

PROTOCOL TITLE: Comprehensive dynamic movement assessment for concussion management

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LOCATIONS OF STUDY Central Arkansas Area High Schools &  
ACH Concussion Clinic

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## **I. LIST OF ABBREVIATIONS**

ACH	Arkansas Children's Hospital
COD	Change of Direction
IAGT	Illinois agility test
ImPACT	Immediate Post-Concussion Assessment and Cognitive Testing
ICF	Informed Consent Form
IRB	Institutional Review Board
SEBT	Star Excursion Balance test
PVT	Psychomotor Vigilance Task
RTP	Return to Play
UAMS	University of Arkansas for Medical Sciences

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## II. PROTOCOL SUMMARY

Previous work in the area of concussion management has focused heavily on neuro-cognitive testing. In addition to routine neuro-cognitive testing through Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT), the first year of the pilot study established normative data for a comprehensive battery of clinical assessment through the utilization of functional movement and dynamic postural control assessments. Year one of the assessments was focused on the male high school football player (who is at increased risk for concussion). Year one of the pilot study collected initial data on 10-12<sup>th</sup> grade football players in three area high schools to begin to determine the stability of ImPACT testing in youth athletes in light of ongoing neurodevelopment in this population. In addition, year one implemented additional tools focused on assessment of dynamic balance, reaction time, and agility. This battery of tests will provide clinicians with invaluable information to guide both rehabilitation of and return to play (RTP) decisions for concussed high school athletes. Year one of the pilot began to track those athletes who sustained a concussion and assessed increased risks for musculoskeletal injury. This more global approach will significantly enhance predictions of subsequent concussions and musculoskeletal injuries that have been shown to occur in concussed collegiate and professional athletes and that we believe are also occurring in our high school athletes.

Year two and three of the pilot study will expand data collection from year one to include 1) **concussed** high school patients (male and female high school athletes) presenting to clinic at Arkansas Children's Hospital (ACH), (n=50) 2) 9<sup>th</sup> grade male athletes (a younger population than was tested in year one) (n=90) and 9<sup>th</sup>-12<sup>th</sup> grade female athletes participating in soccer (an at risk and under-represented group in the concussion literature), (n=85) and 3) continue to use injury tracking software to document concussion and musculoskeletal injury as they occur in high school male and female athletes.

## III. BACKGROUND AND RATIONALE

Sport-related concussion is a pervasive problem in varsity and collegiate athletics. The Center for Disease Control reports an estimated 1.6 to 3.8 million concussions related to sports and recreational activities annually in the United States, concluding that sport concussion has reached an epidemic level.<sup>1-5</sup> Of that number, an estimated 50,000-300,000 concussions are sustained by high school athletes each year.<sup>6-10</sup> This number likely under-represents the actual injury rate since many concussive injuries that are mildly symptomatic are not diagnosed.<sup>7</sup> **Prevention of concussion is essential for the safety of youth athletes.** Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT) has been utilized to establish baseline neuro-cognitive abilities and to provide data for return to play decisions after concussion. The frequency of ImPACT administration (biennial or annually), however, has been called into question in the young, neuro-developmentally immature athlete.<sup>11</sup> Additionally, while it provides valuable information, ImPACT is not a comprehensive measure of the numerous, dynamic requirements for safe athletic play. There is currently no definitive, comprehensive battery of tests known to identify increased risk for concussion in youth athletes. Moreover, collegiate and professional athletes have been shown to be at an increased risk for subsequent musculoskeletal injury following concussion as far as one year out. Previous authors suggest that continued deficits in neuro-motor control may be implicated, though current concussion management does not sensitively measure dynamic movement and control.<sup>12-14</sup> This connection between concussion and subsequent musculoskeletal injury rate has not been studied in the high school population and represents a major gap in our knowledge of identification of risk and injury prevention in this population.

### **Significance**

The overall goal for year two of this pilot study (May 2017-April 2018) is three-fold. We will, 1) implement the battery of tests constructed in year one that are sensitive to neuro-motor control (i.e. balance, reaction time, and agility) in **concussed** high school patients presenting to clinic at Arkansas Children's Hospital (ACH), 2) examine the frequency of current neurocognitive measures in 9<sup>th</sup> grade male athletes (a younger population than was tested in year one), 9<sup>th</sup>-12<sup>th</sup> grade female athletes participating in

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soccer (an at risk and under-represented group in the concussion literature), and annual assessment of athletes participating in football for a consecutive year, and 3) use injury tracking software to document concussion and musculoskeletal injury as they occur in high school male and female athletes.

Achievement of this pilot work will provide essential data that will considerably advance our ability to identify youth athletes at risk for serious injury including concussion and subsequent musculoskeletal injury. We anticipate that completion of these innovative studies will not only enhance our knowledge of the relationship between concussion and subsequent musculoskeletal injury, but that also implementation of these clinically applicable tests will allow us to more accurately define the impairments that are factors for increased injury risk.

#### IV. HYPOTHESES

Our *central hypothesis* is that, like collegiate and professional athletes, high school athletes who sustain a concussion are at an increased risk for future concussions or subsequent musculoskeletal injury. However, unlike the adult athletes whose cognitive function is mature, annual assessment of cognition (ImPACT) in youth athletes, whose cognition is developing over time, may be insufficient as a baseline measure, and so, we plan to test the youth athletes tri-annually to determine how stable ImPACT testing is in this population.

#### V. TRIAL DESIGN

**Experiment 1.** Concussed (sports related) adolescent males and females (n=50) ages 14-18-years-old presenting to the ACH concussion clinic, will complete our battery of functional tests constructed during year one. The battery includes the Star Excursion Balance Test (SEBT), a divided attention gait task, the Psychomotor Vigilance Task (PVT), and the Illinois Change of Direction (COD) Illinois agility test (IAGT). The SEBT is an established, reliable outcome measure of **dynamic** postural stability through measurement of lower extremity reach distance.<sup>15</sup> Our study can utilize a force plate during SEBT testing to allow the investigators to sensitively measure center of mass in all planes. To test gait, balance, control and adaptation of gait strategy which have each been shown to be impaired in concussed individuals acutely and chronically, athletes will walk at a self-selected speed on the GAITRite<sup>®</sup> portable gait analysis walkway for three undivided attention trials and three divided attention trials during which a cognitive task will be imposed.<sup>18-25</sup> The GaitRite<sup>®</sup> will calculate spatio-temporal parameters during gait and has been used in the concussion literature.<sup>24,26</sup> The PVT is a reliable and valid measurement of simple reaction time to an auditory cue. The outcome measure will be the mean reaction time.<sup>28-30</sup> The COD IAGT is a valid and reliable protocol to assess agility in male team athletes.<sup>31-32</sup> This test yields a completion time in seconds. These tests will be administered by licensed physical therapists, assisted by students from both the Doctorate of Physical Therapy (DPT) and PhD physical therapy programs at UCA. The total testing time per athlete will not exceed 1.5 hours. All athletes will be asked to complete between 1-3 functional tests with a maximum of 4 functional tests (the SEBT, IGAT, and divided attention gait task), in addition to the standard static Balance Error Scoring System (BESS) test. The tests can be administered (1-2 additional times) for follow-up, if Dr. Israel or the PT have made a clinical decision that the athlete is not prepared for return to play.

**Experiment 2.** Qualified athletic trainers or Physical Therapists, with oversight by Dr. Israel will administer the ImPACT. The ImPACT is a widely used neurocognitive testing component of the standard three-prong approach to concussion management which also includes symptom inventories and static balance assessment.<sup>33</sup> The computerized test evaluates concentration, attention, memory, visual motor speed, and reaction time. High sensitivity and specificity for concussion using the ImPACT has been shown.<sup>34-37</sup> The test also has been shown to be a valid and reliable measure in the high school and collegiate populations.<sup>34-40</sup> Composite scores for each of the non-injured athletes will be stratified by age to examine changes across the

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three assessments. Hunt and Ferrara have shown significant change in baseline assessments between 9th grade and 11th and 12th grade age groups driven by 9th grade test scores indicating that biennial testing for young adolescents may not be sufficient.<sup>8</sup> The current recommendation for this younger age group is annual testing, though recent studies call for the investigation of even more frequent testing<sup>11</sup>, thus year one testing was test pre-season, post-season and prior to the end of the school year for 10<sup>th</sup> -12<sup>th</sup> grade athletes. ImPACT testing will not exceed 1 hour. In year two and three, it is essential that we collect ImPACT data on 9<sup>th</sup> grade male football athletes. The female gender has also been identified as a population at increased risk for concussion.<sup>15-16</sup> In year two and three, we will expand ImPACT testing to include female soccer (the second most concussive sport) players in 9<sup>th</sup>-12<sup>th</sup> grades. Composite scores for each of the non-injured athletes will be stratified by age and gender to examine changes across the three assessments. ImPACT testing will not exceed 1 hour and will be completed at the computer lab of the athlete's school or in the ACH concussion clinic.

**Experiment 3.** Athletic trainers will use the established injury tracking system or Athletic Trainer System<sup>®</sup> injury tracking software mobile application to record incidence of injury, both musculoskeletal and concussive, during all practice and game play. Injuries acquired outside of the athletic and school setting will also be documented through athlete questionnaire. Retrospective injury data for the previous school year were obtained through athlete questionnaire and review of current charting system to control for confounding variables. To accurately document injury and care-received, medical records may be obtained through ACH Adolescent Sports Medicine and Rehabilitation departments, and the ACH emergency department.

## **VI. STUDY POPULATION**

### **A. Accrual of Research Subjects**

Healthy athletes who have completed pre-participation examinations by physicians (on file at their respective school) will be enrolled following parental consent at the area schools. Concussed athletes who are identified as meeting the criteria will be identified by Dr. Israel through the ACH concussion clinic and enrolled following parental consent.

### **B. Inclusion criteria (for area school athletes)\_**

- Healthy athletes who are participating in football or soccer programs at their high schools
- Age 14-18
- Male football player or female soccer player
- Written, informed consent.

Inclusion criteria (for ACH concussion clinic athletes)

- Previously healthy athlete participating in high school sports who suffered a concussion
- Able to participate in functional testing and/or ImPACT computerized testing per Dr. Israel
- Written, informed consent

### **C. Exclusion criteria (for area schools)**

- Athletes who have not completed pre-participation physicals
- Any condition the investigator determines will put the subject at risk if participating in the study

**Exclusion criteria (for athletes in concussion clinic)**

- **Athletes who suffered additional injuries beyond the concussion that would prohibit participation in functional testing and/or ImPACT computerized testing per Dr. Israel**
- **Any additional condition the investigator determines will put the subject at risk if participating in the study**

### **D. Withdrawal**

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Subjects may be withdrawn from the study by the investigator at any time if the investigator believes for any reason that continuing in the study is not in the best interest of the subject. The parent or legal guardian may revoke consent at any time and the subject will be withdrawn from the study. The subject can choose to withdraw from the study at any time. Data collected up to the point of withdrawal will be used in the analysis unless forbidden by the parent or legal guardian.

## **VII. INVESTIGATIONAL PLAN**

**VII.1 Randomization Procedures:** The order of functional movement testing will be randomized for each athlete enrolled.

**VII.2 Consent Process:** Athletes in area schools will be screened using the inclusion and exclusion criteria noted above. Athletes in area schools will have an educational session on concussion injury provided by the coach or the research team. The study will be explained during a designated time determined by the coach of the team. The parents of eligible athletes will then receive a written detailed description of the study procedures distributed with the participation for high school sports packet. The consent process will be initiated prior to any scheduled testing so that parents have enough time for determining the risks and benefits of the proposed study and have related discussions with study personnel. Study personnel will be available by phone for consultation and available at the end of the educational session for further discussion.

The investigators are requesting a waiver of the verbal consent process to the parent for healthy athletes participating in the area school. The investigators will have verbal communication with the athlete at the team meeting or another time as allowed, written communication to the parent through a informational sheet that will be sent home following the team meeting, and will be available to the subjects/family for phone consultation. The packet will be returned by the subject or mailed to the study group. The study has met the required waiver elements as outlined in IRB protocol 15.3. By having the athlete sign the consent form, the investigators are requesting a waiver for the requirement that a participant who turns 18 during the duration of the study be re-consented. The study will attempt to include wards of the state using the approved process in policy 17.1.

The information will be given in language understandable to the reader. All questions regarding participation will be answered. No coercion or undue influence will be used in the consent process. No research related procedures will be performed prior to obtaining informed consent. All signatures and dates will be obtained. Once a signed consent is obtained the participant becomes eligible for the study. A copy of the signed consent will be mailed home to the participant or delivered to the athlete at their school. A copy of the consent will be maintained in a locked cabinet of the PI. After written consent has been obtained from the parents, the athlete's functional testing assignment will be randomized by the investigator.

*Dr. Israel will screen athletes in the concussion clinic using the inclusion and exclusion criteria. The study will be explained to the athlete and parent by a study investigator.* The parent(s) of the eligible athlete and the athlete will receive a detailed description of the study procedures. The consent process will be initiated prior to any functional testing so that the parent(s) will have enough time for determining the risks and benefits of the proposed study and have related discussions with study personnel.

The investigators will conduct the consent discussion and will be prepared to devote approximately 30 minutes (longer if needed) to the discussion. The consent process will take place in a quiet and private room in a location that is convenient for the person authorized to give informed consent. The person obtaining consent will thoroughly explain each element of the protocol and outline the risks and benefits, and follow-up requirements of the study. The information will be given in language understandable to the reader. Participation privacy will be maintained. All questions regarding participation will be answered. No

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coercion or undue influence will be used in the consent process. No research related procedures will be performed prior to obtaining informed consent. All signatures and dates will be obtained. Once a signed consent is obtained the participant becomes eligible for the study. A copy of the signed consent will be given to the parent or legal guardian. A copy of the consent will be entered into Medical Records.

If the athlete is participating in functional testing, the investigator will randomize the order of the functional tests.

## **VIII. OUTCOME ASSESSMENTS**

ImPACT neuro-cognitive testing, SEBT, PVT, COD IAGT, divided attention gait task, as well as incidence of musculoskeletal and concussion injuries will be used to assess neuro-cognition, functional movement, and injury occurrence in these athletes. In the event that a subject has a significant decrease in neuro-cognition on the repeat of the ImPACT testing (If the ImPACT software identifies a reliable change score that shows a decline in two or more of the subtests, or greater symptoms (of concussion) at retest verses baseline), our monitoring physician will examine the testing data and the study physician (Dr. Israel) will directly contact the parent with a recommended course of action.

## **IX. COMPENSATION**

Participants from area schools will be remunerated \$60 for completing the entire study protocol and pro-rated \$15 for the first two testing session and \$30 for the final session. Subjects enrolled from ACH clinic will be compensated \$30 per visit and can include 2 follow-up visits for a total of \$90.

## **X. DATA SAFETY AND MONITORING PLAN**

Before the study begins, approval of the UAMS/ACHRI IRB will be obtained. All IRB policies and procedures will be followed with regard to initial approval, continuing review, protocol and consent modifications, and adverse event reporting. In addition, all relevant policies and procedures of the National Institutes of Health will be observed. The PI will carefully monitor study procedures to protect the safety of research subjects, the quality of the data, and the integrity of the study. All study subject material will be assigned a unique identifying code or number. The key to the code will be kept in a locked file in the principal investigator's office. Only the PI will have access to the code and information that identifies the subject in this study. The risk level associated with this study is estimated to be minimal. Data will be published in aggregate form. No individual subjects will be identified. The data will be de-identified after analysis and included in the long term database without identifiers. The data will be destroyed per ACH document destruction policy.

### **Risks**

The risk level associated with this study is estimated to be minimal. A licensed physical therapists or Dr. Israel will be onsite during all clinical functional testing. The neuro-cognitive testing will be supervised by a co-investigator or the athletic trainer assigned to the school.

### **Benefits**

This study is seeking to determine the stability of neuro-cognitive testing for developing athletes. This study is also seeking to determine normative data on dynamic movement testing in the high school athlete collected in year one as a comparison for scores obtained in the concussed athletes to more accurately identify remaining deficits that could place these athletes at risk with return to activity or play. The subjects will receive concussion education as part of the study.



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## XI. STATISTICAL PLAN

All data will be analyzed by the investigators. Dr. Keith Williams, a co-investigator in the Biostatistical Department will oversee the analysis.

### **Data Analyses:**

**Experiment 1:** Comparisons will be made for each concussed athlete's measurement on the 4 functional tests with baseline data collected in healthy athletes during year one of our study. Additionally, comparisons will be made between our battery of dynamic tests and the static BESS for the concussed athletes. For the returning uninjured subjects from year one, we will again examine them individually and as a cohort including important covariates (age, position played, and history of concussion) and trends of the means will be assessed.

**Experiment 2:** Individual athlete neurocognitive assessment will be observed over time to determine if scores remain within expected norms or change over time. Athlete assessment will be examined as a cohort including important covariates (age, position played and history of concussion) and trends of the means will be assessed. Data will be analyzed using a repeated measure model. Post hoc comparisons will be performed using the Bonferroni adjustment.

**Experiment 3:** Continued documentation of concussion and injury rates (during and beyond football season) and in expanded populations will provide a more robust data set on which a regression analysis may be run to examine predictive factors to move toward the goal of ascertaining the incidence of musculoskeletal injury after concussion in the high school population.

## XII. STUDY REGISTRATION AND PUBLICATION

Data obtained during the course of this study may be used in publications and presentations. The study is registered with [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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