Date: 6-25-2020

IRB #: IRB-20-129
Title: VR PNE for middle school students
Creation Date: 6-5-2020
End Date: 6-25-2021
Status: Approved
Principal Investigator: Kory Zimney
Review Board: USD Institutional Review Board
Sponsor:

Study History

Submission Type	Initial	Review Type	Expedited	Decision	Approved
Submission Type	Closure	Review Type	Unassigned	Decision	

Key Study Contacts

Member	Kory Zimney	Role	Principal Investigator	Contact	kory.zimney@usd.edu
Member	Kory Zimney	Role	Primary Contact	Contact	kory.zimney@usd.edu
Member	Adriaan Louw	Role	Co-Principal Investigator	Contact	adriaan@eimpt.com

Initial Submission

Welcome

Please complete the application with as much detail as possible. If you need assistance, feel free to contact the office at 605-677-6184 or humansubjects@usd.edu, or contact us directly using the information provided below.

- Linda Rupp, IRB Coordinator, 605-658-3743 or Linda.Rupp@usd.edu
- Jackie Stelling, IRB Reviewer, 605-658-3763 or Jackie.Stelling@usd.edu
- Ann Waterbury, Director, 605-658-3767 or Ann.Waterbury@usd.edu
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Helpful Links:

- Application resources and guidelines
  USD Consent form templates
- Other study forms, as applicable
- VA- specific forms

Researcher Training

If you haven't yet completed GCP or CITI training, please do so. We accept the following CITI courses:

- GRP 2 Social Behavioral Research for Investigators and Key Personnel, Basic Course.
- GRP 1 Biomedical Research Investigators and Key Personnel, Basic Course
-

- VA- Human Subjects Protection and Good Clinical Practices.

  Note: If your CITI profile is affiliated with USD and includes your USD email as your perferred email, Cayuse will automatically link your profile with all completed CITI modules.

Determination

Are you unsure if this project requires IRB review?

Yes- I need the IRB to determine.

✓ No- My study needs IRB Approval.

Personnel

Please select the Principal Investigator.

1. Name: Kory Zimney
Organization: Physical Therapy
Address: 414 E Clark Street SCSC A384, Vermillion, SD 57069-2390
Phone: 605-658-6373
Email: kory.zimney@usd.edu

Please select the Primary Contact.
(This person will be the main point of contact for the IRB reviewers. VA researchers, please add your R&D Officer)

2. Name: Kory Zimney
Organization: Physical Therapy
Address: 414 E Clark Street SCSC A384, Vermillion, SD 57069-2390
Phone: 605-658-6373
Email: kory.zimney@usd.edu

Please select the Co-Investigators.

3. Name: Adriaan Louw
Organization: External IRB Study
Address:
Phone: , Vermillion, SD 57069-2390
Email: adriaan@eimpt.com

4. Please select the Student Investigators.

Please attach all CITI certificates not taken through USD affiliation.

5.

CITI_Louw_2024.pdf

Describe the Principal Investigator's qualifications to perform or oversee the research.

6.

Dr. Zimney is an Associate Professor on faculty in the University of South Dakota, Department of Physical Therapy actively involved with scholarly work as part of his workload. He is a candidate in the PhD program from Nova Southeastern University. He has been involved in multiple peer-reviewed publications from methodology, data analysis, and dissemination.

If any of the research team members have relevant training, education, or experience that may be valuable to the conduct of this study, please describe here.

7.

Dr. Louw has been involved in multiple research studies in the area of Pain Neuroscience Education (PNE) some of these have been done with middle school students in the past. He has been involved in the development of the virtual reality PNE educational tool to be studied.

8. Are you a VA Researcher?

Yes

✓ No

9. Do you or any of the investigators have a potential conflict of interest associated with this study?

Yes

✓ No

Study Details

1. Is this study externally funded?

- Yes
- ✓ No

2. Have you, or do you plan to, submit this study to another IRB?

- Yes
- ✓ No

3. Is this project for a student thesis or dissertation?

- Yes
- ✓ No

4. Are you attaching letters of approval from any schools or businesses involved?

- Yes
- No
- ✓ N/A

What is the purpose of your research?

5. Investigating the use of a Virtual Reality (VR) pain neuroscience education (PNE) platform with middle school students. We have previously studied the use of PNE with in person educational sessions with middle school kids and video recorded sessions. This study will be looking into utilizing the VR platform for delivery of the educational information.

Study Type

1. Check ALL procedures included in your study:

- [ ] Survey
- [ ] Interview or focus group
- [x] Other non-medical procedures
- [ ] Analysis of biospecimens, existing data, documents, or records
- [ ] Medical intervention

Procedures

From the initial contact of participants through the last contact with participants, please describe the study procedures.

How will you contact them? What will they do as a part of the study?

Potential middle school students will be contacted through fliers to local parents in the Louisville, KY area via various sports team events. We have secured a meeting room space at a large reception room at Lake Forest Country Club (Louisville, KY) on August 4, 2020. Potential participants will call to schedule time for participation to allow for proper staggering of participants arriving on the day of data collection.

1. Research team will set up informed consent space at the entrance to the reception room and stagger participant arrival time to reduce contact with other participants. This space will be cleaned and disinfected regularly during the consenting process as new participants arrive. Once student and parent arrives they will complete informed consent and COVID-19 screening form before being allowed into research space (reception room). Each participant will be given a pen to keep during the research study and go home with also provided with hand sanitizer to use before and after. No pens will be reused with other participants. Masks will be made available for anyone that requests one, but they will not be required while at the testing location. Parents of child will be allowed to sit in waiting chair keeping 6 feet of distance from anyone else. The child research participant will be lead to a chair in the room and complete pre-test questionnaire and then they will be set-up with a Virtual Reality (VR) device (cleaned and disinfected between each use) and go through a VR educational experience (~30 minutes) on Pain Neuroscience Education (PNE). Upon completion of the VR educational session they will complete post-test questionnaire and then be able to leave.

List all surveys, interviews, tests, and interventions from initial screening to closeout, that participants will undergo in the research.

2. Questionnaire for pre and post VR experience provided in attachment. Questions regarding favorite color, favorite TV show and hair color will be used only to match pre and post surveys.

   COVID-19 screening form used to ensure safety of participants and research team.

Attach all surveys, interview questions, tests, ect. here.

COVID_screening form.docx

School_Post_PNE_VR.docx

School_Pre_PNE_VR.docx

3. Where will the research take place?

Large reception room at Lake Forest Country Club; 14000 Landmark Drive, Louisville, KY 40245.

4. Have you notified all areas (personnel and facilities) that need to be prepared to assist you in your research?

No

Yes

✓ N/A

Describe how the subjects' privacy will be protected (i.e. testing or interviewing in private).

5. Privacy is about the person, not the data.
Student participants will complete pre and post test questionnaires at individual station in reception room. We will have only 4 spaces of individuals going through VR experience at any one time to allow for enough physical distance (> 6 feet). All forms will be filled out on paper so participant does not have to verbalize responses.

Staggered times to minimize the number of participants (max of 4) at anytime in the meeting room.

6. Will you be offering compensation or extra credit for participants?

Yes

✓ No

7. Is it possible that medical or psychological services may be needed from participating in this research?

Yes

✓ No

8. Describe how you will ensure that all study personnel are adequately informed about the protocol and their research-related duties?

Dr. Louw and Dr. Zimney have meet and will continue to meet to ensure that research protocol is carried out properly.

9. Will you be using an investigational drug or device?

Yes

✓ No

Participants

What is the maximum number of participants you plan to enroll?

1.

You may estimate, however, your enrollment or data collection and analysis cannot exceed this number.

32

Please describe the study population.

2.

Check all that apply.

- ✓ Males
- ✓ Females
- University Students
- ✓ Students in Grades K-12
- Non-English Speaking

Are you specifically targeting an ethnic group?

3.

Check all that apply.

- American Indian
- African American
- Caucasian
- Alaskan Native

Asian

Pacific Islander

Hispanic

Other

What are the age ranges of the subjects to be enrolled?

4. _____

Check all that apply.

Birth-3

Preschool 3-5

Elementary 5-10

✓ Middle School 10-13

✓ High School 14-17

Adult 18-64

Senior Citizens 64 and up

Select any of the vulnerable populations listed below that will be be enrolled in the study.

5. _____

Check all that apply.

✓ Children

Native American

Pregnant Women

Prisoners

Individuals with diminished mental/physical capacity

Economically/educationally disadvantaged persons

Your Students

Your Employees

Sexuality: Lesbian/Gay/Bisexual/Other Sexual Identities

Gender: Transgender

Please state any inclusionary and exclusionary criteria and how you will screen for this criteria.

6. Inclusion: willing to view VR educational session, in grades 5, 6, 7, or8.
Exclusion: has been through PNE educational program previously, aversion to VR or problems with viewing VR in the past, history of epilepsy or seizures, eye surgery or injury within the last 6 months, open sores or wounds around where VR googles are worn on face, anyone who has had a concussion that has not been cleared for full activity or experiencing any post-concussion syndrome symptoms currently.

How do you have access to the study population?

7. Dr. Louw knows people in the Louisville, KY area. We have provided the PNE education to some of the schools in the area in past and others have expressed interest in getting the education.

8. Will the participants be your students or employees?

Yes

✓ No

Recruitment and Consent

1. How will you contact and select participants?

(i.e. email, flyer, social media)

We will create a flyer to post at athletic team meeting places.

2. How will you obtain consent?

Online

In the content of the email

Mailed to the subject

✓ Verbal/Handout (in person)

Please describe what will be said to the participant to introduce the research, or you may attach a script.

Participants and parent/guardian will be provided informed consent form and given instructions to read the consent form and to ask any questions that they may have.

Attach script here.

Verbal (over the phone)

3. Are you collecting signatures on the consent form?

✓ Yes, hand-written.

Yes, electronic signature.

No, my survey doesn't ask for any identifying information and I wish to keep participation anonymous.

4. Are there any reasons you may need to withdraw a subject from participating?

(not attending appointments, getting injured, etc.)

✓ Yes

Please explain:

If they start to experience any adverse response to the VR environment. If they start to experience any symptoms (severe dizziness, seizures, eye or muscle twitching or blackouts) the VR educational session will be stopped and suggested they follow up with family physician.

No

5. Are there any consequences for participants who voluntary withdraw early from the study?

(such as return of study devices, return to routine care, etc.)

Yes

✓ No

6. Will you be recruiting and enrolling non-English speaking subjects?

Yes

✓ No

Attach ALL recruitment materials and consent forms.

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7. Consent Form Templates can be found here.

Recruitment flier.docx

ConsentStatement_VR_PNE.docx

InformedConsentAssentForChild_VR_PNEI.doc

Risks and Benefits

1. What direct or societal benefits do you expect the subjects to receive from this study?

If there is no direct benefit to the subjects, simply state that.

No direct benefit to participants beyond the educational material provided.

2. Are there any of the following risks associated with the research?

Check ALL that apply:

- [ ] Economic Risk
- [ ] Psychological Risk
- [x] Physical Risk
- [ ] Legal Risk
- [ ] Social Risk

- [ ] Collection or use of audio or video recordings.
- [ ] Use of private records, including educational records or medical charts.
- [ ] Collection of information that would be reportable to authorities or collection of information that might render the subject prosecutable under the law. (e.g. child abuse, use of illegal substances, danger to self or others.)

3. Describe the nature of <u>each</u> risk and how you've attempted to minimize it.

Physical risk as a small percent of the normal population can react to flashes of light as occur in virtual reality or watching TV. They may experience severe dizziness, seizures, eye or muscle twitching or blackouts. The participants will be told to remove the VR headset if they experience an

adverse or abnormal responses while viewing the content. Researchers will also be observing the participant to see if they present with any adverse response to the VR.

4. Are you collecting any of the following information?

Depression

Suicide ideation or thoughts of self-harm

Thoughts of harming others

Traumatic events or experiences

Abuse of any sort (to children, elderly, or spouses, and either emotional or physical)

Illegal activity (alcohol use for those under 21, drug use, criminal acts)

Sexual misconduct (as either victim or perpetrator, and may include dating violence, stalking, assault, or harassment)

Privacy & Confidentiality

Are you collecting an identifier or a link to identify subjects?

1. This could be a name, code, or reference number that might be used to identify the subject outside the context of the research setting. The key question is, "Is there any way that anyone, including the investigator, could start with a data record and trace it back to the person being studies?" If yes, then there is an identifier linked to the subject.

✓ Yes

Explain the link and justify its use.

1a. Each pre and post questionnaire will have the same number on the form to link forms. We do ask general questions about favorite color, favorite TV show, and hair color to match surveys in case the number on the survey gets removed. There will be no names attached to the survey, but the other identifiers could provide a small link to the individual.

Who will have access to the identifiers and who will keep the link?

1b. Only the researchers will have access to the pre and post questionnaires and the identifying information will not be transposed to the excel spread sheet that will eventual house the information provided in the questionnaires once they are matched up pre and post VR session.

How will you limit access to the subjects identifiers?

1c. pre and post questionnaires will be destroyed once information is recorded in Excel file that will be kept on researchers power-on password protected computer.

How and when will the data be de-identified?

1d. It will be de-identified when data entered into computer Excel file.

No

2. Describe the security plan for your data, including where it will be stored and for how long.

You may NOT keep identifiable data indefinitely.

Data will be saved for 3 years on a power-on password protected computer.

3. Per federal law and USD IRB policy, do you agree to keep a copy of the de-identified data for three years (six years for VA)

✓ I agree

I do not agree

HIPAA

1. Will you be ACCESSING Protected Health Information (PHI) for screening and recruitment purposes?

- Yes
- ✓ No

2. Will you be COLLECTING Protected Health Information (PHI)?

- Yes
- ✓ No

Closure Submission

Project Closure Form

1. Please check the reason for closing the project:

✓ Project complete

Enrollment closed; research activities limited to analysis of data or biospecimens only.

Investogator is moving to another institution.

Project not conducted or canceled.

2. How many total subjects were enrolled (or data points/biospecimens analyzed)?

20

3. How many total subjects did the IRB approve to be enrolled (or data points/biospecimens analyzed)?

32

If more subjects were enrolled than what was approved, please explain how this happened and why an amendment was not submitted:

n/a

4. Are the data de-identified?

✓ Yes
No

5. Does a code key linked with the identifiers still exist?

Yes
✓ No

6. Have all recordings been transcribed without identifying information and destroyed?

Yes
No
✓ N/A

7. Describe how and where you will store your data and/or biospecimens?

Data stored on PI's power-on password protected computer.

8. What will be done with the data and/or biospecimens from this study after it is closed?

Check ALL that apply.

✓ Possibly used in future research.

Will not be used in future research.

Copies of data or biospecimens will be taken with PI to new institution.

Briefly describe your study and, if applicable, your findings and a final summary:

9. 20 participants viewed the PNE VR session. No adverse events were reported during or after viewing the 45 minute VR session. A few small positive shifts in pain beliefs occurred after viewing the VR session, but none rose to level of significance. Also there was a reduction in fear related to pain, but only one question within the FABQ PA rose to significance. There was a significant shift in pain knowledge post viewing the PNE VR session.

If applicable, please attach your final report.

PNE Virtual Reality Middle School.pdf

Reminder: The Principal Investigator is required by federal law to maintain all study records, including consent forms and a copy of the de-identified data.

- After study closure, research records must be kept for 3 years (5 years if VA research and 6 years if HIPAA protected), regardless of why the study was closed.
- Studies that involve FDA-approvals must maintain records for 2 years after the FDA has taken final action on the marketing application.
- All records of human subject research are subject to inspection by federal authorities and the IRB.

✓ I agree

Date: June 25, 2020

The University of South Dakota
414 E. Clark Street
Vermillion, SD 57069

PI: Kory Zimney Adriaan Louw

Re: Initial - IRB-20-129, VR PNE for middle school students

The University of South Dakota Institutional Review Board has rendered the decision below for this study. The approval is effective starting June 25, 2020 and will expire on June 25, 2021.

Decision: Approved
Category: Expedited 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Associated Documents: Date-Stamped Advertisement, Date-Stamped Parental Consent, Date-Stamped Assent,

Screening Form, Questionnaires

Dear Kory Zimney,

The study submission for the proposal referenced above has been reviewed and approved via the procedures of the University of South Dakota Institutional Review Board.

Attached in your file is the original consent document that has been stamped with IRB approval and expiration date. You must keep this original on file. Please use the original document to make copies for subject enrollment. No other consent form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject must be given a copy of the signed consent form.

Prior to initiation, promptly report to the IRB, any proposed updates/amendments (e.g., protocol amendments/revised informed consents) in previously approved human subjects research activities.

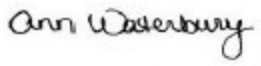
Any research-related injuries (physical or psychological), adverse side effects, or other unexpected problems encountered during the conduct of this research study needs to be reported to the IRB within 5 days of notification of the occurrence.

Any modifications to the approved study must be submitted for review through Cayuse IRB. All approval letters and study documents are located within the study details in Cayuse IRB.

You have approval for this project through June 25, 2021. When this study is completed please submit a closure form through Cayuse. If the study is to last longer than one year, a continuation form needs to be submitted through Cayuse at least 14 days prior to the expiration of this study.

If you have any questions, please contact: humansubjects@usd.edu or (605) 658-3743. Sincerely,

The University of South Dakota Institutional Review Board



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