material, etc.).
- 10. Organization and layout of material.

"RcRn" App-Evaluation rubric

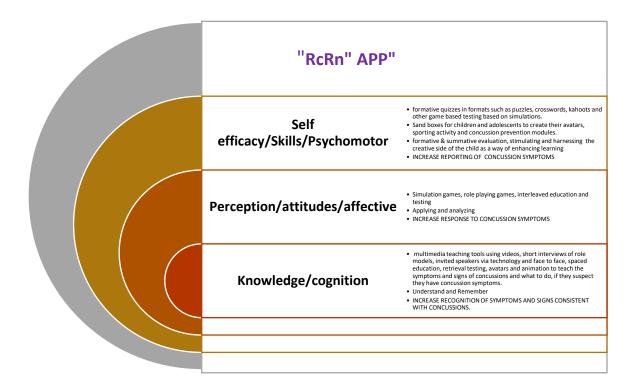
Each of the above components used in the design of the app would also be part of the evaluation of the intervention at the end of the study and will be evaluated on a Likert scale of 1-5.

"RcRn" App-Content Framework

Principles of the Blooms revised taxonomy for teaching, learning and assessment (Anderson & Krathwohl, 2001; Bloom, Englehart, Furst, Hill, & Krathwohl, 1956) as described in the goals; spaced education and distributed practice testing (Kerfoot et al., 2006; Kerfoot, 2010; Long, Kerfoot, Chopra, & Shaw, 2010; Dunlosky, Rawson, Marsh, Nathan, & Willingham, 2013); and the SCT will be employed. Concussion-related content will include: improving the recognition and recall of concussion symptoms and signs, and improving the understanding and interpretation of concussions by the aid of examples and comparisons. Also, the App will encourage the application of the new knowledge learned by use of concussion-related simulations. Ongoing feedback, assessments via spaced education and practice testing, as well as formative and summative evaluations, will be used. Also, we will provide the opportunity for the learners to create, generate or plan further educational resources that can be used to teach other learners.

Figure 2

"RcRn" App-Framework Schema



"RcRn" App-Delivery

The RcRn App will contain information presented in a mixed format; short didactic lessons, with each lesson lasting no longer than five mins to enhance concentration and retention, gaming using avatars to simulate sports-related concussions, symptoms, risk and protective factors, and expected response to symptoms consistent with concussions. The participants will be able to personalize their avatars and also choose their favorite sporting activity for the games and simulations. Each game will be available in 10-minute blocks, interleaved with 3-5-minute summary didactic lessons and one to two interspersed practice testing for formative assessments and immediate feedback. The total session which will be no longer than 30 mins, corresponds to a school physical education period. Each session will end with an open discussion to encourage student participation by talking about their interests relating to sports, avatars, and ideas for new concussion prevention games. The RcRn App will be used once a week from October 2017 to April 2018, a total of approximately 22 weeks which accounts for the holidays and other school breaks. *See diagram below.*

There will be two, 10-15 min question and answer sessions led by a panel of local neurosurgeons, orthopedic surgeons, athlete role models, and high school athlete role models. The first session will be in November 2017, one month after introducing the

RcRn App and the second session will be in March 2018. This timing of the first session will allow the participants get the basic knowledge and understanding of concussions from the App so that they will be more engaged during the initial question and answer session. The second session will be timed to take place a month before the final month of the intervention so that the participants can have the opportunity to ask questions to clarify any remaining issues about recognition of, reporting of, and response to concussion symptoms. *See table below.*

Figure 3

"RcRn" App schema to "report concussions and respond now."

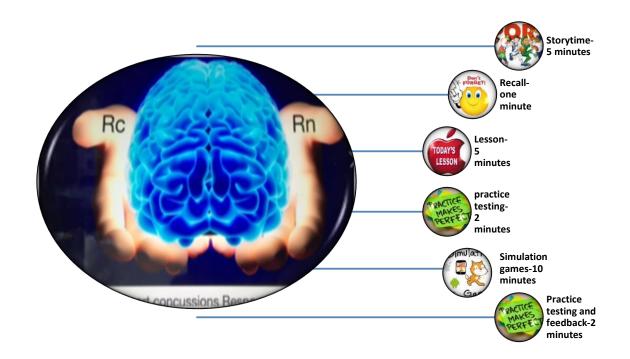


TABLE 1

SCHEDULE OF ACTIVITIES

Month	Weeks	Activity
January-June 2017	24	App development and
		testing
June-August 2017	12	IRB, site meeting, consents,
		and agreements.
September 2017	4	Survey and Focus group
October 2017	4	RcRn App
November 2017	3	Panel discussion +RcRn
		App
December 2017	2	RcRn App
January 2018	3	RcRn App
February 2018	4	RcRn App
March 2018	4	Panel discussion + RcRn
		App
April 2018	4	Survey and Focus group
May-July 2018	12	Analysis and Evaluation
August-October 2018	12	Dissemination of Results.

The "RcRn" app summary

- "RcRn" app– this free teaching tool will be available on all platforms,
 (IOS and Android) with functionality that allows for interface with social media. The "RcRn" app will be age- appropriate and provide interactive sport-specific content knowledge about concussions. Additionally, precise procedural knowledge, on how to avoid unhealthy sporting behavior (risky behavior), and rather engage in healthy behavior (protective behavior) such as reporting and responding to concussions will be provided. The "RcRn" mobile app will feature games, quizzes, and information for children to interact with on mobile devices. (collaborators: Harvard Macy Institute, Georgia Tech, CDC, and Research Team)
- Avatars will guide these interactive sessions; they will be created to simulate athletes in different situations that lead to concussions; we will use cues to action to teach reporting and response to concussions.
 Participants who successfully report and respond adequately to the case scenarios involving concussions will be able to move to the next session, demonstrating increasing knowledge and virtual self-efficacy.
 (collaborators: Harvard Macy Institute, Georgia Tech students and faculty, and Research Team)
- Video-conferencing sessions by trauma surgeons and neurosurgeons as well as TED talks with age appropriate and suitably rated pictures and

explanation of concussions will also be used to enhance this curriculum.

(collaborator- Local surgeons and Research Team)

Rewards (positive reinforcement) in forms of certificates, coupons and other special honors including being able to participate in building newer versions of RcRn Youth Sports Concussion app, in addition, graduates of the "RcRn" Program will be eligible to serve on special youth concussion committees as peer leaders to improve self-efficacy (collaborators-school headmaster, coaches and athletic director, students and research team)

Key constructs of the Education phase-knowledge, perception, clarity of value and self-efficacy.

The LOGIC BDI of RcRn Education intervention is shown in APPENDIX D1

STATISTICAL ANALYSES

Epi-INFO statistical package, as well as STATA, will be used for the primary analysis of the quantitative data obtained from this study. Descriptive estimates will be obtained from middle school participants' data. The determinants of risky sporting behavior assessed by validated age appropriate attitudinal and behavioral questions will be analyzed. Furthermore, the sample will be sub-stratified by age and gender to obtain within stratum descriptive summaries as well as a comparison of groups pre-and postintervention.

The qualitative data will be analyzed according to the procedures outlined in Patton (Patton, 2014). Each focus group transcript will be read carefully; a coding structure will be created to form the basis of a meaningful framework to capture the respondents' attitudes, beliefs, perceptions, values, and experiences. Once a structure has been agreed upon among the three members of the analysis team, the data will be coded and entered into the Ethnograph (Hammersley, 1990). The analysis team will identify the codes that are relevant to each research question. This process will involve reading the coded text and identifying salient themes that are relevant to each research question. A fourth individual will reread the coded text for the purpose of validation using the Cohen's Kappa coefficient (Cohen, 1960). This validated data will provide information about trends and patterns of awareness, recognition, and response to concussions among this population.

Limitations and challenges:

We will need a multi-layered consent process to survey children in schools, therefore, in order to mitigate this time-delay threat, we will build in additional time for IRB approval and consent processes.

All information will be self-reported; thus, bias could arise from self-reporting. In addition, since all participants may not complete the questionnaire, non-response bias from low response rates could occur. This will be mitigated by pre-study meetings with the Head of School, Athletic Director, coaches, and parents. Also, school website announcements and buy-in by the pilot school will improve engagement and participation.

Making questions on the survey clear, concise and short; and administering the survey electronically during a school period such as physical education to avoid interfering with the participant's normal school schedule will add to the simplicity and ease of the study.

To mitigate against non-response bias, we will provide ongoing transparency and feedback to stakeholders as well as assurance to the school and the participant's parents; emphasizing, that results will be de-identified and the name of the pilot school would not be mentioned in the disseminated results. We will also emphasize repeatedly, the overall goal of the study which is to- "Play safe by Recognizing and Reporting Concussions."

Using survey instruments based on the recall of prior concussions can lead to recall bias. In addition, peer pressure and fear of being stigmatized for speaking up about concussions, from peers or coaches can influence the outcome of the focus group discussion. This threat can be minimized by engaging coaches, teachers, and students as collaborators and participants in this community-based, pilot study from the initial prestudy phase to the final stage of result dissemination; and by remaining engaged with the school and community long after the first phase of the study has been completed. However, coach influence will not be assessed at the school level during this phase of the pilot study.

Threats from possible exposure to other concussion prevention programs is possible. The sample size may be adequate to detect overall changes in knowledge and perception, however a change in reporting behavior may be more difficult to detect if few concussions occur. Finally, because this pilot study will be carried out in a single, southeastern U.S. school selected by convenience sampling, generalizability to other schools and regions will be limited.

EVALUATION PLAN

INTRODUCTION:

The proposed evaluation will be undertaken from May 2018 to July 2018. The evaluation will focus on the effectiveness of the intervention and the short term impact of the study.

A) Intervention

"RcRn" App-Evaluation rubric

Each of the components below will be used in the design of the "RcRn App". The rubric listed below will be evaluated as part of the evaluation for the intervention. The evaluation for the RcRn App will be carried out using a survey of all App users and scored on a Likert scale of 1-5.

- 1. Accessibility.
- 2. Enagement of App user.
- 3. Knowledge assessment component.
- 4. Teaching to the goals and objectives of the proposal.
- 5. Alignment with goals and objectives of the proposal.
- 6. Supports individual and personalized learning.
- 7. Allows for specific feedback to App user.
- 8. Allows specific feedback to App developers.
- 9. Aesthetically pleasing (fonts, colors, layout, flow of material, etc.).
- 10. Organization and layout of material.

B) Behavior Change

The evaluation will 1) determine if attitudes and behavior toward concussions changed post implementation of the "**RcRn**" App-based intervention, 2) assess whether or not the "**RcRn**" App-based intervention successfully increased recognition, response and reporting of concussions among middle school participants at the selected school, 3) assess the process and program outcomes to evaluate sustainability and extensibility of the "**RcRn**" program to other schools for the purpose of concussion prevention education initiatives. The findings from this evaluation will be used to develop larger scale studies that are targeted at the prevention of youth concussions.

The evaluation shall be carried out by consultants called the "Evaluation Group." The evaluation team will consist of four people. Two individuals who are professional evaluators from the company "The Evaluation Group" and two graduate students from the Rollins School of Public Health at Emory University who have volunteered to assist The Evaluation Group.

The following overarching objectives will guide the evaluation

- 1. Determine if the individuals conducting the study are qualified to do so.
- 2. Determine if the attitude towards sports concussions has changed among middle school participants.
- 3. Establish if there has been a 75% increase in the recognition of concussion symptoms among middle school athletes.
- 4. Establish if there has been a 50% increase in reporting and response to concussion symptoms.

Individual	Title or Role	Responsibilities	
RSPH Student 1	Graduate Student Volunteer	Assist the professional evaluators with collecting new data by distributing post-questionnaires to participants.	
RSPH Student 2	Graduate Student Volunteer	Assist the professional evaluators with collecting new data by distributing post-questionnaires to participants.	
The Evaluation Group Evaluator 1	Evaluator	Evaluate the program based upon the proposal objectives, the results from the program provided by the modulators and the post questionnaire distributed to the participants.	
The Evaluation Group Evaluator 2	Evaluator	Evaluate the program based upon the proposal objectives, the results from the program provided by the modulators and the post questionnaire distributed to the participants.	

Table 2. Roles and Responsibilities of the Evaluation Team Members

STAKEHOLDERS:

The Centers for Disease Control and Prevention (CDC) who are the proposed sponsors of this study, will be the primary stakeholders. Results from an effective and efficient evaluation plan will play a significant role in future funding opportunities.

The research study team are also stakeholders for this evaluation. They have an interest in making this program succeed. Therefore, they will provide their perspective and contribute to the evaluation process by providing quality data collected during the study as supporting evidence to be used by the Evaluation Group. Other stakeholders will include, the School Headmaster, Athletic Director, Coaches, Middle School Students and Parents.

During this evaluation, the stakeholders will have ongoing access to the pertinent information as they are being collected, analyzed and summarized; this will serve to improve trust and transparency among stakeholders.

EVALUATION DESIGN:

The proposed evaluation will be a complete evaluation consisting of formative and summative sections. A post-test design will be used to measure the participants after the implementation of the "**RcRn**" App-based intervention. It will include 1) usability analysis (accessibility of the program; ease and engagement of program; presence of knowledge assessment), 2) design analysis (teaching to the objectives and goals of the program; allows feedback to program coordinators; program/app organization and layout), 3) Success of the pilot program, measured by achievement of listed outcome goals, 4) Achievement of the objectives listed in the proposal. The tools used in this program, as well as the process in which the program was implemented, will be evaluated to see if the participants in this program have had significant changes in behavior and attitude towards concussions.

The evaluation will include a post-intervention questionnaire distributed to all participants in the program by those conducting the evaluation. They will use information from the pre-intervention survey to serve as baseline, so that each participant will serve as their own control and therefore, pre-and post-study differences in knowledge, recognition & reporting of, and response to symptoms consistent with concussions can be compared, to evaluate for achievement and success of the proposals objectives and goals. In addition, the Formative evaluation will take the following criteria into consideration.

- a) Need- is there sufficient evidence in the literature to support the importance of this study? Have there been other studies involving other concussion prevention programs? If so how effective have they been? What are the characteristics of the target population being studied? Is this pilot program appropriate for each age group in the study?
- b) Context- Does this program fit well into the school sports environment? Are there any other programs addressing the same issue in the school? If so, what programs currently exist? What are the contributing factors to its success or challenges? And how is this new intervention different from the existing school concussion program if applicable to the participating school? If it is the case, that there is an existing concussion provention program in the participating school, then, is the internal validity of the results affected by participation or response bias?
- c) **Target Population -** Is the target population for this study appropriate? What are the inclusion and exclusion criteria? Are the participant characteristics generalizable?

The Summative evaluation will be done in the 9th month of the study period, beginning at the termination of the intervention phase of the study, which means the "**RcRn**" intervention will be evaluated the month after being in place for six months. Focus will be placed on determining the effectiveness of the intervention based on the objectives of the study to increase recognition by 75 % and, reporting and response by 50 %% at the

end of the study. In addition to the outcome evaluation, the process of achieving the outcomes and the implementation of the intervention will be assessed.

EVALUATION QUESTIONS:

Questions that will be addressed in this evaluation are as follows:

- 1. Were the modulators/facilitators of this program adequately trained to do so?
- 2. Was there a considerable amount of research conducted before the implementation of this program?
- 3. Was the app content and discussion session appropriate for each group?
- 4. Were the program materials relevant to the issue?
- 5. How big is this difference or change in knowledge, attitudes, or behavior?
- 6. Did middle school participants become more aware of sports related concussions? And were they able to respond to, and report concussions better than they did before the intervention?
- 7. Do the middle school participants and athletic coaches feel that the program was beneficial? If so, how? If not, explain why.
- 8. Has there been a 75% increase in the recognition of concussion symptoms among middle school athletes?
- 9. Has there been a 50% increase in reporting and response to concussion symptoms among the middle school participants?

DATA COLLECTION METHODS FOR EVALUATION:

This section aims to provide information on how data will be collected and compiled for the purpose of this evaluation. A quantitative approach will be undertaken for primary data collection purposes. Data regarding the knowledge, attitudes and behaviors towards concussions before the intervention will be obtained from the study investigators. This data will be retrieved by reviewing all documentation as well as focus group and survey results from the study. Primary data will be collected via surveys of the participants after the end of the intervention phase of the study by the evaluation team. This will allow them to collect data directly from the individuals who participated in the program. The data will be collected from the same sample of middle school participants who took part in the focus groups and surveys pre-and post "**RcRn**" intervention. This data will be protected by the evaluation team until the official dissemination of the results of the study.

DATA ANALYSIS AND INTERPRETATION:

The purpose of the data analysis and interpretation for this evaluation will be to transform the data that has been collected into credible evidence that can be used to implement future programs to aid in youth concussion prevention in sports.

The Criteria Standards for Organizing and Analyzing Data will be used to organize and analyze the data; these will include relevance, effectiveness, efficiency, results, impact and sustainability. Also, descriptive statistics will be employed to analyze the data from this evaluation. The use of this statistical method will allow the evaluation team to present the data in clear, simple and understandable terms, in both written format and graphical displays. Quantitative analysis would include comparing means of a developed recognition, response and reporting score, and the use of multivariate analysis to control for confounding between subgroups.

Analysis and Interpretation of the evaluation results will be made solely by "The Evaluation Group," and success of this intervention will be decided based upon the criteria standards listed in Table 3.

Criteria For Organizing/Analyzing Data	Standards (What Constitutes "Success"?)
Relevance	Does the program address the need to prevent concussions in youth? Were the outcomes properly aligned with the goal of the program?
Effectiveness:	Did the program achieve its goal?
Efficiency	Did the program achieve all possible results with the resources that were provided?
Results/Impact	Have there been any significant changes among the target group as a result of the program?
Sustainability	Will the outcomes have the ability to be sustained after the program has ended?

 Table 3. Data Plan Evaluation Criteria

COMMUNICATION, REPORTING, AND DISSEMINATION:

Evaluation findings will be used by the CDC and other potential funders to determine the effectiveness of the education phase of the "RcRn" App-based intervention, and for decisions regarding subsequent funding for the Empowerment phases of the RcRn concussion prevention program. The evaluation findings will also assist the PI and her study team in refining the current intervention and designing future interventions to decrease sports related concussions in youths. Therefore, communication will be kept open between the evaluators, the PI and her study team throughout the entire process. They will be given updates on the status of the evaluation and will also have the opportunity to sit in on meetings. The final status of the evaluation will be shared with the sponsor of the program as well as the participants. Dr. Odama and her study team will be responsible for implementing any recommendations that are made as a result of the evaluation team's conclusions. The final evaluation will be a formal written report with appropriate statistical data submitted to the PI, her study team, and the sponsor. The final evaluation will also be made available to the participants through newsletters, links to the results on relevant websites and presentations. During the month of September-October, 2018, a comprehensive report will be presented to stakeholders including the leadership of the participating school.

The purpose of communicating the results to this particular audience is to create a collective understanding of the potential impact of concussion prevention interventions. It will also provide information on how to improve current interventions and implement future phases of the "**RcRn**" intervention program. These reporting sessions will set the

stage for phase 2 of the "RcRn" intervention program and allow for ongoing

collaboration with stakeholders.

Applicable?	Purpose of Communication	Possible Formats	Timing/Dates
Yes	Document the evaluation and its findings Present complete/final findings	Brochures or newsletters that show results for participants. Links to evaluation results on relevant websites	July 1, 2018– August 31, 2018
Yes	Comprehensive Report		September 1, 2018 – October 30, 2018

Table 4. Communication and Reporting Plan

Evaluation Budget

- The budgeted cost for this evaluation will be a total of \$2500.00 for the two professional staff members; this will be added to the projected total budget for this study.
- The two volunteer evaluators from Rollins School of Public Health (RSPH) will be unpaid.

Chapter 4

Incorporation of Grant Reviewers Comments

I would like to thank Dr. Westfall, Ms. Hinman, and Ms. Carlson, the reviewers of my Grant Proposal Plan. I am grateful for their time, effort and comments which were invaluable in improving my Grant Proposal Plan.

This chapter discusses the specific comments made by the reviewers and how I have incorporated them into the final proposal.

Reviewer 1 comments based on external review template (Appendix J)

Question 1. Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.

Comment 1. Strongly agree.

Question 2. How could the submission have been more responsive to the call for proposals?

Comment 2. N/A - I think it is already as responsive as necessary.

Question 3. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

Comment 3. Strongly agree

Question 4. What improvements could be made to the theory and structure of the proposal?

Comment 4. Perhaps it would help to clarify if all of the students chosen for the study would be residents of Alabama, and to sample students from different socioeconomic and geographical backgrounds to look for other similarities or differences.

Response to comment 4.

In response to comment 4, the participants will be recruited from a conveniently sampled school anywhere in the south-eastern U.S due to the location of the investigators. Students from different socioeconomic and geographical backgrounds will be included in this sample of participants. This is shown on "page 72, paragraph 1, line 2, & page 155, paragraph 2, line 1

Question 5. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.

Comment 5. Strongly agree

Question 6. What would have improved the argument that the proposed activities are necessary?

Comment 6. I think that the PI made the case very well, and don't feel that improvements are necessary.

Question 7. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.

Comment 7. Strongly agree

Question 8. What changes would improve the perceived feasibility of the proposed activities?

Comment 8. I think that it is feasible as presented.

Question 9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

Comment 9. Strongly agree

Question 10. What additional comments and suggestions do you have for the PI? Comment 10. I am impressed with the amount of detail included in the proposal and think that the deliverables described would be quite interesting and useful to all concerned.

Reviewer 2 comments based on external review template

Question 1. Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.

Comment 1. Agree.

Question 2. How could the submission have been more responsive to the call for proposals?

Comment 2. The description of the RFP that is included indicates the focus should be on primary prevention of concussions or on secondary prevention, meaning reducing the impact of concussions that have occurred. The proposed program seems to straddle the line between these approaches, in that it seeks to promote better recognition and reporting of concussions (presumably, falling into the secondary prevention track) but claims it will ultimately also result in primary prevention of concussions occurring at all. More explicit description of how the RcRn program could actually prevent concussions (and meet the primary prevention) would be useful. The link between the program and actual reduction in incidence of concussions is vaguely drawn. Barring that, a greater focus on the secondary prevention aspect of reducing the impact of concussions would be wise, to make the proposal more explicitly responsive to the RFP.

Clearly, the proposal is topically related to the RFP and responsive in that sense.

However, in a competitive review environment, the ties to the specific types of programs requested need to be extremely tight and clear. Much of the proposal focuses on gaining more knowledge about youth perceptions and behaviors regarding concussions but not on specifically preventive intervention.

Response to Comment 2.

Our proposal aligns well with the funding opportunity call for proposal to develop and evaluate sports concussion prevention strategies that are social and behavioral in nature by developing and pilot testing a new intervention.

The RcRn App is a concussion prevention intervention that will be developed, used and evaluated during this study. It will provide both content and procedural knowledge about concussions. This intervention will be created specifically for the middle school students. We will use it to raise awareness of concussions among middle school students so as to prevent new cases of concussions, as well as prevent secondary or "second impact" concussions.

The intervention will be based on the SCT framework and target the individual participant. The App will serve to increase knowledge, raise awareness of concussions, discuss sports-related risk and protective behavior, and encourage students to change risky perceptions and behavior regarding concussions to protective sporting perceptions and behavior. The ability of the student to choose non-impact sports or develop protective sports behavior will lead to primary prevention of sports-related concussion.

The intervention will also educate the students about what to do if they have already experienced symptoms consistent with a concussion, such as reporting the symptoms and responding to these symptoms by asking to be pulled out of the game, sitting out a game, or following a post-concussion treatment plan. In this situation, the RcRn App may serve to prevent a second impact syndrome (secondary prevention).

A full description of the RcRn App, its design, model, application, and its sociobehavioral based framework can be found on pages 87-97 A Logic BDI model of the RcRn App in Appendix D1 and D2, on pages 177-179 also describes the intervention.

Question 3. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

Comment 3. Agree

Question 4. What improvements could be made to the theory and structure of the proposal?

Comment 4. The RFP, at least as described, calls for strategies that are "social and behavioral in nature." The proposal includes the use of the SEM as well as elements of Social Cognitive Theory, which both seem superficially appropriate. However, the specific constructs of these theoretical frameworks are not described specifically regarding how they inform the particular elements of the proposed intervention. How are these constructs represented in the focus group and/or interview questions? What are the connections among the constructs that suggest SCT is the most relevant theoretical basis for the RcRn materials?

(Of note, the first mention of the SEM does not include a citation and merely refers to the model as "CDC's social-ecological framework." This should be cited properly.

Response to comment 4.

The SCT's constructs of knowledge, perception, self-efficacy and goal formation are invaluable in understanding concussion determinants among middle school students. Therefore, these constructs were used in every aspect of the study, including the design of the questionnaire and focus group study guide as well as in the design of the RcRn App intervention. Since this proposed study focuses mainly on the individual student with some input from their peers during focus group discussions, the individual and interpersonal levels of the SEM were also used as an anchoring model. Together, the chosen theory and model, complement each other in the design of this proposed study.

A full description of the relevance of the SCT framework and the CDC's SEM in increasing recognition, reporting and response to concussions is shown on pages 37-50 and in the logic BDI model in Appendix D1, page 177 The citation for the CDC's SEM has been added to the final proposal plan on page 142, paragraph 1, line 3.

Question 5. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.

Comment 5. Agree

Question 6. What would have improved the argument that the proposed activities are necessary?

Comment 6. The data presented do indicate a significant public health problem occurring in youth sports, and the potential harms of concussions are well documented. There are some discrepancies in the data between sections, primarily due to a switch between discussion of concussions and of TBI, which may or may not necessarily mean concussion. Also, there is some mixing of age groups in the statistics presented. These factors make the proposal less specific and tight than it should be, though they still demonstrate an important problem to address and a potentially useful and innovative focus by targeting middle school primarily over high school or college-level athletes. More data on levels of participation in sports at the middle school level would strengthen the argument for focusing on this age group.

Response to comment 6

The rationale for selecting middle school children are: A) Timing of our concussion intervention to a period just before youth athletes enroll in high impact competitive sports, like high school football, soccer, lacrosse, etc., B) Selecting middle school-aged children, is also in response to the call by the IOM to address the silent epidemic of concussions in those athletes younger than high school. C) Middle school students often explore various sporting activities before enrolling in high school sports and therefore, it is invaluable to increase their awareness, recognition, and responsibility of reporting concussions. This would prepare them to be part of the first line of response, by early recognition and reporting of concussions. D) This age group will help to 'catch them young' before they buy into the known sports culture of high school and college sports of "keeping silent" and "playing through the pain." Intervening early is particularly important because studies have suggested that to change the behavior of athletes, you need to intervene earlier than high school with theory-based interventions that increase awareness and knowledge of concussions, change harmful perceptions, and modify peer influence by increasing self-efficacy and positive reinforcement (Bloodgood et al., 2013). E) The ultimate goal is to develop targeted interventions to prevent concussions in youth athletes at the various socio-ecological levels, beginning with the young athlete. This is shown on pages 73, paragraph 1, 145-149 & 149, paragraph 3.

Furthermore, the IOM report pointed out that there was no national data collection tool, capturing equivalent sports injury information on athletes younger than high school age, or high school aged children participating in sports outside of the school setting (e.g., recreational leagues, summer leagues, travel teams, all-star tournaments, summer camps, etc.). The IOM stated that "this means that no one is currently capable of providing reliable data on concussion incidence, rates, or patterns among the many millions of U.S. children younger than high school age or high school aged athletes playing outside the school setting." (Institute of Medicine of the National Academies, 2013).

Due to the paucity of data regarding concussions in younger athletes, much of the available concussion rates and trends are combined with TBI data which often includes information on mild, moderate and severe traumatic brain injury. Since concussions are sometimes referred to as mild TBI's, I have made corrections to the areas of text where TBI's data could inadvertently be confused with concussion data.

In addition, the number and rising trends of youth sports concussions are further supported by the CDC's estimates of roughly 2.7 million children under 20 that were treated for "sports and recreation" injuries from 2001 to 2009. They also reported that head injuries were especially on the rise (Centers for Disease Control and Prevention, 2011). Others have estimated that between 1.1 and 1.9 million SRRCs occur annually in US children aged 18 years. (Bryan, Rowhani-Rahbar, Comstock, & Rivara, 2016)

In addition, more than 44 million youth participate in sports annually, and thus, understanding the frequency of sports---related concussions in children and adolescent is important on a population level (Centers for Disease Control and Prevention, 2011; National Council of Youth Sports, 2016).

It is estimated that; 26.6 % to 30.2% of youth ages 6 to 12 years old and, 39.3 % to 42.7 % among 13-to-17 year olds were active to a healthy level through sports, organized or unstructured (Sports & Fitness Industry Association, 2015). The most robust data on sports participation and physical activity rates is generated from an annual household

survey conducted by the Sports & Fitness Industry Association (SFIA). Results from their 2015 survey showed that among 13- to 17-year-olds, the rate of participation fell from 42.7% to 39.3%. However, there were still approximately 5.5 million basketball players; 5 million soccer players; 4.5 million baseball players and 1.3 million football players between the ages of 6-12 years old ("2015 U.S. trends in team sports", 2016)

Question 7. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.

Comment 7. Neither agree nor disagree

Question 8. What changes would improve the perceived feasibility of the proposed activities?

Comment 8. The timeline of proposed activities is ambitious but potentially feasible to complete the proposed activities. The challenge is whether or not the duration of exposure to the RcRn program would be adequate to make any significant changes. A central feasibility problem is the perceived assumption that participating students will

begin the program with some experience already with concussion (whether their own or a friend's), and that participants or their classmates will experience concussions during the course of a single school year. Being able to measure any success of the program depends upon changing their knowledge substantially.

In addition, the sample size seems quite small to be able to detect real change (among 70 students, how many concussions might reasonably be expected in the span of a school year? how many concussions would then be reported more fully or earlier?). More

granular detail on actual incidence of concussions in the target population potentially a larger sample size could address some of these concerns.

Response to comment 8

In response to comment 8, the sample size has been recalculated using a power of 80 % and an anticipated participation rate of 80 %. The new sample size is 384 middle school students. The full details of participant recruitment and sample size calculation are shown on page 162, paragraph 3, lines 1-6

Question 9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

Comment 9. Agree

Question 10. What additional comments and suggestions do you have for the PI? **Comment 10.** The stated problem and seriousness of this issue are well described and clearly important. Being more explicit in drawing the links between the specific research questions and the development of future interventions would be useful. Including example content from the RcRn program would help clarify the vision of the program and how it will assist future work in this area.

Response to comment 10

In response to comment 10. Detailed information about the content from the RcRn App is shown on pages 87-97, 148 & 160.

Reviewer 3 comments based on external review template

Question 1. Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.

Comment 1. Agree.

Question 2. How could the submission have been more responsive to the call for proposals?

Comment 2. Strongly recommend correcting the name of the funder (Centers rather than Center) from whom you are requesting money.

Response to Comment 3.

Thank you, the corrections have been made.

Question 3. Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.

Comment 3. Agree

Question 4. What improvements could be made to the theory and structure of the proposal?

Comment 4a. Sample size calculations are not my area of expertise, yet seem to be in need of strengthening. Similarly, the evaluation section may need attention.

Response to Comment 4a

The sample size has been recalculated. 384 middle school students will be recruited. This is shown on page 162, paragraph 3, lines 1-6

The program evaluation is discussed in detail as shown on page 171

Comment 4b What is meant by "all data will be kept strictly confidential"? If only aggregate data will be used, and the PI intends to disseminate results, then isn't that in conflict with this statement? Be clear about what is protected and what will be shared and how.

Response to comment 4b

Once the participant's parents sign the consent form, and the participant signs the assent form, he or she will be automatically enrolled in the study. Each participant will receive a subject ID number to protect any confidential information they may share during the interviews and to protect any other personal protected health information and/or identifiers. Only aggregate data regarding results of the study will be disseminated. No information about the participant's name or other identifier would be disseminated.

Comment 4c. The PI states that consents will be sought from 5 types of people. This is a heavy burden when multiplied by the number of people in each category – is every one necessary?

Response to Comment 4c

Consents will be sought from parents, assents from middle school participants and agreements from the Headmaster and Athletic Director of the selected school. This is shown on page 155, paragraph 1, lines1-4.

Comment 4d: In describing the quantitative component, there is no mention of developing survey items related to concussions in teammates, although this is included earlier in objectives of the study.

Response to comment 4d

The single developed survey instrument will be given to all participating middle school students (grades 6-8), and therefore there will be no need to develop additional surveys for peers.

Comment 4e: Why are the specific numbers for the focus groups chosen (6 students per each of 4 groups at start and 4 at end)? How will the PI account for when saturation is (or is not) reached?

Response to comment 4e

Guidelines for determining non-probabilistic sample sizes are virtually nonexistent. Though there are no rules for sample size in qualitative inquiry; purposive samples are the most commonly used form of non-probabilistic sampling. Their size typically relies on the concept of "saturation," or the point at which no new information or themes are observed in the data (Patton, 2002). Although the idea of saturation is helpful at the conceptual level, it provides little practical guidance for estimating sample sizes, prior to data collection, necessary for conducting quality research (Guest, Bunce, & Johnson, 2006; Patton, 2002). Guest et al., reviewed twenty-four research methods books and seven databases, and found that very little headway had been made regarding sample size guidelines. Morse's (1995) comments succinctly summed up the situation. She observed that "saturation is the key to excellent qualitative work," but at the same time noted that "there were no published guidelines or tests of adequacy for estimating the sample size required to reach saturation.

However, several studies have shown that when the aim of a study is to understand common perceptions and experiences among a homogeneous group, twelve interviews should suffice (Guest, Bunce, & Johnson, 2006). Since we aim to understand the perceptions and experiences that drive behavior regarding concussions in a middle school population in a single pilot school, we will randomly select participants to participate in 12 focus group interviews. This number is consistent with previously mentioned studies shown by Guest et al., (2006). However, as Morse (1995) pointed out, saturation can be an "elastic" concept and therefore "there must be flexibility built in regarding sample size of focus groups especially in field work, and sample size must be judged in context." (Patton, 2014)

"Focus group interviews are typically homogenous and involve open-ended questions with groups of five to eight people on specially targeted or focused issues" (Patton, 2014). Therefore, for the purpose of the focus groups interviews, two groups of six children each will be selected randomly from each grade for same-sex focus group discussions at the beginning and end of the study, for a total of six focus groups at the beginning and six at the end of the study. This is shown on pages 156-157 **Comment 4f:** The PI states that "a single survey will serve as the instrument for this study" in reference to a quantitative study, yet also says that a focus group guide will be development. This is also an instrument. More details need to be provided about how the guide will be developed.

Response to comment 4f

A focus group guide will be developed based on the constructs of the social cognitive theory. The guide will start with a standard introduction and opening question, followed by discussion topics, and probes. The focus group discussions will have questions about the knowledge of concussions, beliefs about concussions, views and values of sports, the perception of concussion risk and recognition and reporting behavior.

Each focus group will be audio recorded and a second facilitator will take notes on key issues during the discussion. The focus group discussion topics will follow the main themes found in the survey questionnaire but will attempt to collect in-depth information about youth sports concussion behavior and also give a chance for the participants to share some stories from the field regarding sports-related concussions and their reporting and response behavior. This is shown on page 156, paragraph 3 **Comment 4g:** Who will moderate the focus group discussions? What background will they have?

Response to comment 4g

Each discussion will be facilitated by professionals with training and experience conducting focus groups. The main facilitator, Dr. Unini Odama (PI) and her assistant (CoPI) will leverage their public health knowledge, experience in conducting previous focus groups and knowledge about concussions to lead the discussions. Further details are shown on pages 156 & 159

Comment 4h: Description of proposed qualitative analysis plan could be strengthened.

Response to comment 4h

The qualitative data will be analyzed according to the procedures outlined in Patton (Patton, 2014). Each focus group transcript will be read carefully; a coding structure will be created to form the basis of a meaningful framework to capture the respondents' attitudes, beliefs, perceptions, values, and experiences. Once a structure has been agreed upon by the three members of the analysis team, the data will be coded and entered into the Ethnograph (Hammersley, 1990).

The analysis team will identify the codes that are relevant to each research question. This process will involve reading the coded text and identifying salient themes that are relevant to each research question. A fourth individual will reread the coded text for the purpose of validation using the Cohen's Kappa coefficient (Cohen, 1960). This validated data will provide information about trends and patterns of awareness, recognition, and response to concussions among this population. A full description of the analysis is shown in the methodology section, on page 98. **Question 5.** Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.

Comment 5. Agree

Question 6. What would have improved the argument that the proposed activities are necessary?

Comment 6. Need for proof-reading.

Response to comment 6.

Thank you for your comment.

Question 7. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.

Comment 7. Neither agree nor disagree

Question 8. What changes would improve the perceived feasibility of the proposed activities?

Comment 8. The proposal is unclear about the length of the grant period. Under research design, the study period is defined as 12 months. Later, under Outcome Measures, the PI states there will be a 5-year follow-up, which at this point seems well past the end of the study, which is assumed to be in concert with the length of funding requested. Under Time Line, the PI states that the 12 months begin "after" the development of the app. Under this, the Phases listed include seeking funding from CDC, which is presumably

this grant application – so this must not be within the requested grant period. How long is the grant period? It should be clear where the activities begin and end within the requested funding period, and the overall length thereof. Be clear about grant and budget periods, not just study period (as you have defined it). To attempt to get clarity about this, the reviewer went to the budget in the Appendix – unwise to make your reviewers have to work so hard to understand what you're proposing – and found that the proposed budget period is only 12 months. How does that PI intend the fund the activities to develop the app, conduct the analysis and evaluation, and follow up?

Response to Comment 8.

The proposed study period will be 22 months in total. It will consist of two main parts. The first six months will be used to design the RcRn App intervention. The next ten months including, months corresponding to a school calendar year, September 2017-April 2018 will focus on the qualitative and quantitative data collection, as well as the intervention phase. The final six months of the study will focus on analysis, evaluation of the study process and outcomes, as well as, the dissemination of results. This time frame is consistent with the funding period of two years.

Future phases of the study will focus on athlete and student empowerment as well as longitudinal follow-up of the initial cohort of participants through their high school years. This will allow us further investigate behavior and attitudes towards concussions in aging athletes.

All changes have been made to the final proposal plan to indicate the proposed study and funding period for phase. This is shown on page 153.

Comment 8b: Under Research in Children, the PI provides rules for Alabama, without previously stating that the study would be in Alabama. Later, under Recruitment, the PI says the study will be in a Southeastern state. Be consistent.

Response to Comment 8b

This has been corrected. A school in the south-eastern US will be chosen conveniently, not necessarily in Alabama... as shown on page 72, paragraph 1 & page 155, paragraph 2, line 1.

Comment 8c: In describing the qualitative component, the PI describes 45-minute focus groups that also include making of name tags, icebreakers, and a 10-minute break with young children who will need to be brought back together. It seems unlikely this leaves much time in the window left for the focus group discussion itself.

Response to comment 8c

The 10-minute break has been taken out to maximize time spent discussing with students as suggested. The focus group discussion time has to be limited to 45 minutes, which is the school time-limit for physical education classes. This is shown on page 167.

However, the investigators will pay close attention to the needs of the middle school participants. Since their ages will likely range from 11-14 years, they will have varying concentration abilities. Therefore, if they show any evidence of discomfort especially for the younger participants in 6th grade, or if they express that they need a break, such as for bathroom needs, a maximum10 minute break will be included, to keep the participants comfortable, and engaged in the discussions. (Page 159, paragraph 1).

Question 9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.

Comment 9. Agree

Question 10. What additional comments and suggestions do you have for the PI?

Comment 10. The first mention of the web aspect of the project is under the Specific Aims – there is no mention in the over-arching request or summary that the project will be web-based. This seems a significant oversight, especially since the intervention is compelling.

Response to Comment 10

The App based intervention has been mentioned in the cover letter on page 132 paragraph 1, line 2 & 3. The RcRn App based intervention can also be found on pages 87-97, & 160

CHAPTER 5

FINAL GRANT PROPOSAL PLAN

Cover Letter

Centers for Disease Control and Prevention Division of Injury Prevention & Control 1600 Clifton Road Atlanta, GA 30329

Grant Proposal Application

Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition of, Reporting of, & Response to Concussions in Middle School-Aged Athletes.

Dr. Unini Odama

Funding Opportunity Announcement Number: RFA-CE-17-002

Dear CDC Representative,

Enclosed is an application for a Department of Health and Human Services/Centers for Disease Control and Prevention, Grant. The Proposal is titled "**Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition of, Reporting of, & Response to Concussions in Middle School-Aged Athletes.** Emory University Principal Investigators and research staff in collaboration with the Harvard Macy Institute and Georgia Tech wish to develop, pilot test and evaluate an APP based intervention program that will increase the recognition of, reporting of, and response to sports-related concussions in youth athletes. This team science approach will advance concepts and approaches to prevention of concussions in children. The request for funding aligns well with the call for proposal announcement listed above, to promote concussion prevention in youth sports through the use of an innovative and interactive intervention. If funding is provided, the program will serve both as a primary and secondary prevention intervention aimed at sports-related concussions in youth athletes.

Respectfully,

Dr. Unini Odama

Principal Investigator, Rollins School of Public Health

Emory University

Please assign this application to the following:

Institutes/Centers

Centers for Disease Control and Prevention, Injury Center

We do not wish to exclude anyone from the review of this application.

All required documentation is enclosed.

Grantor Request

We are requesting sponsorship from the Centers for Disease Control and Prevention (CDC) for this research project because they have an extensive experience in the field of unintentional injury and specifically youth concussions. They have access to many resources and various organizations whose sole purpose is to bring awareness to concussions in youth sports.

The CDC has partnered with experts and organizations to establish and develop programs such as the "Heads Up Concussion in Youth Sports Initiative." This initiative serves as a tool to help parents, youth athletes, health care providers and coaches, recognize and minimize the risk and amount of concussions among children and teens (Centers for Disease Control and Prevention, 2015). The CDC has recognized the importance of concussion prevention in youth and has been at the forefront of research and program formation targeted at concussion prevention.

They have successfully partnered with over 85 organizations in an effort to reduce concussions in youth athletes. With these efforts, over 3 million coaches in youth sports have successfully completed the Heads Up training, over 50 different products to train people on youth concussion issues have been developed, more than 6 million copies of Heads-Up Material have been distributed, contact with about 40 million Americans on social media has been made and over 215 million media representations through print and TV have been made. As of January 2013, the CDC and the Heads-Up program had reached over 65 million people. The impact of the CDC has been monumental in the fight against the silent epidemic of sports related youth concussions, therefore, partnering with them will align our common goals to reduce childhood injury from concussions and preserve the mental and physical status of our youth.

Specifically, we would like to partner with the CDC to find ways to understand youth specific concussion behavior, develop targeted concussion prevention interventions aimed at youth athletes, and finally evaluate concussion prevention programs with an ultimate goal of decreasing sports related concussions and preventing unintentional injury from concussions; specifically, in at-risk groups such as younger athletes. Heretofore, the focus has been on athletes engaged in high school and collegiate sports. This grant proposal is in response to the request for application (RFA) by the CDC-Funding Opportunity Announcement Number: RFA-CE-17-002. Opportunity Title: Development and Evaluation of Sports Concussion Prevention Strategies.

Our grant proposal aligns perfectly with the description of the aforementioned RFA announced by the CDC which is to: "either (a) develop and pilot test a new intervention OR (b) rigorously evaluate an existing intervention that targets young athletes participating in sports programs." According to the CDC, "interventions should be social and behavioral in nature and should represent either primary prevention or secondary prevention of sports-related concussion. Primary prevention interventions aim to prevent sports-related concussions before they occur, while secondary prevention interventions aim to reduce the impact of concussions that have already occurred. Information gleaned from this research can inform mechanisms of change in the culture of youth sports and support multi-stakeholder approaches to promoting a positive (preventive) culture of sport to mitigate negative norms, beliefs, attitudes, and policies that may increase risks of concussion among young athletes."

(http://www.grants.gov/search-grants.html?fundingCategories%3DHL%7CHealth) Our proposal also aligns well with the funding opportunity call for proposals to develop and evaluate sports concussion prevention strategies that are social and behavioral in nature by developing and pilot testing a new intervention.

The RcRn App is a concussion prevention intervention that will be developed, used and evaluated during this study. It will provide both content and procedural knowledge about concussions. This intervention will be created specifically for the middle school students. We will use it to raise awareness of concussions among middle school students so as to prevent new cases of concussions, as well as prevent secondary or "second impact" concussions.

The App based intervention will be based on the social cognitive theory (SCT) framework and target the individual participant. The App will serve to increase knowledge, raise awareness of concussions, discuss sports-related risk and protective behavior, and encourage students to change risky perceptions and behavior regarding concussions to protective sporting perceptions and behavior. The ability of the student to choose non-impact sports or develop protective sports behavior will lead to primary prevention of sports-related concussion.

The App based intervention will also educate the students about what to do if they have already experienced symptoms consistent with a concussion, such as reporting the symptoms and responding to these symptoms by asking to be pulled out of the game, sitting out a game or following a post-concussion treatment plan. In this situation, the RcRn App may serve to prevent a second impact syndrome (secondary prevention).

A full description of the RcRn App, its design, model, application, and its sociobehavioral based framework can be found on pages 87-94. A Logic BDI model of the RcRn App in Appendix D1, on page 177 also further describes the intervention App.

Project Summary/Abstract

A concussion, also called a mild traumatic brain injury (mTBI), is "a complex pathophysiological process affecting the brain. Sports-related concussions can be induced by biomechanical forces caused either by direct or indirect trauma to the head, face, neck, or elsewhere on the body with an impulsive force transmitted to the brain. "This results in a rapid onset of, and usually short-lived impairment of, neurological function, which largely reflects a functional disturbance rather than a structural injury, and as such no abnormality is seen on standard structural neuroimaging studies." (McCrory et al., 2013) Importantly, approximately one-third of children and adolescents with concussions will experience diverse patterns of physical, cognitive, or emotional symptoms beyond one month after an injury that can affect everyday functioning and quality of life (Eisenberg, Meehan, & Mannix, 2014).

Among individuals 15 to 24 years of age in the United States, an estimated 300,000 sports-related concussions occur annually, and sports are second only to motor vehicle crashes as the leading cause of concussions (Marar, McIlvain, Fields, & Comstock, 2012). This is likely a significant underestimation of the true burden of concussions because many patients only seek care in nonemergency settings, such as physician offices, or are evaluated on the sidelines of athletic events by non-physicians, i.e., athletic trainers. Neither of these encounters is routinely captured in systematic

databases (Babcock & Kurowski, 2016). According to the Institute of Medicine (IOM) 2013 report, much is known about college sports, but little is known about awareness, recognition of injuries, and frequency of concussions among athletes younger than high school (Institute of Medicine of the National Academies., 2013).

This project, therefore, proposes to fill the identified gap in knowledge, using social-behavioral frameworks, models, and interventions to improve our understanding of the determinants of concussions in youth athletes, and subsequently, increase the recognition and reporting of, and the response to concussions among athletes younger than high school.

This project will use an innovative and interactive App called "RcRn" (Report concussions, Respond now). It will be based on constructs of the Social Cognitive Theory (SCT) (Bandura 2004) and the Centers for Disease Control and Prevention (CDC) social ecological model (SEM) (Centers for Disease Control and Prevention, 2015). The "RcRn App" will be created specifically for middle school-aged participants but made easily adaptable for use by older children. The goal of the intervention will be to educate and empower youth athletes to recognize, report and respond to concussions. Evaluation of the process and impact of the intervention will be an integral part of this proposal, thus, aligning our proposal with the call to "*develop and evaluate sports concussion prevention strategies that are social and behavioral in nature by developing and pilot testing a new intervention.*" To achieve our health goal of preventing sports-related concussions in youth, our interventions and activities will target middle school-aged children and address three main behaviors: a) Increase recognition of concussion symptoms, b) Increase reporting of concussion symptoms and c) Increase response towards symptoms consistent with concussions (by showing evidence of self-efficacy and resilience such as: asking to be removed from a game, sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion).

Project Narrative

Sporting activities remain an integral part of most communities, often acting as an important social connector for them. Importantly, physical activity, sports participation, and play, in general, are great ways for children and teens to build and maintain healthy bones and muscles. Unfortunately, the framework which provides guidelines, rules, and regulations for youth sports has been established with very little scientific evidence (Institute for the Study of Youth Sports., 2004). Since an important tenet of public health is the focus on primary prevention of disease and injury, concussion prevention interventions should begin early in childhood, to intercept the occurrence of concussions and avert their potential short and long term sequelae.

Reports from the CDC estimate that 4 to 5 million concussions occur annually, with rising numbers among young athletes (Centers for Disease Control and Prevention, 2012). In addition, an estimated 90% of diagnosed concussions do not involve a loss of consciousness (Centers for Disease Control and Prevention, 2012). Research suggests that too many young athletes in high school still do not report their concussion symptoms (Chrisman, Quitiquit, & Rivara, 2013; Rivara et al., 2014), are not removed from play, and continue to play with symptoms, or return to play too soon. (Register-Mihalik et al., 2013; O'Kane et al., 2014; Hwang, Trickey, Lormel, & Bradford, 2014).

In addition, more than 44 million youth participate in sports annually, and thus, understanding the frequency of sports-related concussions in children and adolescents is important on a population level (Centers for Disease Control and Prevention, 2011; National Council of Youth Sports, 2016).

The most robust data on sports participation and physical activity rates is generated from an annual household survey conducted by the Sports & Fitness Industry Association (SFIA). Results from their 2015 survey showed that among 13- to 17-year-olds, the rate of participation fell from 42.7% to 39.3%. However, there were still approximately 5.5 million basketball players; 5 million soccer players; 4.5 million baseball players and 1.3 million football players between the ages of 6-12 years old ("2015 U.S. trends in team sports", 2016). It is estimated that 26.6 % to 30.2% of youth ages 6 to 12 years old and, approximately 39.3 % of 13-to-17 year olds were active to a healthy level through sports, organized or unstructured (Sports & Fitness Industry Association, 2015).

Therefore, the focus of this proposal is to provide new information about middle school athletes pertaining to the determinants of youth sports concussions, with the objectives of influencing or changing unhealthy, risky sporting behavior into healthy, protective sporting behavior. Our strategy is to primarily influence sporting behavior early (primary prevention) before they buy into the sports culture of playing through pain or keeping silent about symptoms consistent with concussions. The desired behavior changes are an increase in recognition of, reporting of, and response to symptoms and signs consistent with concussions.

To achieve our desired behavior change listed previously, and health goal of reducing concussions in youths, we will identify and select determinants known to protect or put athletes at risk for concussions. Subsequently, we will plan activities and interventions specifically targeted at the selected determinants. Determinants of behavior often do not occur in a silo. The concept of the Reciprocal Triadic Causation (RTC) in the social cognitive theory (SCT) (Bandura 2004), explains much of the behavior seen in today's sports. At the collective level, SCT suggests that people shape the environment, which in turn shapes the people. Thus, depending on the context, the environment can either promote healthy behavior, through the availability of resources and social norms or it could hamper such efforts (DiClemente, Salazar, & Crosby, 2013). The person and their behavior have a reciprocal effect as well, so there are limitations to only focusing on the environment. This single pathway means that people's cognitions can also dictate their behavior.

In addition, the social norm for an athlete is to be strong. These social norms exist at the interpersonal level and the community level. Nike's "Just do it" slogan is a good example. Although Nike isn't promoting injury, they are promoting a behavior of pushing through pain and exceeding one's limit as an athlete. This social norm of being "tough" is a risk factor as it leads to another psychologically related determinant- **stigma associated with reporting injury as an athlete.** These social norms can be broken down through vicarious learning and observational modeling.

The CDC's social-ecological model (SEM) recognizes the individual or intrapersonal, interpersonal, community, and society ecological levels ("The Social-Ecological Model: A Framework for Prevention|Violence Prevention|Injury Center|CDC," 2016). Each level represents a key point in disease or injury process, thus offering an opportunity to intervene for prevention. Therefore, the SEM will enrich our understanding and identification of the youth athletes' concussion risk and protective health behavior, as well as the factors that come into play during interpersonal relationships with other athletes, peers, coaches and athletic directors, regarding concussions in youths. The individual and interpersonal levels of the SEM framework will be the focus of the first phase of our study, while subsequent phases will involve the community.

Furthermore, the decision to adopt a healthy protective behavior, rather than an unhealthy risky behavior, does not merely lie with the individual athlete, but can also be influenced by social and cognitive factors. Social cognition is concerned with how individuals make sense of social situations and focus on individual cognitions or thoughts as processes which intervene between observable stimuli and responses in specific real world situations (Fiske & Taylor, 1991). Social factors such as peer influences, role modeling by another athlete, coach influence and parental models, self-esteem, cultural values, and access to medical care are important factors in health behavior (Norman, Abraham, & Conner, 2000); Bandura, 2000).

Likewise, cognitive factors play a role in the choice of individual health behavior. For example, knowledge about the link between certain health risk behaviors and injury is important for an individual to make an informed choice (Norman, Abraham, & Conner, 2000). Additionally, cognitive risk factors (Bandura, 1986; Bandura, 2004), such as decreased perceptions of concussion risk, perceived social pressures to continue to play through pain, decreased self-efficacy in reducing risk by reporting concussions, insisting on staying out a game, or avoiding high impact sports, as well as emotional factors, can all influence behavior towards concussions in youth athletes.

Consequently, based on the premise that assessing the youth athletes' knowledge, attitudes, intentions, and behaviors concerning concussions will be invaluable in formulating interventions to prevent concussions in youth, the key constructs of Bandura's Social Cognitive Theory (SCT) (Bandura, 1986, 2004) will be selected as an additional framework in our target population. The intrapersonal and interpersonal levels of the CDC's SEM (Center for Disease Control and Prevention, 2015) together with the constructs of the SCT will be the foundational framework and theory used in formulating the interactive, App-based intervention, which will be targeted to middle school-aged children.

Since the SCT's constructs of knowledge, perception, self-efficacy and goal formation are invaluable in understanding concussion determinants among middle school students, these constructs were also used to plan every aspect of the study, including the study design, instruments (questionnaire and focus group study guide), and evaluation

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plan. A full description of the relevance of the SCT framework and the CDC's SEM in increasing recognition, reporting and response to concussions is shown on pages 37-50 and in the logic BDI model in Appendix D1 on page 177

Specific Aims

Previous studies have focused on high school and collegiate sports concussions and very little on those younger than high school (Institute of Medicine of the National Academies, 2013; (Chrisman, Quitiquit, & Rivara, 2013). Also, the available youth sports concussion data show that the number of concussions and underreporting of concussions for youth is still high (Centers for Disease Control and Prevention, 2015). This project will, therefore, focus on understanding the factors associated with the recognition of, reporting of, and response to concussions in youth sports. Furthermore, we will use an App-based interactive intervention to reduce youth sports concussion among middle school-aged students. To achieve these goals, we propose the following Specific Aims.

Aim 1. Understand the behavior. Understand the socio-behavioral concussion risk factors among youth athletes in middle school and understand the gender variations of these risk factors as it pertains to concussion-related behavior.

Aim 2. Interactive Intervention. Increase recognition of, reporting of, and response to concussion symptoms among middle school children, through the use of an innovative App-based interactive concussion prevention intervention.

Aim 3. Develop more programs and provide additional literature. Use the information gathered from this study, intervention, and evaluation to further develop youth sports concussion programs for middle school students and also provide additional literature that is relevant to the subject.

Research Strategy

a. Problem Statement

The human brain is a complex system of connections that continue to be refined and reshaped throughout an individual's lifespan. During development, rapid changes in synapses, myelination, and metabolism occur, with the brain achieving adult-like connections by the mid-20's. Therefore, concussions in young children and adolescents are of particular concern as they are still undergoing developmental brain changes leading to a greater impact of injury at this age (Institute of Medicine and National Research Council., 2014). A prior concussion puts young athletes at increased risk of another concussion. In addition, children and adolescents take longer to recover than adults. (Centers for Disease Control and Prevention, 2012). Furthermore, diffuse cerebral swelling with delayed catastrophic deterioration, a known complication of brain trauma, has been postulated to occur after repeated concussive brain injury in sports. This is called, "second impact syndrome" (SIS) (McCrory & Berkovic, 1998). Severe consequences such as second impact syndrome may also be a concern for the young athlete when returning to activity while the brain is still in a vulnerable state (Buzzini et al., 2006).

The IOM report further pointed out that there was no national data collection tool, capturing equivalent sports injury information on athletes younger than high school age, or high school aged children participating in sports outside of the school setting (e.g., recreational leagues, summer leagues, travel teams, all-star tournaments, summer camps, etc.). The IOM stated that "this means that no one is currently capable of providing reliable data on concussion incidence, rates, or patterns among the many millions of U.S. children younger than high school age or high school aged athletes playing outside the school setting." (Institute of Medicine of the National Academies, 2013).

Due to the paucity of data regarding concussions in younger athletes, much of the available concussion rates and trends are combined with TBI data which often includes information on mild, moderate and severe traumatic brain injury.

However, the number and rising trends of youth sports concussions are further supported by the CDC's estimates of roughly 2.7 million children under 20 that were treated for "sports and recreation" injuries from 2001 to 2009. They also reported that head injuries were especially on the rise (Centers for Disease Control and Prevention, 2011). Others have estimated that between 1.1 and 1.9 million sports and recreationrelated concussions occur annually in US children aged \leq 18 years. (Bryan, Rowhani-Rahbar, Comstock, & Rivara, 2016)

The impact of concussions in the U.S goes beyond the estimated 1.7 million people who sustain a traumatic brain Injury. It is also associated with 1,365 million emergency room visits and 275,000 hospitalizations annually with associated direct and indirect costs estimated to have been \$60 billion in the United States in 2000 (Faul, Xu, Wald, Coronado, & Dellinger, 2010; Finkelstein, Corso, & Miller, 2006) These figures vastly underestimate the total TBI burden, as many individuals suffering from mild or moderate TBI (concussions) do not seek medical advice. (Faul et al., 2010). Alarmingly, the CDC

reported an overall increasing rate of TBI-related emergency department (ED) visits from 2001 through 2010, with **concussions representing 75% of the visits** (Centers for Disease Control and Prevention., 2015).

Even though children 0 to 4 years of age had the highest rates of any age group for TBI-related ED visits, the next highest age group was 15-24-year-olds (Centers for Disease Control and Prevention., 2015). These findings were supported by multiple studies of TBI and concussion diagnosis incidence in EDs, including a 2010 article demonstrating an 8-fold increase in ED visits for TBI (compared with all ED visits) from 2006 to 2010 (Bakhos, Lockhart, Myers, & Linakis, 2010). These available data may greatly underestimate the total TBI burden, as many individuals suffering from mild or moderate TBI (concussions) do not seek medical advice (Faul, Xu, Wald, Coronado, & Dellinger, 2010).

Clearly, most athletes have heard about concussions. Nevertheless, young athletes may be unable to identify whether their symptoms are caused by a concussion or another condition (Register-Mihalik et al., 2013a; Chrisman, Quitiquit, & Rivara, 2013). This inability to promptly recognize and report a concussion could lead to a delay in concussion diagnosis and treatment, which may be fatal. Sadly, during the fall of 2015 alone, at least 11 U.S high school athletes died playing football, seven of which were likely related to second impact syndrome from prior concussions ("Tackling in Youth Football," 2015; National Center for Catastrophic Sports Injury Center (NCCSIR), 2015).

b. Innovation

Our approach will be to employ an interactive App-based intervention employing learning frameworks and leveraging 2.0 social media tools, and other interactive visual and auditory cues, to enhance reporting and response to symptoms consistent with concussions among middle school students. A socio-behavioral based interactive concussion prevention app will be developed in collaboration with the Harvard Macy Institute and Georgia Tech, first to educate young athletes about concussions, second to inform them of their role in reporting concussions, and finally to empower them to report and respond to symptoms consistent with concussions, or behaviors they may observe in a teammate that may indicate a concussion.

The App called, "RcRn" will draw from effective teaching principles and techniques used in other fields. These will include the strategy of 'spaced education and testing effect', where the concussion prevention material will be spaced over a 6-month period (instead of in binges). The information will repeatedly be presented in various formats, including a test/question format instead of long reading sections. These techniques have been shown, not only to "increase the uptake of knowledge, but such information is encoded in ways that cause it to be preferentially retained and retrieved" (Kerfoot et al., 2006; Kerfoot, 2010; Long, Kerfoot, Chopra, & Shaw, 2010). In addition, the RcRn app will use avatars in an interactive platform (similar to the video games that children like to play) to provide not only content knowledge about concussion (causes, symptoms, signs, consequences of concussion), but also procedural information on how to recognize and promptly report and respond to concussions.

c. Methods

Research design

This proposal will be a pilot study carried out among middle school-aged students, in a Southeastern U.S school selected via convenience sampling. The study period will be 22 months in total. It will consist of three main parts. The first six months will focus on the development of the RcRn Intervention App. The next ten months, including the school calendar year, from September 2017-April 2018, will focus on data collection and intervention. The last six months will focus on the analysis of results, evaluation, and dissemination of results.

Studies have focused on the value of mixed-methods approaches for researching questions about social experiences and lived realities. These studies stress the importance of qualitative data in addition to quantitative data (Mason, 2006). We will, therefore, utilize a mixed-methods approach for researching questions about the social and behavioral factors that affect recognition of, response to, and reporting of, sports-related concussions. We will also study the gender differences in awareness, knowledge, attitude, behavior, perception, value and self-efficacy regarding youth sports concussions. Finally, the effect of an interactive theory based concussion prevention intervention on the previously mentioned attitudes and behaviors towards concussions will be studied.

The rationale for selecting middle school children are: A) Timing of our concussion intervention to a period just before youth athletes enroll in high impact competitive sports, like high school football, soccer, lacrosse, etc., B) Selecting middle school-aged children is also in response to the call by the IOM to address the silent

epidemic of concussions in those athletes younger than high school. C) Middle school students often explore various sporting activities before enrolling in high school sports and therefore, it is invaluable to increase their awareness, recognition, and responsibility of reporting concussions. This would prepare them to be part of the first line of response, by early recognition and reporting of concussions. D) This age group will help to 'catch them young' before they buy into the known sports culture of high school and college sports of "keeping silent" and "playing through the pain." Intervening early is particularly important because studies have suggested that to change the behavior of athletes, you need to intervene earlier than high school with theory-based interventions that increase awareness and knowledge of concussions, change harmful perceptions, and modify peer influence by increasing self-efficacy and positive reinforcement (Bloodgood et al., 2013). E) The ultimate goal is to develop targeted interventions to prevent concussions in youth athletes at the various socio-ecological levels, beginning with the young athlete.

The importance of studying subgroups such as gender groups stems from the variation in concussion rates and severity, which has been reported amongst male and female athletes (Frommer et al., 2011; Marar, McIlvain, Fields, & Comstock, 2012) Undoubtedly, awareness, recognition, reporting and response to sport-related concussions plays an important role in preventing concussions in youth athletes. Middle school-aged children are therefore positioned to be part of the first line of response, by avoiding risk factors for concussions (primary prevention) or by early recognition and reporting of concussion symptoms (secondary prevention).

To achieve this goal, we will focus on two overarching components a) understanding the socio-behavioral factors that are associated with youth sports concussions in middle school-aged students and b) developing and evaluating the impact of a targeted, innovative, interactive, concussion prevention, App-based intervention. Our ultimate goal is to use the information obtained to develop further sports related concussion prevention programs targeted at youths to reduce fatal and non-fatal concussions in youth athletes.

To guide our pilot study, we will ask the following questions.

Research questions:

1. What are the social and behavioral factors that affect recognition of, reporting of, and response to symptoms consistent with sports-related concussions among middle school- aged students?

2. Are there gender differences in awareness, knowledge, attitude, behavior, perception, value, and self-efficacy regarding sports-related concussions in middle school-aged students?

3. What is the effect of an interactive theory based concussion prevention intervention on the recognition of, reporting of, and response to youth sports concussions in middle school-aged students?

Objectives:

The objectives of this pilot study are to:

A) Increase recognition of concussion symptoms by middle school participants by 75 % in one year.

B) Increase reporting of concussion symptoms by middle school participants by 50 % in one year.

C) Increase response towards concussion by middle school participants by 50 % in one year.

Outcome and Outcome Measures

We expect to answer our research questions using quantitative and qualitative data obtained from the middle school participants.

First, the influence of socio-behavioral factors on youth sports concussions, gender variations, and influence of sports culture of playing through pain or keeping silent will be measured using behavioral and attitudinal surveys and focus group interviews. Additional information regarding awareness, knowledge, perceptions, recognition, reporting, response, self-efficacy, peer influence and psychology will be obtained quantitatively and qualitatively.

Second, our intermediate objective, the changes in behavior that result from changes in knowledge, attitudes, and efficacy, will be measured by pre-and postintervention surveys and focus group interviews of middle school children. This will help us to determine the change in the recognition of, reporting of, and response to symptoms consistent with concussions.

Evaluation of the intervention and outcomes will be based on results from the preand post-intervention surveys and the focus group interviews of participants. We expect that the answers to these questions in conjunction with what is known about the protective and risk determinants of concussions will be useful towards the development of future programs targeted at preventing concussions in young athletes. In future follow-up studies, we would like to investigate further behaviors and attitudes towards concussions, as well as, concussion trends in the cohort of middle school participants that will be recruited for the current study.

Time Line and Task Chart

The study will follow a time and task chart which will be summarized here but shown in details in **Appendix A.**

A) Our proposed study will be completed within 22 months, from January 2017-October 2018. This time frame accounts for: 6 months for App development and testing; 2-3 months for IRB, consents, assents and agreements; 1 month for pre-intervention survey and focus group sessions; 6 months for the RcRn App intervention; 1 month for post-intervention survey and focus groups; 3 months for analysis and evaluation; 3 months for disseminating results. This estimate is based on the anticipated adequate number of enrolled participants. To achieve the objectives of this study, the research will be divided into phases.

B) Phase 1: A detailed protocol will be submitted to the Institutional Review Committee/Ethics Committee for approval, and a thorough consent process will be put in place as well as a process for accumulating and protecting data. Ethics approval will be obtained from EMORY

C) Secure funding from the CDC.

D) **Phase 2**: Enlist collaborating sites; begin to obtain signed consents from parents and agreements from the Head of School, Athletic Director, and other stakeholders.

Training of volunteers to follow protocol and guidelines, especially regarding research involving children

E) **Phase 3**: Continue consent and assent process, screening and enrollment, data and sample collection, data storage and warehousing, data lock/study closeout process and statistical analysis.

F) **Phase 4**: Evaluation and preparation of the manuscript for the dissemination of results in national and international journals and conferences.

Research in Children

In the Southeastern U.S where the study will be conveniently located, the age of majority is 18 except in Alabama where it is 19. Based on concerns for the welfare of children as research subjects, protections for children that exceed those for adults are often incorporated into the federal regulations for protecting research subjects. At the same time, regulators recognize that some research presents no more than minimal risk to children and allow for flexibility in the parental permission and child assent processes (U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)., 2012).

Since this study involves interviews, surveys, and observations, in which the researcher participates in the activities being observed, the IRB will determine if the Subpart D, U.S. Department of Health and Human Services (HHS) regulations should apply (U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), 2011). However, the basic federal regulations for protecting research

subjects known as the Common Rule: U.S. Department of Health and Human Services (HHS) Regulations, Subpart A will be adhered to (Protection of Human Subjects, 45 CFR § 46 (2009; U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)., 2012)

Consent/confidentiality

After obtaining IRB and Ethics approval, informed consent would be obtained from parents and assent from middle school children below the age of 19. Also, agreements will be obtained from the school headmaster and athletic director. No personally identifiable information would be collected, and only aggregate data will be disseminated.

Participant recruitment & Sample Size

Our primary audience will be middle school students in grades 6-8 in a conveniently identified pilot school. The pilot school will be selected by convenience sampling and located in the Southeastern U.S since all the investigators are located in this region. An estimate of the number of participants needed for the study, calculated based on an expected participant rate of 80 %, power of 80 % (B= 0.20) and a 95 % confidence Interval is 384. However, the final sample size will depend on participant recruitment based on parental consent. Attempts will be made to optimize the sample size from a single school due to feasibility and funding considerations. This will be achieved by

conveniently selecting a school that has at least 500 middle school students. We will also focus on achieving buy-in by the School Headmaster and Athletic Director and other stakeholders before the initiation of the study via meetings and site visits.

If the recruited participants from the 6-8th grades are not sufficient from the first school, additional participants will be recruited from a second school in the same southeastern region. Care will be taken to match participants according to demographics and other variables such as socioeconomic status, grade, gender and sporting activity

Methodology:

Qualitative component

Qualitative data will be gathered via focus group interviews of middle school participants to investigate determinants of concussions in middle school-aged children. Research suggests that focus groups with children and youth work best when the age ranges are kept narrow (Gibson, 2012). Therefore we will randomly select children from the same grade for the focus groups while all students willing to take part in the study will fill out the questionnaire.

A focus group guide will be developed based on the constructs of the social cognitive theory. The guide will start with a standard introduction and opening question, followed by discussion topics, and probes. The focus group discussions will have questions about the knowledge of concussions, beliefs about concussions, views and values of sports, the perception of concussion risk and recognition and reporting behavior.

Guest et al. reviewed twenty-four research methods books and seven databases, and found that very little headway had been made regarding sample size guidelines. Morse's (1995) comments succinctly summed up the situation. She observed that "saturation is the key to excellent qualitative work," but at the same time noted that "there were no published guidelines or tests of adequacy for estimating the sample size required to reach saturation.

However, several studies have shown that when the aim of a study is to understand common perceptions and experiences among a homogeneous group, twelve interviews should suffice (Guest, Bunce, & Johnson, 2006). Since we aim to understand the perceptions and experiences that drive behavior regarding concussions in a middle school population in a single pilot school, we will randomly select participants to participate in 12 focus group interviews. This number is consistent with previously mentioned studies shown by Guest et al., (2006). However, as Morse (1995) pointed out, saturation can be an "elastic" concept and therefore "there must be flexibility built in regarding sample size of focus groups especially in field work, and sample size must be judged in context." (Patton, 2014)

"Focus group interviews are typically homogenous and involve open-ended questions with groups of five to eight people on specially targeted or focused issues" (Patton, 2014). Therefore, for the purpose of the focus groups interviews, two groups of six children each will be selected randomly from each grade for same-sex focus group discussions at the beginning and end of the study, for a total of six focus groups at the beginning and six at the end of the study. The same groups will participate in the pre-and post- focus group interviews for comparative ease and to improve internal validity. These sessions will last no longer than 45 minutes and would be conducted by an experienced moderator (PI) and a trained assistant moderator (CoPI).

Quantitative component

A single survey will serve as the quantitative instrument for this study. This instrument will be pretested for face validity by three content experts at the Rollins School of Public Health, Emory University. This validated attitudinal and behavioral questionnaire, tailored to middle school aged participants will be administered electronically to students whose parents have consented and who have themselves assented to participate in the study. An alternate option of administering the questionnaire will include a paper-based questionnaire prepared by EPI-info for the 6-8th-grade participants.

This questionnaire, regardless of the format, will be administered at the same time during a school physical education period. The questionnaire would be more acceptable via an electronic format and cause minimal disruption to the students if the students in the pilot school already have and are using IPADs/laptops/computers for daily school activities. The short (15-20 minute) questionnaire will be administered during normal class hours during a physical education period after obtaining consent from parents, assent from students, and agreements from PE teachers, Athletic Directors and the Principal of the selected school.

Survey Instruments

Quantitative component

The survey questionnaire will consist of 25 multiple choice questions, made up of closedended questions, categorical questions, Likert-scale questions, and a few options for open-ended responses. Information on middle school participants' knowledge, attitudes, and beliefs regarding concussions will be obtained. The survey will also ask all participants if they have ever had symptoms consistent with concussions and if yes, to recall previous concussions and concussion-like events. They will also be asked to indicate whether they reported the events to a coach or a medical professional.

See Appendix B-Survey Questionnaire

Qualitative Component

The focus groups will consist of six students at a time, each session lasting no more than 45 mins to fit into the student's usual school physical education period. Care will be taken to engage participants by the use of fun activities (making own name tags, icebreakers, etc.). To maximize student participation, and account for age variabilities in attention span, a 10-minute optional break will be allowed in situations where the facilitators consider it necessary. Specifically, during discussions with the younger middle school aged participants in 6th grade, they may become uncomfortable and start fidgeting, they may begin to lose interest in the discussion or become distracted by other things, or they may need a bathroom break. At the end of each session, participants will receive a small incentive of \$5.00 in a thank you card. School physical education credit will be given to every participant at the end of the study.

Facilitators would follow a focus group guide with standard introduction and opening questions, discussion topics, and probes. Focus group discussions will have questions about the knowledge of concussions, beliefs about concussions, views and values of sports, the perception of concussion risk, and concussion recognition and reporting behavior. Each focus group will be audio recorded and a second facilitator will take notes on key issues during the discussion. Participants will be offered a brief break with light refreshments approximately half way through the discussion. Each focus group interview will be subsequently transcribed verbatim. Due to the importance of hearing directly from the participants without contamination in any way, we will complete the surveys after each focus group session to maintain the integrity of the qualitative data and to minimize the threat of the survey questions influencing the discussion during the focus groups

See Appendix C-Focus Group Guide

Intervention phase: Novel app "Report Concussions Respond Now."

This Novel app to enhance reporting and response to concussions will be called "**RcRn App**," and it will be used once a week during a normal physical education period for 6-8th graders for six months (October 2017- March 2018).

The "RcRn" app will be a free teaching tool available on all platforms, (IOS and Android) with functionality that allows for interface with social media. The "RcRn" app will provide age- appropriate, interactive, sport-specific, content knowledge about concussions. It will feature games, quizzes, and information for children to interact with on mobile devices. Avatars will guide interactive sessions via simulated scenarios of athletes in different situations that could lead to concussions. Cues to action, spaced teaching, and testing techniques will also be incorporated to increase knowledge and awareness of symptoms and signs of concussions, and encourage self-efficacy in reporting and responding to concussions. Embedded video-conferencing sessions by

trauma surgeons and neurosurgeons, as well as TED talks, and age appropriate and suitably rated pictures and explanation of concussions will be used to enhance this app based intervention. The goal is for participants to avoid unhealthy sporting behavior (risky behavior) and rather engage in healthy sporting behavior (protective behavior) including reporting and responding to concussions. The detailed description of this app in a Logic BDI model can be found in **Appendix D1**.

d. Data Analysis and Evaluation

Epi-INFO statistical package, as well as STATA, will be used for the primary analysis of the quantitative data obtained from this study. Descriptive estimates will be obtained from middle school participants. The determinants of risky sporting behavior assessed by validated age appropriate attitudinal and behavioral questions will be analyzed. Furthermore, the sample will be sub-stratified by age and gender to obtain within stratum descriptive summaries as well as a comparison of groups pre-and postintervention.

The qualitative data will be analyzed according to the procedures outlined in Patton (Patton, 2014). Each focus group transcript will be read carefully, and a coding structure will be created to form the basis of a meaningful framework to capture the respondents' attitudes, beliefs, perceptions, values, and experiences. Once a structure has been agreed upon by the three members of the analysis team, the data will be coded and entered into the Ethnograph (Hammersley, 1990). The analysis team will identify the codes that are relevant to each research question. This process will involve reading the coded text and identifying salient themes that are relevant to each research question. A fourth individual will reread the coded text for the purpose of validation using the Cohen's Kappa

coefficient (Cohen 1960). This validated data will provide information about trends and patterns of awareness, recognition, and response to concussions among this population. **Evaluation:** The goals of the proposed evaluation, to be undertaken from May 2018 to August 2018 are to:

1) Determine if attitudes and behavior toward concussion symptoms changed post implementation of the RcRn App-based intervention.

2) Assess whether or not the RcRn App-based intervention successfully increased recognition and reporting of, and response to, concussion symptoms among middle school participants at the selected school.

3) Assess the process and program outcomes to evaluate sustainability and extensibility of the RcRn App-based intervention to other schools for the purpose of concussion prevention education initiatives. The findings from this evaluation will be used to develop larger scale studies that are targeted at the prevention of youth concussions.

e. Dissemination of Project Results

Findings of this study will be shared using visual aided presentations and posters targeted at middle school students/participants, the pilot school, and parents. The aim is to develop an ongoing conversation about prevention of concussions as well as the implementation and adoption of programs that promote healthy sporting behavior in youth athletes. Subsequently, manuscripts containing a description of the study, its findings, and lessons learned will be submitted to peer-reviewed journals for publication. The added knowledge regarding concussion in an understudied population (youth athletes) will help in creating large-scale concussion prevention programs.

APPENDIX A: TIME AND TASK CHART.

ACTIVITY	BEGIN DATE	END DATE	RESPONSIBILITY
PRESTUDY: 1	January 2, 2017	July 1, 2017	PI, Harvard Macy Institute,
	•		Georgia Tech
1.1 RcRn App development and testing	January 2, 2017	June 1, 2017	
1.2 IRB approval	January 2, 2017	April 1, 2017	PI and research team
	Junuary 2, 2011	, pm 1, 2011	members:
1.3 Establish formal Collaborations Get official signed consents from the school headmaster, athletic director, nursing school, local surgeons, evaluation Group.	April 1, 2017	June 1, 2017	PI/Head of School, Coaches, Athletic Director, School of nursing, Local Neuro Surgeons, Evaluation Group
1.4 Train volunteers	June 1, 2017	July 1, 2017	Nursing students from School of nursing
1.5 Hold informational meetings with school staff and parents. Consent and assent forms Obtain informed consents from parents and assents from subjects under 19 years of age.	July 1, 2017	August 15, 2017	PI/Co PI/School Staff/Parents
STUDY BEGINS: 2	September 1, 2017	September 1, 2018	
2.1 Pre-intervention Focus groups Conduct focus groups with 6 students at a time for 45 mins or less and document results.	September 1, 2017	September 30, 2017	PI/Co-PI /Parents/6-8 th Graders
2.2 Pre-intervention Survey Administer survey questionnaire and document results (25 questions)	September 1, 2017	September 30, 2017	PI/Co PI
INTERVENTION:3	October 1, 2017	April 1, 2018	
3.1 RcRn Education App	October 1, 2017	March 1, 2018	PI/Co PI/PE teachers
3.2 Panel discussion	November 2018	March 2018	Co-PI/School staff
3.3 Post Focus Group	April 1, 2018	April 30, 2018	PI/Co-PI (1)
3.4 Post Survey	April 1, 2018	April 30, 2018	Co PI (1 & 2)
STUDY END 4 4.1 Data Collection, analysis & summarization Carefully analyze all questionnaire and focus group results and compile using Epi Info and Stata. Results will be provided to the evaluation Group as well.	May 1, 2018 May 1, 2018	September 1, 2018 August 1, 2018	PI/Co-PI (1& 2)
4.2 Evaluation	May 1, 2018	September 1, 2018	The Evaluation Group and two volunteer RSPH graduate students.
4.3 Dissemination Dissemination of Study results including evaluation results.	September 1, 2018	October 30, 2018	Executive Summary-School participants/Staff/Head Public Health and Pediatric Conferences Social Media-Podcast,

APPENDIX B

Survey Questionnaire for Concussions in Youth Sports

1. How old are you?

- o 10 years or younger
- o 11 years-old
- o 12 years-old
- o 13 years-old
- o 14 years-old
- o 15 years-old or older

2. What is your gender?

- o Male
- o Female

3. What grade are you in?

- $\circ \quad 6^{th} \ grade$
- \circ 7th grade
- \circ 8th grade

4. What is your race?

- American Indian or Alaskan native
- Hispanic or Latino
- White American
- o Black or African American
- o Asian
- Native Hawaiian or Pacific Islander
- Decline to answer

5. Please tell us which school or after school sports you participate in regularly?

- o Baseball
- o Football
- o Basketball
- o Soccer
- o Softball
- Cheerleading
- o Ice Hockey
- o Tennis
- Volleyball
- Other: -----

6. Do you wear protective helmets, clothing or other safety equipment while playing

sports?

- o Always
- Most of the times
- I do not know
- \circ Sometimes
- o Never
- Not applicable

7. Describe how much you know about sports related concussions?

- I know a lot about concussions
- I know a little about concussions
- I don't know about concussions

8. Have you received teaching or education material on how to recognize and report

a concussion?

- o Yes
- o No
- o Not sure

9. Have you ever known anyone with a concussion?

- o Yes
- o No
- o Not sure

10. Do you know to whom you should report concussion symptoms to?

- o Yes
- o No
- o Not sure

11. Which of the following is a symptom of a concussion? (Check all that apply)

- Confusion
- o Headache
- o Nausea
- o Stomach pain
- Poor balance
- Ringing in the ears
- o Blackout
- Vomiting
- Itchy toes

12. What sign may tell you that an athlete's concussion is getting worse? (Check all

that apply)

- Worsening headache
- Weakness, numbness
- Decreased coordination
- o Seizures
- Fading in and out of consciousness
- Worsening confusion, restlessness or agitation
- All of the above

13. Do you know the meaning of "Second Impact Syndrome"?

- o Yes
- o No
- Not sure
- If you answered yes, please explain: ------

14. After having one concussion, what are your chances of getting another

concussion?

- Greater chances of having a second concussion
- o Lesser chances of having a second concussion
- Same chances of having a second concussion
- o Not sure

15. Which of the following statements do you believe about concussions?

- Boys get more attention after a concussion
- Girls get more attention after a concussion
- Both boys and girls get equal attention
- o Not sure

16. Which of the following statements do you agree with about reporting concussion

symptoms?

- Boys report more concussions
- Girls report more concussions
- Both boys and girls report concussions equally.
- Not sure

17. Have you ever had a concussion?

- o Yes
- o No
- o Not sure

18. If you answered "yes" to question 18, please tell us how many concussions you had?

• I cannot remember

19. If you answered "yes" to question 18, do you think you got proper

attention/aid/help after you sustained a concussion?

- o Yes
- o No
- o Don't know
- o Decline to answer
- o Not sure

20. If you answered "yes" to question 18, Did you always report symptoms of a concussion to your coach or another adult?

o Yes

- o No
- o Not Sure
- o Sometimes

21. If you answered no to question 20, how many times have you NOT reported a concussion-related symptom to your coach or another adult?

- o 1
- o 2
- o 3
- o 4
- o 5
- \circ 6 or more
- Never had a concussion
- Always reported them to the coach/instructor/adult

22. If you answered in numbers to the above question, what were the reasons you

did not report your concussion-related symptoms? (Check all that apply)

- I did not think it was a serious issue
- I did not want to leave practice or game in progress
- I did not know I had sustained a concussion at the time

- o I did not want to let my teammates or coach down
- I was afraid I might lose my starting position
- Other: please explain.....

23. Do you think you would report concussion symptoms in a teammate if they

didn't report it to the coach/instructor themselves?

- o Always
- Most of the times
- Don't know
- Sometimes
- o Never

24. If you answered sometimes or never to the above question, why do you think

you would NOT report an injury of a teammate to the coach/instructor?

- I do not think it's a serious issue
- Unsure if it was a concussion symptom
- Fear of upsetting coach/instructor
- Fear of upsetting my friend
- Peer pressure
- Don't know
- Other: -----

Focus Group Questions: Sports related concussion among Youth Athletes

Introduction:

My name is Unini. I and my colleague are graduates of the Emory University, Rollins School of Public Health. The purpose of this interview is to collect information about concussions in youth sports. You are in a unique position to provide information about this topic because you are youths engaged in various sporting activities. The answers you give will be combined with other interviews for our report. Nothing you say will be identified with you personally. Please, may we have your permission to interview you? As we go through the interview, please free to ask us to clarify any questions and if there are any questions you don't want to answer, just say so. Lastly, with your permission, we would like to record this interview so that we do not miss anything. Do we have your permission?

Do you have any questions before we begin?

Discussion: (moving clockwise around the table or room)

Opening Question

1. Let's start by asking everyone to tell us about their experience with youth sports.

Probes: Give us examples of youth sports you are experienced with.

What type of involvement have you had with youth sports?

This question is meant to be an icebreaker and to elucidate experience with youth sports.

2. What do you think about youth sports?

Probe: How meaningful is youth sports to you?

How significant is youth sports to you?

This question is meant to elucidate values of the respondent towards youth sports

3. What do you think about sports related concussions?

Probes: What are your opinions about concussions in youth sports? Do you think it is part of sports? Do you think it can happen to you? Do you worry about sustaining a concussion? Do you consider the risk of sustaining a concussion when you choose a sport? Have you discussed concussions with your parents, friends, coach or others? If yes, with whom?

Please tell me your personal views about sports related concussions?

This question is meant to elucidate opinion about concussions.

4. What types of sporting behavior can protect youth athletes from concussions?

Probe: Please use examples to describe protective sporting behavior **This question is meant to elucidate perception of protective sporting behavior**

5. How would you describe sporting behavior that puts youth athletes at risk for concussions?

Probe: What kind of sporting behavior can increase the risk of concussions in youth athletes? Please use examples to describe risky sporting behavior

This question is meant to elucidate perception of risky sporting behavior

6. How would you recognize a youth athlete with a possible concussion?

Probe: Please tell me what you know about the symptoms of concussions

This question is meant to elucidate content knowledge about concussions

7. Let's talk about your experience with what happens after a concussion?

Probe: What do you do after you suspect you have a concussion?

What happens after your teammate has a concussion?

Describe the steps taken during youth sporting activities to respond to concussions. Describe the steps taken to report a concussion

This question is meant to elucidate procedural knowledge about concussions.

8. What is your experience with reporting of sports related concussions?

Probe: What prevents you from reporting?

What makes it easier to report?

This question attempts to elucidate self-efficacy

9. Let us talk about the consequences of not reporting concussions.

Probe: What are possible consequences of concussions?

Probe: What are possible consequences of not reporting concussions?

This question attempts to elucidate perceptions of concussion risk

10. What can be done to ensure that youth understand the consequences of NOT reporting sports related concussion?

Probe: What are the steps that can be taken by you?

Probe: What are the steps that can be taken by school authorities/coaches?

Probe: What special education/training materials will be helpful?

As we approach the end of the interview, we would like to thank you for taking the time to answer our questions, your answers have been very informative and will play an important part in enhancing our understanding of sports related concussions in youth athletes.

Before we end, is there any other information you will like to share with us or is there any other question we should have asked?

What was the most interesting or important information you gained from this discussion today?

APPENDIX D1: INDIVIDUAL LEVEL BDI LOGIC MODEL YOUTH SPORTS CONCUSSIONS: AN INTERVENTION TO INCREASE RECOGNITION AND REPORTING OF, AND RESPONSE TO CONCUSSIONS AMONG YOUTH ATHLETES.

Specified Intervention & Activities	Chosen Determinants (risk and protective factors	Selected Behaviors	Health Goal
RcRn App will provide educational school-based programs and activities that provide accurate content knowledge, about concussions, how concussions are sustained, what behaviors lead to increased risk of concussions, signs, symptoms and consequences of concussions. Precise procedural knowledge explaining how to avoid unhealthy sporting behavior and rather engage in health behavior specific to the type of sporting activity. RcRn App based simulation games, as well as social media- TED talks, will be employed to increase knowledge.	 Knowledge Protective determinants Increased awareness of concussions Increased knowledge of impact of concussions Increased knowledge of safe practices in sports Increased knowledge of concussion symptoms and signs Increased content & prevention knowledge of concussions Decreased participation in sports related risky behavior Risk of concussions in different sports Decreased participation in sports related risky behavior. Risk of concussions in different sports Decreased participation in sports related risky behavior. 	Increase recognition of symptoms consistent with sports concussion in middle school-aged students	Decrease Youth Sports Concussion
RcRn App will provide activities that foster self-esteem and positive thinking, role play, talks by role models addressing values.	Clarity of values Outcome expectancy Goal formation Protective factors • Increased clarity of values about sports	Increase response towards sports concussion	

 RcRn App based activities aimed to address subjective norms and stress the importance of positive social networks. RcRn App based activities that reinforce healthy values and healthy sporting choices. RcRn App based activities that foster goal setting and goal formation depending on their readiness for change level 	 Decreased peer pressure influence Increased outcome expectation Increased goal formation Risky values Emphasis on financial gain 	Examples: asking to be removed from a game, sitting out a game, refusing to play with symptoms of concussions, following a recovery plan if diagnosed with a concussion, or supporting a teammate with symptoms of concussion). Sub-Goal <i>formation of</i> <i>raising</i> self-awareness, self- reporting, and early intervention in an athlete, this can lead to a medium- term sub-goal, of making every student-athlete aware of the CDC slogan, "It's better to miss one game, than the whole season	Decrease Youth Sports Concussion
RcRn App simulation activities and role play via avatars that foster verbal persuasion, vicarious experience from role models and champions, and enactive attainment to increase self- efficacy	 Self-Efficacy Increased self-efficacy in recognizing signs & symptoms of concussions Increased comfort verbalizing signs and symptoms & seeking appropriate help for concussions Increased resilience Increased self-motivation for care Increased prevention & management skills. 	Increase recognition & reporting of, and response to symptoms consistent with sports concussion in middle school-aged students	Decrease Youth Sports Concussion
Support group by peers and coaches Professional Counselling	 Personality History of stressors Coping resources Previous history of concussion Time lost to the injury Effect of the injury on athletic performance Athletic identity Self-esteem and body image 	Increase reporting of and response to symptoms consistent with sports concussion in middle school-aged students	Decrease Youth Sports Concussion

APPENDIX D2.

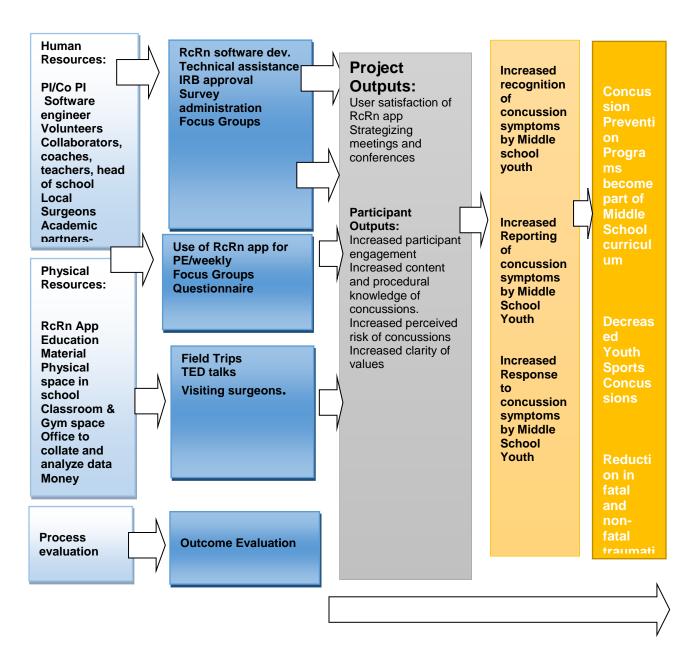
Logic Model for RcRn App Use

Input

Activities

Outcomes

Outputs



Appendix D3

Logic Model — RcRn: Evaluation Plan

Input	Activities	Outputs	Outcome	es
Human Resources:	IRB Approval	Project Outputs:	Increased participant	75 % Increased
Principal Investigator	Consent Signatures	Focus group trainings	engagement Increased content and procedural	recognition of Concussion symptoms
Research Study Team	Survey questionnaires	Post- participant	knowledge of concussions.	by Middle school youth
L_/	Focus groups	questionnaire		50 %
Physical Resources:	RcRn app Use of app for	Summative evaluation data	Increased perceived risk of concussions	Increased Reporting of Concussion symptoms
Funding	PE/weekly RcRn Focus Groups Questionnaire	Strategizing meetings and	Increased clarity of values	by Middle School Youth
Training Materials	Field Trips TED talks	conferences		50 % Increased
Interview/Focu s Group Space	Visiting surgeons.	Outputs: User satisfaction of RcRn app		Response to Concussion symptoms by Middle School
Process evaluation	Outcome Evaluation			Youth
			N	
			٧	

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Unini Odama, M.D. POSITION TITLE Principal Investigator

era Commons User Name N/A

EDUCATION/Training (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Emory University	MPH	2016	Public Health
Harvard Med school	GCRT	2014	Clin. Research
Medical College of VA	Fellowship	2003	Nephrology/Transpl.
Rush-Presbyterian Chicago	Fellowship	2000	Hypertension
Michael Reese, UIC	Residency	1999	Int. Medicine
University of Jos	Medical Scho	ol 1992	Medicine

A. Personal Statement

My varied experience in clinical medicine and extensive research background since

2003 has afforded me the opportunity to focus on Public Health concerns. Furthermore,

my experience in global research and research methods has given me the opportunity to

collaborate with other researchers on disease prevention, social behavioral theories, needs

assessments, curriculum development and evaluation of programs. These opportunities have led to scientific contributions in the form of presentations, books, and publications.

More recently, I have had the privilege of collaborating on and speaking about many public health concerns such as the issue of youth sports concussions at various settings including Rollins School of Public Health, end of semester presentation and guest speaker on podcasts such as (http://adventuresinbraininjury.com/podcast-8/) about the concussion crisis in youth athletes. Finally, I have been the keynote speaker at the *International Symposium of Clinical Neuroscience* discussing the *Epidemiology of Youth Sports Concussions*, and I am currently collaborating with other researchers to create innovative interactive prevention curriculums targeted at preventing youth sports concussions. My current thesis supervisor is the Director of the Division of Unintentional Injury Prevention at the Center for Disease Control and Prevention.

B. Positions and Honors

Positions and Employment

2003-present: Nephrology and Hypertension Specialist- Landmark Nephrology and Hypertension Clinic, P.C Talladega and Anniston AL.

2003-present: Medical Director: RAI/Fresenius Medical Center Dialysis Clinic, Talladega, AL

2003-present: Medical Director: Acute Dialysis, Citizens Baptist Medical Center, Talladega AL

Other experience and Professional Memberships

2003- present: Renal Physicians Association

2013- present: International Society of Nephrology

2000-present: American Society of Nephrology

1999-present: American Society of Hypertension

2013- present: American Red Cross, Calhoun, and Cleburne Chapter

2013- present: Board Member and Volunteer Physician- St. Michaels Church, Anniston AL

2014-present: Board Member, "The Donoho School" Anniston, AL 8/14-present.

Honors

2015- Keynote Speaker Award- International Symposium on Clinical Neuroscience, TBI, and Neurodegeneration.

1999- American Medical Association, Physician Recognition Award

1998- Award for Excellent Research Performance- Residents Research Competition-

Michael Reese Hospital, Chicago, IL

Additional recent publications (in chronological order)

- Habiba Alsafar, Ahmed Hassoun, Shaikha Almazrouei, Unini Odama, et al., "Association of Angiotensin Converting Enzyme Insertion-Deletion Polymorphism with Hypertension in Emiratis with Type 2 Diabetes Mellitus and Its Interaction with Obesity Status," Disease Markers, vol. 2015, Article ID 536041, 7 pages, 2015. doi:10.1155/2015/536041
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C. Research Support

Ongoing Research Support

- Surveillance and Prevention of Chronic Diseases; Hypertension and Kidney Disease Prevention.
- 2. Surveillance and Prevention of Youth Sports Concussion
- Injury Prevention- Increasing awareness, increasing Reporting of and Response to Concussions in Youth Sports.

- 4. Curriculum development for injury prevention based on frameworks and social behavior theories.
- 5. Curriculum Development-Interactive app development for novel curriculum to increase reporting and responding to concussions

Completed Research Support (since 2007)

- 1. The cardiovascular consequences of sports concussion/mTBI
- 2. Relationship of THFR C677T and A1298C gene polymorphisms with type 2 diabetes and its complications in Emiratis population

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Ms. S

POSITION TITLE Co-PI

eRA Commons User Name N/A

EDUCATION/Training (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION STUDY	DEGREE	YEAR(s)	FIELD OF
NUST University, Islamabad, PAK Medicine/Surgery Rollins School of Public Health, Atl, O Science	M.B.B.S SA MPH	2000- 2005 2014 - 2017	Prevention

A. Personal Statement

I am a second-year graduate student currently earning a Master of Public Health degree at Rollins School of Public Health with a focus on prevention science; I will be graduating in the spring of 2017. I was trained as a Physician overseas where I worked in a rural area Cardiology Hospital. I have been a presenter in many Preventive Cardiology workshops throughout her career. I am currently working with "Innovative Solutions for Disadvantage and Disability" (ISDD), to develop a Mental Health Literacy Curriculum for Veteran parents with a focus on PTSD. I am also involved in a faith-based HIV/AIDS prevention program study as a Quality Assurance Specialist. My work for this project will be overseen by the Principal Investigator, Dr. Odama, who has extensive experience regarding concussions in youth.

B. Positions and Honors

Positions and Employment

2005-2008: Resident Medical Doctor, National Institute of Cardiology, Isb,

Pakistan

2015-Present Quality Assurance Specialist, Emory University Faith-based

HIV/AIDS Study, Atlanta, GA

2016-Present Curriculum Developer, Innovation Solutions for the Disadvantage

& Disability, Atlanta, GA

Other experience and Professional Memberships

2005-Present Pakistan Medical and Dental Association

Honors

N/A Selected peer-reviewed publications <u>Most relevant to the current application</u> N/A <u>Additional recent publications (in chronological order)</u> N/A C. Research Support <u>Ongoing Research Support</u> N/A <u>Completed Research Support</u> (since 2007) N/A

APPENDIX E3

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Ms. B

POSITION TITLE Co-PI

eRA Commons User Name N/A

EDUCATION/Training (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

INSTITUTION AND LOCATION DEGREE YEAR(s) FIELD OF **STUDY** Emory University, Atl, GA B.S. 2006 - 2008 Psychology Oglethorpe University, Atl, GA B.S. Psychology 2008-2010 Rollins School of Public Health, Atl, GA MPH 2014 - 2016 Prevention Science

A. Personal Statement

I earned a Master of Public Health degree at Rollins School of Public Health with a

focus on prevention science in August 2016. My thesis focused on how cardiovascular

disease was directly affected by a plant-based diet. I have also worked with the Georgia

Department of Health as a volunteer on their Chronic Disease and Prevention team for a year assisting with analyzing school wellness policies for over 100 counties in the state of Georgia and making recommendations to improve those policies.

The goal of this proposed research is to successfully implement an intervention that will help recognize, report and reduce the number of sustained concussions in middle school athletes. I have taken a keen interest in creating and implementing programs that will prevent or reduce issues that are a threat to the health of individuals. Under the guidance of Dr. Odama who has extensive experience in the field of concussions, I will be able to successfully gather data relevant to the subject of youth sports concussions and use that data to create and implement an intervention program.

B. Positions and Honors

Positions and Employment

2011-2013	Research Protocol Analyst, Office for Clinical Research, Emory
	University, Atlanta, GA

2013-2016 Data Management Systems Analyst, Office of Grants & Contracts

Accounting, Emory University, Atlanta, GA

- 2015-2016 Volunteer, GA Department of Health, Atlanta, GA
- 2016-Present Health Comm. Specialist, Penngood, LLC, Washington, DC

Other experience and Professional Memberships

N/A

<u>Honors</u> N/A

Selected peer-reviewed publications

Most relevant to the current application1.N/A

Additional recent publications (in chronological order)1.N/A

C. Research Support **Ongoing Research Support** N/A

Completed Research Support (since 2007) N/A

APPENDIX F

Personnel Justification

Unini Odama, M.D., Physician/Nephrologist (PI, effort = 12 calendar months). Dr. Odama is a physician whose specialty is in nephrology and hypertension, general internal medicine and clinical research. She has worked in this field since 2003 and has served as Co-PI on several research studies.

Dr. Odama is also earning her Master of Public Health degree with a focus in preventive science, which will be completed in 2016. Her MPH program has given her hands-on experience with social behavioral theories, needs assessment and evaluation of programs. She has also gained skills in collaborative research using both qualitative and quantitative methods in her work. Her contributions as a physician span over a decade with many publications. Some of Dr. Odama's contributions in the medical field include numerous collaborations, books, and publications more recently as a global clinical research scholar at the Harvard Medical School. She has been invited to speak about many public health concerns such as the issue of youth sports concussions at various settings including, Rollins School of Public Health, end of semester presentation and guest speaker on podcasts such as (http://adventuresinbraininjury.com/podcast-8/) about the concussion crisis in youth athletes. Dr. Odama has been the keynote speaker at the *International Symposium of Clinical Neuroscience* where she discussed the *Epidemiology of Youth Sports Concussions*.

As a Harvard Macy Institute Scholar since 2014, she has continued to gain expertise in medical education teaching skills, and recently, she enrolled in a Harvard course specifically targeted at learners and educators in the digital age of technology. This added knowledge and collaboration with other Harvard Macy Scholars will be useful in creating innovative and interactive 2.0-based prevention curriculums targeted at preventing youth sports concussions. Dr. Odama will coordinate and provide ongoing guidance and careful review of the work that will be carried out in her group by collaborators. She will be solely responsible for all aspects of this research from the implementation of the proposed research plan, analysis of data and publication. She will also continue to seek guidance from her current thesis supervisor and field advisor who are both experts in the field of unintentional injury prevention at CDC.

Ms. S, M.B.B.S., MPH (Analyst, Co-PI, effort = 6 calendar months). Ms. S is a second-year graduate student currently earning a Master of Public Health degree at Rollins School of Public Health with a focus on prevention science and will graduate in the spring of 2017. She trained as a Physician overseas where she worked in a rural area Cardiology Hospital. She has been a presenter in many Preventive Cardiology workshops throughout her career. She is currently working with "Innovative Solutions for Disadvantage and Disability" (ISDD), to develop a Mental Health Literacy Curriculum for Veteran parents with a focus on PTSD. Her work for this project will be overseen by the Principal Investigator, Dr. Odama, who has experience regarding concussions in youth.

Ms. B, MPH (Analyst, Co-PI, effort = 6 calendar months). Ms. B earned her Master of Public Health degree at Rollins School of Public Health in May 2016. She has worked in the area of cardiovascular disease and plant based diet. She also worked with the Georgia Department of Health as a volunteer on their Chronic Disease and Prevention team for a year assisting with analyzing school wellness policies, wellness program evaluations, and grant-funded school programs for over 100 counties in the state of Georgia, and making recommendations to improve those policies. Her work for this project will be overseen by Dr. Odama who has direct experience with research as it pertains to concussions in youth.

APPENDIX G

Facilities and Other Resources

<u>Environment</u>: Surveys and focus groups will take place in an open space on the ground of the participating school. Space will be assigned for the project according to the needs and number of students participating in each session. Using space on school grounds will reduce costs for back and forth travel expenses for students.

Laboratory: not applicable

<u>Clinical</u>: not applicable

<u>Office</u>: The PI and Co-PI's have one, shared 500 square foot office in an Emory building located at 1599 Clifton Road, Atlanta, GA 30322.

<u>Library</u>: Professional library services include literature that has been retrieved from research databases such as EMBASE and PubMed. The PI and the Co-PI's have full access to these databases. Any literature that may be useful or relevant to this study, and is unavailable online, can be requested through the Woodruff Health Sciences Library at Emory University.

APPENDIX H

Protection of Human Subjects

Emory University Principal Investigators and researchers subscribe to the basic ethical principles underlying the conduct of research involving human subjects as set forth in Emory's Guidelines for Responsible Conduct of Scholarship and Research which includes the Protection of Human Subjects. Emory's Institutional Review Board (IRB), along with the WIRB Institutional Review Board for protocols related to concussion prevention, is charged with ensuring the protection of human subjects in research, especially minors. The IRB has the responsibility and authority to review, approve, disapprove, or require changes in research activities involving human subjects. All research activities involving human subjects must be reviewed by the Institutional Review Board. This policy applies to all research studies conducted at Emory or by Emory PI's or researchers, regardless of whether the project is funded externally, internally, or receives no funding support.

APPENDIX I

Letters of Support (Proposed)

Arlene Greenspan, Dr.PH, MS, MPH, Associate Director for Science, National Center for Injury Prevention and Control.

Grant Baldwin, Ph.D., MPH, Director, Division of Unintentional Injury Prevention.

National Center for Injury Prevention and Control.

A Letter of Support from the Headmaster of a hypothetical school in the S.E United States is attached below.

Ohonod School

210 North St W, Talladega, AL | 2567612932 | juchin@ohonodschool.com

06/01/16

Recipient Name Rollins School of Public Health Emory University 1518 Clifton Road NE, Atlanta GA 30322

RE: Request to Conduct Research in the Ohonod School

Dear Recipient Name:

Your request to conduct the research described in your letter dated May 6, 2016, at Ohonod Middle School is approved. Participation by Ohonod middle school students remains voluntary.

Sincerely,

Jason Uchin

Headmaster Ohonod School cc: Bailey Rusty, Athletic Director

Title: Concussions! Youth Athletes at Risk: A Socio-behavioral Framework to Increase Recognition of, Reporting of, & Response to Concussions in Middle School-Aged Athletes.

Appendix J

<u>GRANT PROPOSAL THESIS: EXTERNAL REVIEWER FEEDBACK</u> <u>TEMPLATE</u>

- **1.** Please state your level of agreement/disagreement with the following statement: The submission is responsive to the call for proposals.
 - Strongly agree
 - Agree
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree

.....

- 2. How could the submission have been more responsive to the call for proposals?
- **3.** Please state your level of agreement/disagreement with the following statement: The proposal is well thought out and theoretically sound.
 - Strongly agree
 - Agree
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree

.....

4. What improvements could be made to the theory and structure of the proposal?

- 5. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the proposed research/project/program is necessary.
 - Strongly agree
 - Agree
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree

.....

- 6. What would have improved the argument that the proposed activities are necessary?
- 7. Please state your level of agreement/disagreement with the following statement: The PI makes a compelling case that the research team will be able to accomplish the proposed activities with the resources and time allocated.
 - Strongly agree
 - Agree
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree

.....

8. What changes would improve the perceived feasibility of the proposed activities?

- 9. Please state your level of agreement/disagreement with the following statement: The proposed work is innovative and sets the groundwork for future work in this area.
 - Strongly agree
 - Agree
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree

.....

10. What additional comments and suggestions do you have for the PI?

APPENDIX K

RFA-CE-17-002 Development and Evaluation of Sports Concussion Prevention Strategies Department of Health and Human Services Centers for Disease Control and Prevention - ERA

Forecast History:		
Version Modification E	Description	Updated Date
Forecast 1		Jul 28, 2016
GENERAL INFORMATION		
Document Type:	Grants Notice	
Opportunity Number:	RFA-CE-17-002	
Opportunity Title:	Development and Eva	luation of Sports Concussion Prevention
Opportunity Category:	Discretionary	
Opportunity Category Explana	tion:	
Funding Instrument Type:	Cooperative Agreeme	nt
Category of Funding Activity:	Health	
Category Explanation:		
Expected Number of Awards:	2	
CFDA Number(s):	93.136 Injury Preve	ention and Control Research and State an
Cost Sharing or Matching Requirement:	No	
Version:	Forecast 1	
Posted Date:	Jul 28, 2016	
Last Updated Date:	Jul 28, 2016	
Estimated Synopsis Post Date:	Oct 31, 2016	
Estimated Application Due Date:	Feb 03, 2017 Electronically s due date.	submitted applications must be submitted
Estimated Award Date:	Sep 14, 2017	
Estimated Project Start Date:	Sep 15, 2017	
Fiscal Year:	2017	
Archive Date:		

Estimated Total Program Funding:	\$3,300,000	
Award Ceiling:	\$550,000	
Award Floor:	\$200,000	
ELIGIBILITY		
Eligible Applicants:	Nonprofits having a 501(c)(3) status with the IRS, than institutions of higher education Public and State controlled institutions of higher education City or township governments County governments Nonprofits that do not have a 501(c)(3) status with IRS, other than institutions of higher education Special district governments Independent school districts Unrestricted (i.e., open to any type of entity above) subject	the
text field entitled "Additional Native American tribal organi governments) Public housing authorities/Inc Private institutions of higher e For profit organizations other State governments	zations (other than Federally recognized tribal lian housing authorities education than small businesses nments (Federally recognized)	N/
		А
ADDITIONAL INFORMATION		
A NI	Contain for Discose Control and Discontion EDA	

Agency Name:	Centers for Disease Control and Prevention - ERA
Description:	The purpose of this research is to either (a) develop and pilot test a new intervention OR (b) rigorously evaluate an existing intervention that targets young athletes participating in sports programs. Interventions should be social and behavioral in nature and can represent either primary prevention or secondary prevention of sports- related concussion. Primary prevention interventions aim to prevent sports-related concussions before they occur, while secondary prevention interventions aim to reduce the impact of concussions that have already occurred. Information gleaned from this research can inform mechanisms for change in the culture of youth sports and support multi-stakeholder approaches to promoting a

positive (preventive) culture of sport to mitigate negative norms, beliefs, mores, and policies that may increase risks of concussion among young athletes.

Link to Additional Information:	
Grantor Contact Information:	Sue Neurath (770) 488-3368
	SFN8@cdc.gov

<u>http://www.grants.gov/web/grants/search-grants.html?keywords=concussions</u> http://www.grants.gov/custom/printVersionHistoryDetails.jsp

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