

Title: Reducing High School Athletes' Prescription Opioids Misuse and Diversion
Through the Student Athlete Wellness Portal

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Study Protocol

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Abstract

The opioid epidemic has permeated all strata of society over the last two decades, especially within the adolescent student athletic environment, a group particularly at risk and presenting their own challenges for science and practice. Effective interventions to are needed for these young people to help them avoid prescription opioid misuse.

The Student Athlete Wellness Portal models effective opioid misuse resistance strategies for high school athletes. It was adapted from the evidence-based keepin' it REAL curriculum that is recommended for schools in the Surgeon General's 2016 report on addiction.

The process of translating research about opioids and youth sports into the web-based intervention began with formative research among 35 student athletes, ages 14 to 21, who had all been injured in their school-based sport and who received a pain management plan from their doctor. They participated in in-depth qualitative interviews to explore narratives relating to their injuries; their pain management plans; and the ways in which they used, misused, or avoided prescription medication. An inductive analysis of interview transcripts revealed themes of the (a) the challenges of being a student athlete; (b) sports, drugs, and you; and (c) ways to stay healthy.

These themes were then translated into prevention messages for the Student Athlete Wellness Portal intervention, including a series of video docudramas portraying resistance process. A single-group feasibility test was conducted that provided evidence of its usability, engagement and preliminary outcomes.

Introduction

To date, there are no evidence-based interventions addressing prescription opioid misuse among high school athletes. The proposed intervention, adapted from an evidence-based substance use prevention intervention, will be the first to effectively address this problem among at-risk high school athletes.

Background and Rationale

Opioid use and misuse have migrated into the adolescent student athletic environment. This includes athletes who misuse their own prescription opioids (i.e., use them recreationally or for other non-prescribed purposes) as well as those divert prescription opioids to others for their misuse. It is estimated that 2% of youth athletes use heroin, although this, too, varies by sport. Unfortunately, little has been done to address the needs of this at-risk population. This paper addresses these issues.

According to a recent national study, the incidence of non-medical opioid use is higher among athletes than non-athletes. National statistics document the prevalence of the problem among athletes, with some sports (i.e., ice hockey) particularly impacted. Other research shows the incidence of nonmedical prescription opioid use increases when youth are injured. The picture, however, is complex: some studies suggest that rates for athletes merely mirror those for the general adolescent student population, which still puts them at risk, some suggest an increased risk for male athletes but not female athletes, and others suggest greater likelihood of use among those participating in only some sports. Overall, it is estimated that as many as 14% of athletes misuse prescription opioids and that prescription opioid misuse among athletes is associated with somewhat different risk factors from those associated with misuse in the general adolescent population, including the heightened perceived need to compete and arguably a high pain tolerance.

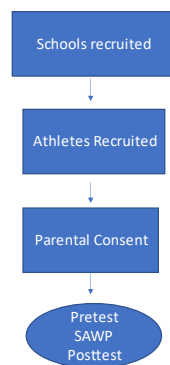
Other reports have highlighted the problem of prescription opioid diversion (e.g., sharing or selling their opioids to others) among student athletes, and schools across the country have begun partnering with law enforcement for National Prescription Drug Take Back Day events, to help students understand the risks of unused medications and prevent old medications from diversion. These trends have underscored the importance of prevention interventions tailored to meet the needs of young athletes and keep them safe.

Objective

The objective of this study was to evaluate the feasibility of the Student Athlete Wellness Portal (SAWP). SAWP is a digital intervention that targets

- 1) prescription opioid misuse among high school athletes
- 2) prescription opioid diversion among high school athletes.

Study Design



Five high school were recruited. Student athletes from the five high schools were recruited through the athletic departments as well as through online advertisements. Parental consent and youth assent was obtained for youth 18 and younger with youth consent for those 19 or older. Consent was obtained online.

After consent was received, participants received a link to the intervention. They first completed a pretest followed by the Student Athlete Wellness Portal program. After completing the program, they responded to a posttest. Participants receive incentives of \$50.

Usability and Engagement scores were from the posttest only and compared to neutral using a one-sample t-test. Efficacy and Willingness posttest scores were compared to pretest schools. Efficacy analysis was conducted using a paired t-test while Willingness comparison used a Chi Square test.

Inclusion Criteria:

- English-speaking male and female adolescents
- Ages 13-19
- Attending middle or high school

- Playing at last one interscholastic sport
- Parental consent

Exclusion Criteria:

- No parental consent
- outside the age range
- not participating in interscholastic sports
- not in middle or high school
- participated in the Phase I formative interviews

Baseline/Pretest Assessment

- 1) demographics
- 2) self-efficacy to resist prescription opioid offers
- 3) willingness to misuse prescription opioids

Immediate Posttest

- 1) self-efficacy to resist prescription opioid offers
- 2) willingness to misuse prescription opioids
- 3) usability of SAWP
- 4) engagement with SAWP
- 5) perceptions of opioids

Intervention Description

The Student Athlete Wellness Portal prototype consists of 3 video docudrama, scripted from the formative interviews and produced by Aaron Matthews of Look Alive Films, an Academy Award winning documentarian. Students received an email with a link, completed an assent, pretest, participated in SAWP and then completed an immediate posttest, all in one session.

Human Subjects Protections

All procedures were approved by REAL Prevention's independent IRB Board. A data safety monitoring board was established and supervised procedures. Data were secured digitally without identifiers by REAL Prevention (formative interviews) and St. Andrew Development (surveys). Risks were minimal because participants were not asked about prescription opioid misuse or diversion.

PARENT CONSENT AND TEEN ASSENT FOR RESEARCH

REAL Prevention LLC (RP)

Title of Project: The Student Athlete Wellness Portal

Principal Investigator: Michael Hecht, Ph.D.
Address: 130 Pearl Brook Drive, Clifton, NJ 07013

Telephone Number: 814-360-1893
Email: michael@real-prevention.com

We are asking your teen to be in a survey study conducted by REAL Prevention and UTMB. This form shares information about the study. Whether or not your teen participates is up to you and your teen. You can choose not to participate, or you and your teen can agree to take part and later change your mind. Your decision will not be held against you. Please ask questions about anything that may be unclear and take your time to make your choice.

Why is this research study being done?

The purpose of this study is to understand how we can keep student athletes safe and teach them about appropriate pain management if they get injured.

Where will this study take place?

Participation will take place completely online. We aim to study about 400 high school students in Texas.

What will my teen be asked to do in the study?

Using a smart phone, tablet, or computer device, your teen will be asked to complete a pretest survey, then view some online materials about how to stay safe as an athlete, then in about 3 months, complete a posttest survey.

How long will my teen be in this study?

Three months.

Can anything bad happen to my teen from being in this study?

We do not expect that being in this study will harm your teen, but if they feel distressed by their participation, please talk with Dr. Michael Hecht or with their school counselor.

Will my teen receive compensation or payment for being in this study?

They will receive a \$10 gift card for participating in the pretest and for viewing the online materials, and a \$20 gift card for completing the posttest. Funding is provided by National Institutes of Health.

What if I sign this form and then change my mind about my teen being in this study?

Your teen's participation in this study is voluntary. They may decide not to continue participating in this study at any time or skip any questions they do not wish to answer. You may withdraw your consent (or permission) for them to be in this study at any time with no

penalty. Your teen can also stop the study at any point.

What about my teen's privacy?

What your teen shares in these surveys will be kept private to the extent allowed by law. We will work to protect their privacy in several ways:

- 1) We obtain a "certificate of confidentiality" that legally protects their privacy.
- 2) Their name will not be used in any publications or presentations of study findings. Their name will not be connected to their responses.
- 3) Nothing they share will appear in your teen's school records.
- 4) All survey data will be kept locked in a secure place that can only be accessed with a password or a key. Only study staff with special research training will ever be able to access these data, and these people must also have a specific reason and prior approval.
- 5) All staff who are involved with this study will have special training in how to keep your information private and confidential.

If I have questions or concerns about this research study, whom should I call?

Please call the RP Project Director, Dr. Michael Hecht, at 814-360-1893 or Cheryl Haworth Wyrick, Prevention Strategies IRB Office, who monitors our research, at (336) 324-1397 or by email at chwyrick@uncg.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Cannot reach the study team or to talk to someone else about any concerns related to the research.

YOUTH ASSENT STATEMENT

I agree to take part in this study about athlete wellness, as described in this form. I have asked any questions I have about this study, and they have been answered for me. I will keep a copy of this form for my records.

Youth Name (First, Last)

Youth Signature

Date

PARENT CONSENT STATEMENT

I agree to have my teen take part in this study about prescription opioid misuse, as described in this form. I have asked any questions I have about this study, and they have been answered for me. I will keep a copy of this form to keep for my records.

Parent Name (First, Last)

Parent Signature

Date

Data Analyses

Sample Size Calculation

We analyzed power to test that our programs would impact targeted outcomes in this project. Since all data were collected during a single session, we fixed a somewhat conservative response rate such as 72%. Using Cohen's formulas for a small effect, our power analysis suggests that the required sample is 100 participants at posttest to detect program effects. We calculated nominal sample size based on the expectation of 72% attrition to require an initial sample of 139 (i.e., 139 athletes x 72% response rate = 100 athletes at posttest). Using these estimates, the proposed study power was good.

Planned Analyses

Missing data was not a problem because the program required responses to every item. We planned listwise deletion if missing data emerged; none did.

To examine findings for usability, engagement, and perceptions of opioids that were measured on the posttest only, we planned on using one sample t-test. For self-efficacy and willingness to misuse, measured on pretest and posttest, we planned on using a paired t-test.