AWARD NUMBER: W81XWH-15-C-0088

TITLE: Improving Access to Care for Warfighters: Virtual Worlds Technology to Enhance Primary Care Training in Post-Traumatic Stress and Motivational Interviewing

PRINCIPAL INVESTIGATOR: Karen H. Seal, MD, MPH

CONTRACTING ORGANIZATION: Northern California Institute for Research and Education at San Francisco Veterans Affairs San Francisco, CA 94121

REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
**4. TITLE AND SUBTITLE**

Improving Access to Care for Warfighters: Virtual Worlds Technology to Enhance Primary Care Training in Post-Traumatic Stress and Motivational Interviewing

**6. AUTHOR(S)**

Karen H. Seal, MD, MPH

Email: karen.seal@va.gov

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**

Northern California Institute for Research and Education at San Francisco Veterans Affairs Health Care System  
4150 Clement Street  
San Francisco, CA 94121

**14. ABSTRACT**

Veterans present to primary care providers (PCPs) with posttraumatic stress (PTS) symptoms because many are resistant to specialty mental health care. Most PCPs have not been trained to assess for and manage symptoms of PTS or motivate Veterans to engage in treatment. This can result in missed opportunities to intervene to prevent chronic mental and physical health problems. Therefore, the project aims to: (1) iteratively design a new web-based PTS and Motivational Interviewing training for PCPs using Virtual World technology to enhance interactivity; (2) implement a robust evaluation including a randomized control trial for clinically valid outcome measurement; (3) Conduct a summative evaluation to inform national “scale-up” dissemination and implementation. The final product will be a deliverable that will improve access to quality clinical care for our warfighters suffering with PTS. This report shares progress made during Year 1 of the project, which includes a developmental formative evaluation and storyboards displaying the training content. Year 2 will be dedicated to the build, refinement, and implementation of the virtual world training.
# Table of Contents

1. INTRODUCTION.........................................................................................................................4
2. KEYWORDS........................................................................................................................................4
3. ACCOMPLISHMENTS.....................................................................................................................5
4. IMPACT...........................................................................................................................................15
5. CHANGES/ PROBLEMS...................................................................................................................16
6. PRODUCTS........................................................................................................................................18
7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS.....................................................20
8. SPECIAL REPORTING REQUIREMENTS.........................................................................................22
9. APPENDICES...................................................................................................................................24
1. INTRODUCTION

Veterans present to primary care providers (PCPs) with posttraumatic stress (PTS) symptoms because many are resistant to specialty mental health care. Most PCPs have not been trained to assess for and manage symptoms of PTS or motivate Veterans to engage in treatment. This can result in missed opportunities to intervene to prevent chronic mental and physical health problems. The project aims are to: (1) iteratively design a new web-based PTS and Motivational Interviewing training for PCPs using Virtual World technology to enhance interactivity; (2) implement a robust evaluation including a randomized control trial for clinically valid outcome measurement; (3) conduct a summative evaluation to inform national "scale-up" dissemination and implementation. The project will produce a deliverable that will improve access to quality clinical care for our warfighters suffering with PTS. This report shares progress made during Year 2 of the project.

2. KEYWORDS

Virtual world; PTSD; medical education; virtual training; curriculum development; motivational interviewing
3. ACCOMPLISHMENTS

Year 1 of the project was dedicated to the developmental formative evaluation and curriculum development for the Virtual World PTSD and Motivational Interviewing training. The Principal Investigator, Project Coordinator, and other Co-Investigators advanced the development of the training curriculum, focusing on building content that is consistent with the overall learning objectives. Concurrently, the vendors at Heyden Ty provided guidance for virtualizing elements of the curriculum to build an engaging and impactful training.

Year 2 of the project was largely dedicated to building the virtual world. The curriculum and content developed during Year 1, were implemented into the learning environment by our developers at Chant Newall Development Group (CNDG). As the virtual world was being built, the team continued to refine the curriculum and content to ensure a high quality educational product that achieves learning objectives and fits within the limitations of the virtual world platform. The research team, vendors at Heyden Ty, and developers at CNDG met weekly to go over the progress of the build and project deadlines.

Furthermore, we conducted a focus group with Co-Investigators to get feedback on the training curriculum and activities. The Co-Investigators range from Primary Care providers to Mental Health providers, giving well rounded feedback. The feedback from the focus group was implemented back in to virtual world learning environment. We recruited for the next focus group that includes providers who are unrelated and unfamiliar with the project. The focus group was conducted on October 18, 2017. These individuals went through a demo training in-world and provided feedback which we are implementing in to the learning environment.

The Project Coordinator continues to work on the control condition (the online training that was tested in our prior study). The slides have been updated and we are in the process of adding interactive content. Because the control is a video, we must re-record some parts of the video to be consistent with the DSM-5 updates. We have identified who will be the voice on the video and are in the process of re-rerecording. The Project Coordinator has also started communicated with universities regarding CME accreditation. Both arms need to be submitted for approval in the CME application process. We estimate that both tasks will be complete in November 2017.

<table>
<thead>
<tr>
<th>a. What were the major goals of the project?</th>
<th>Timeline (Months)</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major Task 1: Obtain local IRB and VA R&amp;D and HRPO Approvals.</strong></td>
<td>1-2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtask 1: File protocol with Local IRB</strong></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtask 2: File protocol with VA R&amp;D</strong></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtask 3: File protocol with HRPO</strong></td>
<td>1-2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Subtask 4: Make any required revisions and resubmit in the above order.</strong></td>
<td>1-2</td>
<td>3</td>
</tr>
<tr>
<td><strong>Subtask 5: Obtain Local IRB/ VA R&amp;D/ HRPO Approval</strong></td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>
### Milestone #1: Local IRB/ VA R&D/ HRPO Approval

#### Aim 1: To conduct a developmental formative evaluation to iteratively inform a Virtual World (VW) design based on our prior web-based posttraumatic stress (PTS) training for primary care providers (PCPs).

<table>
<thead>
<tr>
<th>Major Task 2: Semi-Structured interviews with project stakeholders/key informants to inform curriculum content and instructional design</th>
<th>3</th>
<th>7-10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtask 1:</strong> Recruit &amp; enroll stakeholders/key informants</td>
<td>3</td>
<td>7-9</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Qualitative analysis of curriculum content and instructional design.</td>
<td>3</td>
<td>9-12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major Task 3: Begin Virtual World (VW) build</th>
<th>2-12</th>
<th>7-19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtask 1:</strong> Design curriculum based on data from semi-structured interviews.</td>
<td>2-4</td>
<td>8-12</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Host VW learning environment (initially in Second Life)</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td><strong>Subtask 3:</strong> Build an Orientation Center</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td><strong>Subtask 4:</strong> Create a storyboard</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td><strong>Subtask 5:</strong> Import and create virtual objects</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td><strong>Subtask 6:</strong> Create avatar types</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td><strong>Subtask 7:</strong> Secure the VW environment</td>
<td>10</td>
<td>In progress</td>
</tr>
<tr>
<td><strong>Subtask 8:</strong> Conduct quality checks</td>
<td>11</td>
<td>In progress</td>
</tr>
<tr>
<td><strong>Subtask 9:</strong> Migrate to other VW platform (e.g. UNITY)</td>
<td>12</td>
<td>17</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major Task 4: Independent review of new VW training using a focus group</th>
<th>12-15</th>
<th>24-25</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtask 1:</strong> Recruit stakeholders/key informants, including PCPs, who were not involved in initial build recommendations</td>
<td>12-14</td>
<td>24</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Conduct 1 Focus Group</td>
<td>13, 14</td>
<td>25</td>
</tr>
<tr>
<td><strong>Subtask 3:</strong> Make revisions based on feedback</td>
<td>15</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major Task 5: Refinement of the VW training</th>
<th>16</th>
<th>24-25</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtask 1:</strong> Recruit independent reviewers for Focus Group</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Conduct final focus group to review revisions</td>
<td>16</td>
<td>22</td>
</tr>
<tr>
<td><strong>Subtask 3:</strong> Study co-investigators beta-test training and project staff</td>
<td>16</td>
<td>In progress</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Major Task 6: Refinement of prior online training (Control) to make it a more apt comparison for RCT.</th>
<th>17</th>
<th>17-18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtask 1:</strong> Update content to be consistent with PTS diagnosis in DSM 5</td>
<td>17</td>
<td>20</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Add simple interactive content</td>
<td>17</td>
<td>In progress</td>
</tr>
</tbody>
</table>

**Milestone #2: VW and Control condition complete**
Incomplete, est. 26
<table>
<thead>
<tr>
<th>Specific Aim 2: <strong>Conduct a randomized controlled trial of a Virtual World training vs. a traditional web-based training to evaluate effectiveness using “gold standard” educational outcomes.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major Task 7:</strong> Obtain CME accreditation for the trainings</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Contact Universities’ CME offices and register as a vendor</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Collaborate with CME offices to host training</td>
</tr>
<tr>
<td><strong>Major Task 8:</strong> Develop self-report measure battery to assess relative change in self-reported PTS-related knowledge and clinical skills self-efficacy.</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Develop test of self-reported PTS-related knowledge and clinical skills self-efficacy</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Beta test online hosting of self-report measures</td>
</tr>
<tr>
<td><strong>Major Task 9:</strong> Develop telephone Standardized Patient (SP) Interview to assess relative change in PTS-related competency (Primary Outcome) and MI skills to assess and manage PTS symptoms and to motivate engagement in care.</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Train the SP actors and calibrate fidelity monitoring.</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Calibrate the SP assessment instrument</td>
</tr>
<tr>
<td><strong>Subtask 3:</strong> Calibrate the use of the MITI global rating of MI performance</td>
</tr>
<tr>
<td><strong>Major Task 10:</strong> Recruitment/Eligibility Screening</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Develop and Refine eligibility screening</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Beta test eligibility link to minimize false eligibility</td>
</tr>
<tr>
<td><strong>Major Task 11:</strong> Recruit PCPs from VA, DoD, and community</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Develop recruitment tools (email, e-flyers)</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Send email blasts</td>
</tr>
<tr>
<td><strong>Major Task 12:</strong> Conduct Enrollment and Informed Consent</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Verify eligibility requirements</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Assign subject ID</td>
</tr>
<tr>
<td><strong>Major Task 13:</strong> Conduct baseline assessments</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Disseminate baseline link to eligible participants</td>
</tr>
<tr>
<td><strong>Major Task 14:</strong> Obtain Patient Outcomes</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Make VA data request and clean administrative data</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Obtain and analyze VA outcomes data on patient health services utilization</td>
</tr>
<tr>
<td><strong>Major Task #15:</strong> Randomization</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Develop stratified block randomization list</td>
</tr>
<tr>
<td><strong>Major Task #16:</strong> VW vs. Control training</td>
</tr>
<tr>
<td><strong>Subtask 1:</strong> Conduct 3 VW trainings</td>
</tr>
<tr>
<td><strong>Subtask 2:</strong> Control training</td>
</tr>
</tbody>
</table>
What was accomplished under these goals?

Major Task 1: Obtain local IRB and VA R&D and HRPO Approvals. – Complete

  Subtask 1: File protocol with Local IRB.
  Subtask 2: File protocol with VA R&D.
  Subtask 3: File protocol with HRPO.
  Subtask 4: Make any required revisions and resubmit in the above order.
  Subtask 5: Obtain Local IRB/ VA R&D/ HRPO Approval.

Submitted to and Approved by:
University of California San Francisco Committee on Human Research- 14-15004
- Study Approval (Continuing Review) 09/03/2016-05/04/2017
- Amendment 1: personnel changes - 08/12/2015
- Amendment 2: personnel changes- 21/12/2015
- Amendment 3: personnel changes, increased number of SSIVs, interview guide- 09/03/201)
- Protocol Violation: acknowledged on 09/27/2016- Semi-structured interviews were conducted as part of the study's developmental formative evaluation. The subjects (interviewees) are primary care providers at the VA. The protocol states that the interviews are to be conducted via telephone. On July 13, 2016, immediately prior to the interview, the subject requested to be interviewed in person, rather than over the phone. This was a non-veteran subject, a physician on staff at SFVAMC. The researcher complied with the subject’s request and conducted the interview in person. The verbal consent process was executed as part of the interview, however, no signed consent was obtained for this incident.
- Continuing Review: with personnel changes- approved 22/03/2017
- Amendment 4: personnel changes- 12/05/17
- Amendment 5: personnel changes; administrative changes to the Information Sheet; modification to the recruitment material; addition of a new Interview Guide- 09/06/2017
- Amendment 6: participant thank you letter- 30/8/2017
- Amendment 7: personnel changes, recruitment document changes, website text, interview guide- 13/10/17

VA Research & Development and Clinical Research Workgroup
- CRW- Approval 22/04/2015
- VA R&D - Approval 07/05/2015
  o Renewed 09/03/2016
  o Renewed 22/03/2017

DoD Human Research Protection Office A18590
- Approval 17/9/2015
- Continuing Review Approved 26/04/2016
- Continuing Review Approved 18/04/2017

Major Task 2: Semi-Structured interviews with project stakeholders/key informants to inform curriculum content and instructional design – Complete
• The qualitative team began interviewing 11 Clinical Educators and healthcare leadership. Additional interviews may be conducted with educational experts and Information Technology (IT) experts on an ongoing basis. The Qualitative Researchers assert that this will produce the most relevant data, since there will be beta elements of the training to share and discuss with interviewees at different milestones of the curriculum and virtual training development.

• The overall conclusions from the developmental formative evaluation include:
  1. Findings about challenges in primary care practice related to providing care to veterans with PTSD as well as treatment choices by PCPs and use of motivational interviewing are consistent with the published studies.
  2. Findings support the need for training for PCPs focused on PTSD and MI applied to providing care for patients with PTSD.
  3. Opinions of interviewed PCPs about VW training were limited to their insufficient understanding of VW.
  4. This formative evaluation generated implications for audience generation, content, and training delivery and evaluation, and training generalizability that are being utilized for the VW training development in this project.

Subtask 1: Recruit & enroll stakeholders/key informants
- Project Coordinator and Research Assistant recruited and enrolled stakeholders/key informants from a potential pool of participants established by the PI and Project Team.
- Recruitment began in April 2016 and will continue as deemed necessary.
- PI and Qualitative Researcher have conducted 11 semi-structured interviews, to date.

Subtask 2: Qualitative analysis of curriculum content and instructional design.
- Qualitative Analyst analyzed semi-structured interview results in relation to the curriculum content and instructional design.
- Content experts from the project team have reviewed and offered insight on curriculum storyboards.
- Findings from the analyses of ten interviews were shared in a Technical Report.

Major Task 3: Begin Virtual World (VW) build – In Progress
Subtask 1: Design curriculum based on data from semi-structured interviews.
- Analyzed evaluation data was displayed in a matrix (within Appendix A), and shared with the curriculum development team to inform the refinement of the training curriculum.
- Storyboards detailing the content for Sessions 1 and 2 of the training were refined and submitted to CNDG. CNDG will transform the concepts into a beta version of the training.

Subtask 2: Host VW learning environment (initially in Second Life, now in Unity)
- Project Team members have been oriented to Unity. CNDG hosted team members in an existing learning environment and solicited feedback regarding the characteristics of virtual spaces and avatars to help inform the environment they will build specifically for this project during a project-wide meeting on 26-04-2016.
- They submitted a video detailing their progress on 22-06-2016.
- CNDG created a virtual campus, which contains a hospital building with internal exam rooms for Standardized Patient interviews.
- As the developers at CNDG build additional training components, the Project Team will continue to monitor progress and offer feedback.

Subtask 3: Build an Orientation Center
- CNDG held several orientation sessions for project staff and collaborators in the virtual world. The Orientation Center environment provides instructions on how to navigate, as well as serves as a test for computer compatibility.
Orientation has been completed for the focus groups and is ready for trial initiation.

**Subtask 4:** Create a storyboard
- Heyden Ty, our vendor which specializes in virtual learning curriculums, submitted storyboards for each segment of the two-session training on 15-06-2016. These storyboards contain the proposed learner experience during the various segments of the training: Exploratorium, Didactic/Lecture, Small Group Standardized Patient Interviews, and Homework. Additionally, they contain content and directions for the engineering experts at CNDG.
- Much of Year 1, Quarter 4 was spent refining these storyboards to include feedback from the developmental formative evaluation.
- The story boards have been finalized by Dr. Seal and our consultants.

**Subtask 5:** Import and create virtual objects
- CNDG created a video which presents virtualized elements of the storyboards and curriculum for the project team and Principal Investigator to review. Examples include polling stations, presentation screens, whiteboards for instructor and learner, and click-to-view information posters. They will continue to develop virtual objects and refine the environment until the build is complete.

**Subtask 6:** Create avatar types
- CNDG created sample avatars for the training, based on the specifications provided to them by the Project Coordinator. Additionally, they created a prototype of the veteran, which will serve as the case study for the duration of the training.
- CNDG completed the avatar for the character Alex and 36 avatars for the trial participants to use and customize.

**Subtask 7:** Secure the VW environment- In progress
- The environment is nearing completion, with an estimate of being done in month 27 after adjusting for feedback based on focus groups in month 25. As sections are completed they are secured, such as the orientation center and main hospital lobby. Some areas within the VW continue to be adjusted for optimum user experience.

**Subtask 8:** Conduct quality checks- In progress
- Quality checks are ongoing. Different individuals on the team routinely meet to test out functionality of the virtual world as it is being developed.

**Subtask 9:** Migrate to other VW platform (e.g. UNITY)
- This subtask is no longer relevant. Before the build started, our developers made the decision to use UNITY through the entire build process. The platform is being built in UNITY and will be hosted in UNITY so a migration was never required.

**Major Task 4: Independent review of new VW training using a focus group- In progress**
**Subtask 1:** Recruit stakeholders/key informants, including PCPs, who were not involved in initial build recommendations
- Recruitment for the focus group has been completed.

**Subtask 2:** Conduct 1 Focus Group
- Due to a delay in finding a new project coordinator, there was a delay in completing the focus groups.
- The focus group was completed on October 18, 2017.

**Subtask 3:** Make revisions based on feedback
- The focus group was completed on October 18, 2017 so we have not yet had time to make revisions. The qualitative interviewer will compile the collected data and present the feedback for revisions in late October 2017. The revisions will be made in November 2017.
Major Task 5: Refinement of the VW training- In progress
Subtask 1: Recruit independent reviewers for Focus Group
  • The recruitment for the focus group was completed.
Subtask 2: Conduct final focus group to review revisions-in progress
  • The focus group was completed on July 10, 2017 with PCPs within the VA system.
Subtask 3: Study co-investigators beta-test training and project
  • A meeting with the co-investigators to beta-test the training will we be planned and occur before the RCT starts.

Major Task 6: Refinement of prior online training (Control) to make it a more apt comparison for RCT- In progress
Subtask 1: Update content to be consistent with PTS diagnosis in DSM-5
  • With the help of the Psychologist Co-Investigators we have revised the curriculum to be aligned with DSM 5 PTS criteria.
Subtask 2: Add simple interactive content
  • We are working with our web designer to add some simple interactive content to the Control training.

Major Task 7: Obtain CME accreditation for the trainings- In Progress
Subtask 1: Contact universities’ CME offices and register as a vendor
  • Several universities have been contacted and we will be moving forward with CME accreditation at University of California, San Francisco (UCSF). We have a contact there who is ready to look at our trainings when they are complete.
Subtask 2: Collaborate with CME offices to host trainings
  • No longer applicable. VW will be hosted on CNDG controlled server allowing for easier access by programmers in the event of any difficulty. We will work with UCSF to ensure that this set-up is compatible with their systems.

Major Task 8: Develop self-report measure battery to assess relative change in self-reported PTS-related knowledge and clinical skills self-efficacy- In Progress
Subtask 1: Develop test of self-reported PTS-related knowledge and clinical skills self-efficacy
  • Standardized outcomes assessments have been complied.
  • Assessments include outcomes measures for things such as demographics, clinical skills and comfort for assessing PTS, knowledge of PTS, feedback on training, and intervention usability.
Subtask 2: Beta test online hosting of self-report measures
  • Our data manager will input the self-report measures in to our online host, Qualtrics, in November 2017.
  • Our project coordinator and data manager will beta test the measures in November 2017.

Major Task 9: Develop telephone Standardized Patient (SP) Interview to assess relative change in PTS-related competency (Primary Outcome) and MI skills to assess and manage PTS symptoms and to motivate engagement in care - Incomplete
Subtask 1: Train the SP actors and calibrate fidelity monitoring
  • This task will be completed by the time of the start RCT in January 2018.
  • The hiring and training takes of standardized patients will start in November 2017.
Subtask 2: Calibrate the SP assessment instrument
- This task will be completed by the time of the start RCT in January 2018.
- This task will occur in December 2017.

Subtask 3: Calibrate the use of the MITI global rating of MI performance
- This task will be completed by the time of the start RCT in January 2018.
- This task will occur in December 2017.

Major Task 10: Recruitment/Eligibility Screening – In progress
Subtask 1: Develop and Refine eligibility screening
- The eligibility screener has been developed.
- The project coordinator modified the eligibility screener and will submit to the IRB for approval.
Subtask 2: Beta test eligibility link to minimize false eligibility
- After the changes to the eligibility screener have been approved by the PI and IRB, the project coordinator and data manager will upload the screener to the online platform and beta test for fidelity. We estimate this will occur in November 2017.

Major Task 11: Recruit PCPs from VA, DoD, and community – In progress
Subtask 1: Develop recruitment tools (email, e-flyers)
- The project coordinator has put together recruitment tools and submitted them to IRB for approval.
Subtask 2: Send email blasts
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.

Major Task 12: Conduct Enrollment and Informed Consent - Incomplete
Subtask 1: Verify eligibility requirements
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.
Subtask 2: Assign subject ID
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.

Major Task 13: Conduct baseline assessments - Incomplete
Subtask 1: Disseminate baseline link to eligible participants
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.

Major Task 14: Obtain Patient Outcomes - Incomplete
Subtask 1: Make VA data request and clean administrative data
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.
Subtask 2: Obtain and analyze VA outcomes data on patient health services utilization
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.
Major Task #15: Randomization - Incomplete  
Subtask 1: Develop stratified block randomization list  
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.

Major Task #16: VW vs. Control training - Incomplete  
Subtask 1: Conduct 3 VW trainings  
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.  
Subtask 2: Control training  
- This task is part of the randomized control which cannot start until major tasks 1-10 have been completed. We expect the randomized control trial to begin in January 2018.

What opportunities for training and professional development has the project provided?  
The providers who have participated in the focus groups have had the opportunity to learn more about trainings in a virtual environment.

How were the results disseminated to communities of interest?  
The team presented an abstract at the Society for Academic Continuing Medical Education (SACME) in May 2017 in Scottsdale, AZ. We will continue to create and present products as more data is collected and analyzed.

What do you plan to do during the next reporting period to accomplish the goals?  
We will continue working closely and having weekly meetings with CNDG and HeydenTy to complete the build of the virtual world. The PI and project coordinator will work closely to complete all the necessary task for the randomized control trial by the end of 2017, including, obtaining CME accreditation, completing the changes in the control arm training, finalizing the outcomes assessments, and training of the Standardized Patient.

We will start the randomized control trial at the beginning of 2018 which will include the following tasks:  
Major Task 11: Recruit PCPs from VA, DoD, and community  
Major Task 12: Conduct Enrollment and Informed Consent  
Major Task 13: Conduct baseline assessments  
Major Task 14: Obtain Patient Outcomes  
Major Task #15: Randomization  
Major Task #16: VW vs. Control training
Major Task #17: Post-training assessment
Major Task #18: Follow-up assessment after a period of 90 days of no contact

While, we are currently behind schedule due to delays in the build of the virtual world and the turnover of staff, we are confident that we can make up time during the RCT and still complete the study on time. We will accomplish this with aggressive recruitment of subjects and shortening the time intervals between intervention arm trainings from every 7 months to every 5-6 months.
4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

While it is too early to cite specifics, the project has the potential to make an impact on primary care provider education and continuing medical education relating to health issues affecting both mind and body, including post-traumatic stress disorder. Since the training is delivered virtually, it can easily be disseminated world-wide.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

While the product we are developing is a training for Primary Care Providers, our work has produced a very versatile platform that is now available to the DOD and VA for other purposes. The platform is flexible, extensible, and could easily be used for other types of trainings or gatherings. Furthermore, since this is virtual, it could be used within the DOD or VA for providers around the world to meet, interact and easily disseminate information without costly travel.

What was the impact on society beyond science and technology?

The developmental formative evaluation and focus groups reveal a fair amount of hesitation toward virtual world training for continuing medical education. Several PCPs indicated generational differences in acceptability and ability to navigate and learn in a virtual environment. As the findings are applied to the curriculum and design of the training, the project has the potential to improve public knowledge and attitudes toward virtual world technology for the sake of provider education. We are developing this technology for future healthcare professionals so that they will be able to use the next generation of tools and capability. What feels challenging today will feel like second-nature in the future.
5. CHANGES/PROBLEMS

Changes in approach and reasons for change

We originally proposed prototyping and building in SecondLife and then migrating objects to Unity but over the period of time from proposal to project start, Sinewave developed building tools and the ability to customize the viewer for our learners that gave us much more control and flexibility. Given the needs of the DOD and the VA to house the product on their own servers, behind their firewall, we opted to build directly in Unity and use a customized Sinespace viewer for our learners.

Actual or anticipated problems or delays and actions or plans to resolve them

1. Resolved: Our original project coordinator left in December 2016. We were without a project coordinator for 5 months. In May 2017, we hired a new coordinator and unfortunately he went on to pursue other opportunities in August 2017. Since then an experienced project coordinator, who has worked with Dr. Seal for 2.5 years, has taken over the project. The staff turnover resulted in some delays, however we expect to be back on to schedule and the randomized control trial portion of the trial will still be completed on time.

2. Delay: As previously stated, there is a delay in development of the virtual world (major task 3) because we are using a newly developed platform (Sinewave and Unity) which caused us to hit unavoidable glitches and bugs which we have had to work through.
   • Course of action being taken: We continue to work through these bugs as they occur and are working very hard to have the build of the world complete by December 2017.

3. Delay: We are moving forward with the steps necessary to get the randomized control portion of the study running by January 2018. The delays are largely due to not being adequately staffed in project year 2. Now that we have seasoned staff (Project Coordinator, Qualitative Analyst) on board we are very optimistic that we will be able to meet future milestones. The virtual world build must be complete in order to begin the RCT, as a result other related activities have been delayed in order to adjust the timeline.
   • Course of action being taken: The PI and project coordinator are dedicated to getting the RCT started in January 2018. Therefore, they are scheduling extra meetings and working extremely hard to get everything ready for the RCT.

4. Ongoing Problem: The online platform which will host the product during the development phase, is blocked on the VA network. This makes it difficult for staff to work on the project.
   • Course of action being taken: Project Staff and CNDG have come up with temporary solutions that allow access to the world when needed. Long term, the product will be black boxed and placed behind the firewall so that internal DOD and VA personnel will be able to access the product.
Changes that had a significant impact on expenditures

Less was expended on payroll during the initial budget period due to staffing shortages. We have since worked with the DoD to carry forward those funds and have applied them towards increased staffing in an effort to meet future milestones.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.
6. PRODUCTS

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers, and presentations.

Presentations:


Website(s) or other Internet site(s)

A project website focused on recruitment and dissemination of project information was developed during Year 2. The website is still private because it is undergoing approval from the IRB but it will go live for the start of the RCT in January 2018.

URL: http://pcpsandptsd.com/

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

There are several products for internal use, which facilitate the design and implementation of the virtual world training:

- The qualitative team produced a Technical Report (Appendix A) for internal use. The report details data collected through semi-structured interviews with PCPs and its relevance to current research in the field of PTSD treatment, as well as virtual world education. The qualitative team produced a matrix for internal use with Focus Group data analysis (Appendix B). The matrix will be used to provide feedback to the developers about changes that still need to be made in the world
- A storyboard representing the overall look and feel of the virtual world environment. (Appendix C)
- A storyboard for each of the two training Exploratoriums. (Appendix D)
Within these storyboards is the framework for “Exploratorium” learning stations that potentially can be used as stand-alone training tools.

- A didactic for each of the two training lectures (Appendix E)
  - These didactics could potentially be used as stand-alone training tools
7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

**Project Staff**
Name: Karen Seal, MD, MPH  
Project Role: Principal Investigator  
Nearest person month worked: 2.4  
Contribution to Project: Unchanged

Name: Ryan McCormick  
Project Role: Project Coordinator  
Nearest person month worked: 3.5  
Contribution to Project: Left institution in August 2017

Name: Coleen Hill  
Project Role: Project Coordinator  
Nearest person month worked: 1  
Contribution to Project: Began working on project in September 2017

Name: Nicole R. McCamish  
Project Role: Project Manager  
Nearest person month worked: 7.2  
Contribution to Project: Unchanged

Name: Linda Abadjian, PhD  
Project Role: Evaluator  
Nearest person month worked: 1.8  
Contribution to Project: Unchanged

Name: Yongmei Li, PhD  
Project Role: Statistician  
Nearest person month worked: 6  
Contribution to Project: Unchanged

Name: Shira Maguen, PhD  
Project Role: Co-Investigator  
Nearest person month worked: 0.6

Name: Thomas Neylan, MD  
Project Role: Co-Investigator  
Nearest person month worked: 0.3  
Contribution to Project: Unchanged

Name: Beth Cohen, MD, MAS  
Project Role: Co-Investigator  
Nearest person month worked: 0.6  
Contribution to Project: Unchanged

Name: Greg Reger, PhD
Project Role: Co-Investigator  
Nearest person month worked: 0.6  
Contribution to Project: Unchanged  

Name: Jamie Chang, PhD  
Project Role: Qualitative Researcher  
Nearest person month worked: 0.15  
Contribution to Project: Began working on project in February 2017  

Name: Natalie Purcell, PhD  
Project Role: Qualitative Researcher  
Nearest person month worked: 0.0  
Contribution to Project: Began working on project in October 2017  

Vendors  
Name: Chant Newall Development Group  
Project Role: Consultant  
Paid by deliverables per the SOW  
Contribution to Project: Unchanged  

Name: Forefront Collaborative  
Project Role: Consultant  
Paid hourly on a semi-annual basis  
Contribution to Project: Unchanged  

Name: Heyden Ty  
Project Role: Consultant  
Paid by deliverables per the SOW  
Contribution to Project: Unchanged  

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**  
Natalie Purcell, PhD joined the team in October 2017 at 3 calendar months to finish the focus groups and begin preparations for the standardized patient portion of the study.  

**What other organizations were involved as partners?**  
Nothing to report.  

8. **SPECIAL REPORTING REQUIREMENTS**
<table>
<thead>
<tr>
<th>Aim 1 Formative Eval/Design</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
<th>FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Task 2: Semi-Structured interviews with project stakeholders/key informants to inform curriculum content and instructional design</td>
<td>Anticipated: N=up to 20</td>
<td>Actual: N=11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Task 4: Independent review of new VW training using a focus group - Recruit stakeholders/key informants who were not involved in initial build recommendations</td>
<td>Anticipated: N=8</td>
<td>Actual: N=3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Task 5: Refinement of the VW training - Independent reviewers for Focus Group</td>
<td>Anticipated: N=8</td>
<td>Actual: N=5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aim 2 RCT</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
<th>FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Task 11: Recruit PCPs from VA, DoD, and community</td>
<td>Anticipated: N=100</td>
<td>Actual:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aim 3 Summative Eval/Disseminate</th>
<th>FY 2016</th>
<th>FY 2017</th>
<th>FY 2018</th>
<th>FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Task 19: Conduct Summative Analysis - Recruit PCPs from each training arm</td>
<td>Anticipated</td>
<td>Actual: N=20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major Task 19: Conduct Summative Analysis - Recruit stakeholders from Aim 1</td>
<td>Anticipated:</td>
<td>Actual: N=10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Updated 10/23/2017
“Improving Access to Care for Warfighters: Virtual Worlds Technology to Enhance Primary Care Training in Posttraumatic Stress and Motivational Interviewing”

Log #JW140067  Award # W81XWH-15-C-0088

PI: Karen Hope Seal, MD MPH  Org: Northern California Institute for Research and Education  Award Amount: $931,538 Directs + $496,510 F&A

Study Aims
Veterans present to primary care providers (PCPs) with posttraumatic stress (PTS) symptoms because many are resistant to specialty mental health care. Most PCPs have not been trained to assess for and manage symptoms of PTS or motivate Veterans to engage in treatment. This can result in missed opportunities to intervene to prevent chronic mental and physical health problems. We propose to:
1. Iteratively design a new web-based PTS and Motivational Interviewing training for PCPs using Virtual World technology to enhance interactivity.
2. Add a more robust evaluation including a randomized control trial for more clinically valid outcome measurement.
3. Conduct a summative evaluation to inform national “scale-up” dissemination and implementation.

The proposed project is aligned with the needs of JPC 5 (Psychological Health and Resilience) and will produce a deliverable that will improve access to quality clinical care for our warfighters suffering with PTS.

Approach
We are using mixed qualitative and quantitative observational and experimental methods to conduct a 4-year effectiveness-implementation randomized controlled trial (RCT), in which project stakeholders participate from start to finish. A formative evaluation consisting of focus groups and semi-structured interviews captures stakeholder input in how we can best design and implement the Virtual World (VW) training. We will then conduct an RCT to compare the new VW training to our prior online PTS training. Pre-/post- and follow-up standardized patient interviews, provider self-report measures, and patient outcomes will be compared between groups. A summative evaluation will solicit feedback of PCP participants and stakeholders to expedite dissemination of the new VW training.

Goals/Milestones

Major Task 1: Obtain local IRB and VA R&D and HRPO Approvals
Major Task 2: Semi-Structured interviews with project stakeholders/key informants to inform curriculum content and instructional design
Major Task 3: Begin Virtual World (VW) build
Major Task 4: Independent review of new VW training using a focus group
Major Task 5: Refinement of the VW training
Major Task 6: Refinement of prior online training (Control) to make it a more apt comparison for RCT.
Major Task 7: Obtain CME accreditation for the trainings
Major Task 8: Develop self-report measure battery to assess relative change in self-reported PTS-related knowledge and clinical skills self-efficacy.
Major Task 9: Develop telephone Standardized Patient (SP) Interview to assess relative change in PTS-related competency (Primary Outcome) and MI skills to assess and manage PTS symptoms and to motivate engagement in care.
Major Task 10: Recruitment/Eligibility Screening
Major Task 11: Recruit PCPs from VA, DoD, and community

Timeline and Cost

<table>
<thead>
<tr>
<th>Projected Period of Performance and Proposed Direct Costs Per Year</th>
<th>FY16</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim 1 Formative Eval/Design</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aim 2 RCT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aim 3 Summative Eval/Disseminate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated Costs/Year ($)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FY16</td>
<td>495,224.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FY17</td>
<td>436,314.56</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FY18</td>
<td>310,165.91</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FY19</td>
<td>312,640.78</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Direct: $931,538 Directs + $496,510 F&A

Budget Expenditure to Date
Projected Expenditure: $436,314.56
Actual Expenditure: $397,222.00

Accomplishment: Beta versions of the learning environment, Orientation Center, avatar types, virtual objects, and key exercises of the training, as described in the storyboards.
9. APPENDIX: N/A