Study name: Use of Virtual Reality for Overdose Management Educational Trainings

Short title: VR OD Education

Registration: NCT04091659

Attached protocol approved by University of Pennsylvania Institutional Review Board:

08/22/2019 10:07:46 AM

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# Submission Activity

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| | |
|---|---|
| **Confirmation number:** | cjgbgeif |
| **IRB status:** | Exempted |
| **Created by:** | GIORDANO, NICHOLAS A |
| **Principal investigator:** | GIORDANO, NICHOLAS A |
| **Protocol title:** | VR OD Education |
| **Protocol description:** | This cluster-randomized trial will compare changes in attitudes and knowledge on administering naloxone based on exposure to either a virtual reality educational training or the current standard educational trainings (e.g. on-line videos, printed information handouts) offered at local libraries. Individuals attending local library's naloxone training days will voluntarily complete an anonymous validated survey pre and post attending either the virtual reality or standard educational training. |
| **Resubmission:** | No |
| **Application type:** | EXEMPT Category 1 |

**View Protocol Application Form**

## List of Attached Documents

There are no documents.

**Revision History:** **Assigned to IRB #8, created on 08/08/2019 (cjgbgeif)**

## Department Review History

| Date | Reviewer | Dept Approval | Comments |
|---|---|---|---|
| 08/11/2019 06:13:27 PM | GIORDANO, NICHOLAS A | Approved | Principal Investigator submitted the protocol. |
| 08/12/2019 05:37:40 AM | COMPHER, CHARLENE W | Approved | |

## IRB Review History

| Decision date | Reviewer/approver | Decision |
|---|---|---|
| 08/22/2019 10:07:46 AM | IRB chair/designee | Approved |

## IRB Correspondence

| Date | Attached by | Attachment |
|---|---|---|
| 08/23/2019 | BURGESS, BARBARA K | **EXEMPTED (2019-8-22exemptgiordano833978kb.pdf)** |

## Ancillary Committee Correspondence

*None*

# Protocol Details

**Basic Info**

| | |
|---|---|
| Confirmation Number: | **cjgbgeif** |
| Protocol Number: | **833978** |
| Created By: | **GIORDANO, NICHOLAS A** |
| Principal Investigator: | **GIORDANO, NICHOLAS A** |
| Protocol Title: | **Examining the Use of Virtual Reality for Overdose Management Educational Trainings** |
| Short Title: | **VR OD Education** |
| Protocol Description: | **This cluster-randomized trial will compare changes in attitudes and knowledge on administering naloxone based on exposure to either a virtual reality educational training or the current standard educational trainings (e.g. on-line videos, printed information handouts) offered at local libraries. Individuals attending local library's naloxone training days will voluntarily complete an anonymous validated survey pre and post attending either the virtual reality or standard educational training.** |
| Application Type: | **EXEMPT Category 1** |

**Resubmission***
No

## Study Personnel

### *Principal Investigator*

| | |
|---|---|
| Name: | **GIORDANO, NICHOLAS A** |
| Dept / School / Div: | **602 - Biobehavioral and Health Sciences** |
| Campus Address<br>Mail Code | |
| Address: | **418 Curie Blvd, Philadelphia PA** |
| City State Zip: | **-** |
| Phone: | |
| Fax: | |
| Pager: | |
| Email: | **Yes** |
| HS Training Completed: | **03/04/2022** |
| Training Expiration Date: | **CITI Protection of Human Subjects Research Training - ORA** |
| Name of course completed : | |

products, tissues or body fluids)?
No

**Medical Information Disclosure***
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

**If the answer is YES, indicate which items is is provided with this submission:**

**CTRC Resources***
Does the research involve CTRC resources?
No

**Pathology and Laboratory Medicine Resources***
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

**Research Involves Apheresis, Cell Collection, and/or Blood Product Collection***
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

**Research involving blood transfusion or drug infusions***
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

**Trial in Radiation Oncology**
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

**Study in Radiation Oncology**
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

**Use of UPHS services***
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

**Primary Focus***
Survey research (the main focus of the research is administration of a survey to research subjects)

### *Protocol Interventions*

| | |
|---|---|
| | **Sociobehavioral (i.e. cognitive or behavioral therapy)** |
| | **Drug** |
| | **Device - therapeutic** |
| | **Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)** |
| | **Surgical** |
| | **Diagnostic test/procedure (research-related diagnostic test or procedure)** |
| | **Obtaining human tissue for basic research or biospecimen bank** |
| x | **Survey instrument** |
| | **None of the above** |

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

## Sponsors

### *Business Administrator*

| | |
|---|---|
| Name: | **GIORDANO, NICHOLAS A** |
| Dept / School / Div: | **602 - Biobehavioral and Health Sciences** |
| Phone: | **-** |
| Fax: | **-** |
| Pager: | |
| Email: | |

### *Department budget code*

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

### *Funding Sponsors*

**Funding sponsors billing address**
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.

**Funding sponsors gift**
Is this research being funded by a philanthropic gift?
No

**Project Funding***
Is this project funded by or associated with a grant or contract?
No

**Sponsor Funding**
Is this study funded by an industry sponsor?

**Status of contract**

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

# Protocol

## *Objectives*

**Overall objectives**
The central hypothesis is that immersive virtual reality opioid related overdose educational trainings will result in increased knowledge retention and comfort level to administer naloxone among community members voluntarily participating in in-person trainings at libraries.

**Background**
Since 2000, the United States has experienced a 200% increase in the rates of deaths by overdose that involve opioids, including opioid pain relievers and heroin. Since 2010, deaths from heroin overdose have more than tripled. In response to this epidemic of deaths by opioid overdose, the state of Pennsylvania, along with more than 40 other states in the nation, have enacted standing orders of Naloxone (Narcan®), a fast acting opiate antagonist. This means that Naloxone, which has been shown to prevent death by reversing opioid overdoses, is available for anyone, without a visit with a healthcare provider, to request and fill a prescription at local pharmacies. As the opioid overdose epidemic worsens, there is an urgent need to prepare individuals to be competent actors in cases of opioid overdoses. Providing access to optimal education on naloxone administration is an important intervention in the effort to reduce deaths by opioid overdose. Library patrons are uniquely positioned to reduce preventable overdose deaths in their communities if properly trained to know when and how to respond. Penn researchers recently developed a nurse led, evidence-based 9 minute virtual reality (VR) naloxone administration educational training. Preliminary results indicate that healthcare profession students participating in VR training at Penn preformed just as well as those who received in person high-tech, high-cost simulation training in regard to their knowledge and attitudes about administering naloxone. Compared to in-person trainings, VR offers an engaging informative naloxone training that requires less manpower and has fewer geographic or time constraints. Assuring optimal education to these key personnel is an important intervention in the fight to reduce deaths by opioid overdose. In September 2019, the Philadelphia Department of Public Health will offer "Narcan Handout Days" at libraries across the city. Health Department staff are present at libraries, sitting at display booths providing training materials and free naloxone kits to library patrons interested in learning more about how to help address the public health crisis. We want to leverage this unique opportunity occurring in September to evaluate the use of virtual reality to provide comprehensive opioid overdose education.

## *Study Design*

**Design**
This study will utilize a cluster-randomized trial design. Entire libraries will be randomized to either offer community members the virtual reality training or the standard educational offerings (e.g. handouts, online videos). Volunteers will be asked to complete the brief, anonymous, and validated Opioid Overdose Knowledge Scale & Opioid Overdose Attitudes Scale prior to receiving an education intervention (pretest) and then again immediately after (posttest). Neither participants nor investigators will be blinded. Library patrons who do not participate in the study will be offered current standard training materials. Regardless of the library's randomization, to either virtual reality or standard training, all patrons completing pre and post test surveys will have the opportunity to view the virtual reality training or other public health department materials.

**Study duration**
The new project dates of the proposed study are September 2019-August 2020. This will enable enrollment to occur throughout September at "Naloxone Handout Days" as well as at once monthly trainings offered by the department of public health at the South Philadelphia Library for local community members to walk in.

# Characteristics of the Study Population

**Target population**
Our target population includes library patrons voluntarily attending the department of public health's "naloxone handout days" and monthly educational trainings. This enrollment strategy across free libraries and zip codes will provide ample opportunities for local city residents living in diverse settings to attend and receive valuable opioid overdose education.

**Subjects enrolled by Penn Researchers**
125

**Subjects enrolled by Collaborating Researchers**
0

### *Vulnerable Populations*

| | |
|---|---|
| | **Children Form** |
| | **Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form** |
| | **Fetuses and/or Neonates Form** |
| | **Prisoners Form** |
| | **Other** |
| x | **None of the above populations are included in the research study** |

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Subject recruitment**
The investigators and personnel listed on this study protocol will be present at each library sitting next to the Department of Public Health staff at a table in each library's lobby. For recruitment of library patrons in September 2019, the investigator or study personnel at the library site on "Naloxone Handout Days" will read a pre-developed script describing the study, explaining potential risks and benefits, and making clear that participation, choosing not to participate, or withdrawing from the study will not influence a patron's ability to use the library or department of public health's resources. This script will be used to guide a brief talk given by a study investigator. A large flyer will be posted next to the table promoting the Virtual reality training for individuals who are interested in learning more and talking to an investigator or study personnel about anonymously participating. Informed consent will be obtained via participants signing the first page before beginning the pre-test survey. After obtaining informed consent, respondents will be asked to complete the pretest baseline assessments. Participants can contact the PI to discuss the study at any time.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Subject compensation***
Will subjects be financially compensated for their participation?
Yes

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document**

None

# Study Procedures

**Suicidal Ideation and Behavior**
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

**Procedures**
During the study period we will be committed to testing the 9 minute virtual reality training to review Naloxone administration and overdose management. The efficacy of this virtual reality education compared to standard educational materials (e.g. online videos, printed handouts) on knowledge retention and attitudes will be evaluated according to the study procedure schema (uploaded separately). As shown in the study procedure schema, all voluntary participants in both experimental and control libraries will complete informed consent documents, provide demographic data, and complete pretest Opioid Overdose Knowledge Scale & Opioid Overdose Attitudes Scale surveys via Qualtrics, a secure online survey system maintained by the University of Pennsylvania and stored behind firewall protected servers. No identifiers will be collected. The surveys are anonymous. Virtual Reality Education (Intervention): The experimental group of libraries will receive the virtual reality simulation, which is guided by the NLN Jeffries Simulation Theory, and lasts 9 minutes. The virtual reality education is based on scenes and dialogue conducted during the hybrid high-fidelity simulation, from a script developed using the existing hybrid simulation on opioid overdose intervention. This virtual reality education is an educational intervention. Standard Educational (Control): The public health department's training includes printed handouts on how to administer naloxone and youtube videos on how to spot signs and symptoms of overdose and administer naloxone. Additionally, staff are on hand to provide one on one verbal educational trainings to local community members voluntarily seeking education. All individuals approaching the table at the library will be introduced to the study and its purpose. If an individual attending the free training is interested in participating the study they will be consented by an investigator listed on this personnel. After consenting all individuals will be asked to complete a brief pre-survey. If the library is randomized to a virtual reality cluster, participants will be asked to view the educational training using provided virtual reality headsets. If the library is randomized to a control cluster the participants will be offered training materials provided by the health department (e.g. youtube videos, printed handouts, on narcan administration). All participants, regardless of cluster will be asked to complete the same survey immediately after either the virtual reality or public health department training. All individuals who participate in the study will have the opportunity to view the virtual reality training or public health department materials at any library regardless of cluster assignment following completion of post-test survey. Those who do not wish to participate in the study will have the opportunity to revieve the public health department's training materials.

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Deception**
Does your project use deception?
No

**International Research**
Are you conducting research outside of the United States?
No

**Analysis Plan**
Descriptive statistics will be calculated for the sample by cluster. Cohorts will be evaluated, pretest, for

differences in demographic characteristics using independent sample t-test, or chi-square test of proportions when appropriate. Similarly, independent t-test will assess differences in pre-test knowledge and attitudes prior to intervention between control and experimental groups, and again with a posttest analysis. Paired t-test will assess within cohort changes in knowledge and attitudes towards recognizing signs of overdose and intervening during an observed opioid related overdose in the community settings. Sample sizes of 30-50 participants, when sampling 6-10 libraries, or clusters, with an with an average of 5 subjects in each cluster, achieves 85% to 94% power to detect a difference in OOKS scores between the group means of at least 4 points using a two sided t-test at significance level of 0.05. The standard deviation of subjects is 5. The intracluster correlation coefficient is assumed to be 0.010. Structural equation modeling will assess differences in control and treatment participants post socres while adjusting for relevant covariates including baseline knowledge and attitudes.

**The following documents are currently attached to this item:**

*There are no documents attached for this item.*

**Subject Confidentiality**
Sources of research material will include data obtained from the Opioid Overdose Knowledge Scale and Opioid Overdose Attitude Scale surveys as well as demographic data. Data will be collected via an anonymous Qualtrics Surveys. Data will be managed by the Principal Investigator on the firewall protected Penn Nursing servers. The minimal risk associated with this study is the risk related to identity protection. Because this study requires measurement of pretest and posttest data, participants data must be matched. Therefore, participants will be given unique identification numbers to use in place of their names to mark their pre- and posttest surveys. In the event of the Qualtrics Survey not being accessible (e.g. wifi outage) hard copies of the survey will be made available. These hardcopies will be stored in a locked file to which only the PI and co-investigator will have access. All electronic and digital data will be stored on a secure survey at the University of Pennsylvania for two years, after which point the data will be destroyed. No identifiers are asked on the anynmous survey.

**Sensitive Research Information***
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

**Data Disclosure**
Will the data be disclosed to anyone who is not listed under Personnel?
No

***Data Protection****

| | |
|---|---|
| | **Name** |
| | **Street address, city, county, precinct, zip code, and equivalent geocodes** |
| | **All elements of dates (except year) for dates directly related to an individual and all ages over 89** |
| | **Telephone and fax number** |
| | **Electronic mail addresses** |
| | **Social security numbers** |
| | **Medical record numbers** |
| | **Health plan ID numbers** |
| | **Account numbers** |
| | **Certificate/license numbers** |
| | **Vehicle identifiers and serial numbers, including license plate numbers** |
| | **Device identifiers/serial numbers** |
| | **Web addresses (URLs)** |
| | **Internet IP addresses** |
| | **Biometric identifiers, incl. finger and voice prints** |
| | **Full face photographic images and any comparable images** |
| x | **Any other unique identifying number, characteristic, or code** |
| | **None** |

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

# Consent

## *1. Consent Process*

**Overview**
For recruitment, a script will be developed describing the study, explaining potential risks and benefits, and making clear that participation, choosing not to participate, or withdrawing from the study will not influence their ability to access library or public health department resources. The study investigators at the library will review the consent form and answer questions any possible volunteer may have. Hardcopies of the form with study contact info will be available for community members to take home. An electronic version will be used for participants to sign and later saved on University firewall protected servers.

# Risk / Benefit

**Potential Study Risks**
The risk associated with this study is the risk related to identity protection. Because this study requires measurement of pretest and posttest data, participants data must be matched pre to post. Therefore, participants will be given unique identification numbers to use in place of their names to mark their pre-

and posttest surveys. All hard copies will be stored in a locked file to which only the PI and co-investigator will have access. All electronic and digital data will be stored on a secure survey at the University of Pennsylvania.

**Potential Study Benefits**
Subjects may personally benefit from increased knowledge retention and attitudes towards intervening in Narcan administration and opioid overdose intervention. This study will produce important knowledge about the comparison of virtual reality simulation and standard education regarding knowledge retention and attitudes about Narcan administration and opioid overdose intervention. Participants also benefit from the opportunity to interact with cutting edge virtual reality simulation technology.

**Risk / Benefit Assessment**
With the knowledge gained from this study, we can determine the optimal means of immersive education, improve Narcan carry-rates, and turn the tide of the opioid overdose epidemic. Because there is minimal risk to the research participants, the opportunity to gain this important knowledge should be supported.

## General Attachments

***The following documents are currently attached to this item:***

**Questionnaires (ooksooas.docx)**

**Recruitment materials (virtualrealityandhybridsimulation_recruitment_library.docx)**

**Informed consent form (informedconsentdocument_library.doc)**

**Additional forms (hco.upenn-vr_los.pdf)**

**Additional forms (studyschema.docx)**

**Cover Letter (coverlettergiordano.pdf)**