AWARD NUMBER: W81XWH-22-1-1114

TITLE: Efficacy of Virtual Warrior Renew Therapy for Veterans Who Experienced Military Sexual Trauma

PRINCIPAL INVESTIGATOR: Amanda E. Wood, PhD

CONTRACTING ORGANIZATION:
Seattle Institute for Biomedical and Clinical Research (SIBCR), Seattle, WA

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Amanda E. Wood, PhD; Belle Zaccari, PsyD

E-Mail: amanda.wood@va.gov; belle.zaccari@va.gov

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

Seattle Institute for Biomedical and Clinical Research
1660 S. Columbian Way, Mailstop: SIBCR-116-MIRECC
Seattle, WA 98108

Portland VA Research Foundation
3710 SW US Veterans Hospital Road
Portland, OR 97239-2964

8. PERFORMING ORGANIZATION REPORT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Background. Survivors of military sexual trauma (MST) have an increased risk for posttraumatic stress disorder (PTSD), depression, anxiety, insomnia, substance use, and suicidal ideation. Research on MST is limited, especially with male subjects, who may have unique challenges related to the psychological sequela of MST. Within a personalized medicine approach to the treatment of the psychological impact of MST, there is a need to address the unique aspects of sexual trauma beyond PTSD, such as lack of closure, shame, self-blame, anger, self-esteem, internalized rejection, and impacts on interpersonal relationships. The Warrior Renew therapy modality is an 8-week group developed to address the transdiagnostic symptoms associated with MST. The group consists of eight 90-minute virtual sessions covering the topics of: feelings, anxiety/triggers, anger/resentment, understanding trauma, relationship patterns, selfblame, grief, and moving forward, based on the Warrior Renew manual. Pilot trials of Warrior Renew have demonstrated significant improvements in PTSD symptoms, psychiatric symptoms, self-esteem, and negative cognitions with low dropout rates.

Study Design. This RCT will compare virtual Warrior Renew active treatment to a wellness control group with three data points: baseline pre-treatment, 8-week posttreatment, and a 16-week follow-up. Veterans (N=134) will be randomly assigned 1:1 to either the Warrior Renew or wellness control group. The 8-week treatment will be provided via a virtual telehealth format to enhance access to care. The groups will be separated by preferred gender to allow for gender-specific nuanced conversations. Both groups will include a facilitator's manual to enhance treatment delivery fidelity. The wellness group will include topics of overall health and coping strategies but will not focus on discussion of MST trauma. Recruitment will occur at two locations to increase subject enrollment: VA Puget Sound Health Care System (VAPSHCS), Seattle WA; and the VA Portland Health Care System (VAPORHCS), Portland, OR.

Clinical Impact: MST is a significant problem within active military and Veteran populations, leading to psychiatric sequela and disability. This RCT for the Warrior Renew treatment may not only provide support for an effective treatment tailored to the unique needs of MST survivors but also further understanding of the specific variables related to clinical outcomes in men with MST. Manualized virtual Warrior Renew treatment is a cost-effective, highly-versatile virtual-format Warrior Renew group intervention, which if effective could be used to significantly improve mental health outcomes and quality of life for Veterans and active-service members who have experienced MST.

15. SUBJECT TERMS
None listed.

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1. INTRODUCTION:

MST is a significant problem within active military and Veteran populations, leading to psychiatric sequela and disability. This RCT for the Warrior Renew treatment may not only provide support for an effective treatment tailored to the unique needs of MST survivors but also further understanding of the specific variables related to clinical outcomes in men with MST. Manualized virtual Warrior Renew treatment is a cost-effective, highly-versatile virtual-format Warrior Renew group intervention, which if effective could be used to significantly improve mental health outcomes and quality of life for Veterans and active-service members who have experienced MST. The objectives of this proposed study are to evaluate the effectiveness of virtual Warrior Renew treatment for military sexual trauma in a Veteran population. These objectives will be accomplished by conducting a randomized, controlled trial of the 8-week version of Warrior Renew therapy versus an 8-week wellness control group in Veterans who had experienced MST. Based on our power analysis, 134 participants will be enrolled to achieve 94 completers at end of study. Recruitment will be equal between two sites: the VA Puget Sound Health Care System (VAPSHCS) and the VA Portland Health Care System (VAPORHCS). A total of 16 groups will be run over the course of the study, including equal numbers between the men's and women's groups, randomized between the two treatment conditions, Warrior Renew and Health & Wellness.

2. KEYWORDS:

Military Sexual Trauma (MST), Posttraumatic Stress Disorder (PTSD), Randomized Clinical Trial (RCT), Warrior Renew, Health &Wellness, Behavioral Intervention, Active Control

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aims 1, 2, 3: (See above)	**Timeline**	**Progress**
Major Task 1: Study Preparation	Months	
Subtask 1: Prepare Regulatory Documents and Research Protocol		
Meet with Community Advisory Board (CAB) for advice and consultation on final protocol, consent forms, recruitment strategies, and materials	1-3	100% Completed
Finalize consent form and human subject protocol	1-3	100% Completed
Refine eligibility criteria and screening protocols	1-3	100% completed

Design Case Report Forms	1-3	100% completed
Submit to VA Central IRB	3	100% completed
Coordinate with Portland site to prepare and submit LSI	3	100% completed
Prepare and submission to VA ORD and all relevant subcommittees for local Research& Development Committee regulatory approval	3	100% completed
DoD HRPO second-level IRB review submission	3-6	100% Completed
Submit amendments, adverse events, and protocol deviations	As needed	Recent amendments approved 5-22-2023
Coordinate with sites for annual IRB and ORD continuing review	Annually	Ongoing
Study registration with the National Institutes of Health (NIH) clinical trial registry www.clinicaltrials.gov	3-6	100% Completed
Milestones achieved: All IRB, ORD, and other regulatory requirements completed and approved for the conduct of the clinical trial	6	Ongoing
Subtask 2: Coordinate Study Staff for Clinical Trial		
Hire Study Coordinators for both sites	1-6	100% Completed
Hire Statistician	1-6	In process
Train staff on study procedures	3-6	100% Completed
Train group leaders on the provision of Warrior Renew and Wellness Control groups	3-6	100% Completed
Establish inter-rater reliability	3-6	100% Completed
Ongoing, regular research meetings of study staff to ensure adherence to the protocol and group treatment fidelity	Bi-weekly	Ongoing
Milestones achieved: Study staff hired and trained. Ongoing trainings to ensure protocol and treatment provision adherence	6	100% Completed
Subtask 3: Study Preparation		
Set up account and prepare digital measures with Qualtrics for virtual data capture and DocuSign for virtual consent (pending regulatory approval).	3-6	100% Completed
Prepare backup methods for consenting and study assessments	3-6	100% Completed

Prepare recruitment and informational materials	3-6	100% Completed
Create database	3-6	In Process – pending statistician hire
Create enrollment logs, including database for participant's address where they will be receiving virtual group therapy and direct number for local emergency response in case of emergency	3-6	100% Completed
Prepare slide presentations and participant handouts for each session of the Warrior Renew and Wellness Control groups	3-6	100% Completed
Milestones Achieved: All materials and procedures prepared in order to conduct the clinical trial	6	90% Completed
Major Task 2: Recruit Study Participants and Perform Study Procedures		
Subtask 1: Recruit study participants on a rolling basis from months 7-31		
Identify appropriate venues for publicizing the study and hold informational sessions	3-6	100% Completed
Identify potential participants through referrals for MST services	7-31	Ongoing
Identify potential referring clinicians and provide information about the study	7-31	Ongoing
Make recruitment materials available in waiting rooms and other public VA spaces	7-31	100% Completed
Respond to referrals by pre-screening and contacting appropriate Veterans for consent	7-31	Ongoing
Milestone Achieved: 134 Veterans randomized and at least 94 completed the study between months 7-31	31	Ongoing
Subtask 2: Perform study procedures		
Meet with Community Advisory Board (CAB) on ongoing basis for advice and consultation on recruitment and study implementation	Bi-yearly	Ongoing
Perform screening procedures on consented participants	7-31	Ongoing
Randomize participants into Warrior Renew or Wellness Control groups (16 groups total: 8 Warrior Renew; 8 Wellness Control; evenly divided between men's and women's groups)	7-31	Ongoing

Conduct group therapy (active and control)	7-31	Ongoing
Collect outcome measures at baseline, 8-weeks, and 16-weeks	7-31	Ongoing
Milestone Achieved: 94 Veterans completed the study	31	Ongoing
Major Task 3: Data Management and Statistical Analysis		
Subtask 1: Continuous double-data entry and data cleaning	7-34	Ongoing
Subtask 2: Final data cleaning in preparation for data analysis	31-32	N/A
Subtask 3: Statistical Analysis of data	32-34	N/A
Milestones Achieved: All data entered, cleaned, and analyzed	34	N/A
Major Task 4: Reporting and Presentation/Manuscript Preparation		
Subtask 1: Write and submit necessary reports		
Write and submit necessary reports to the DoD	As needed	Ongoing
Update ClinTrials website with results	As needed	Ongoing
Milestones Achieved: Submit results to all required agencies	7-36	Ongoing
Subtask 2: Review results for interpretation of outcomes		
Meet with Community Advisory Board (CAB) for advice and consultation on interpretation of results and decisions on presentation of data	32-34	N/A
Share findings with all investigators and discuss interpretation of results	32-34	N/A
Make plan for the dissemination of results at scientific meetings and peer-reviewed journals	33-34	N/A
Milestones Achieved: Determine interpretation of results and plan for sharing results	34	N/A
Subtask 3: Present results at scientific meeting, write and submit manuscripts	34-36	N/A
Milestones Achieved: Dissemination of study results	36	N/A

What was accomplished under these goals?

Meet with Community Advisory Board (CAB) for advice and consultation on final protocol, consent forms, recruitment strategies, and materials: Met with CAB on a quarterly basis regarding input on final protocol, consent forms, recruitment strategies and materials. Next meeting is scheduled for 11/30/2023.

Finalize consent form and human subject protocol: Study has 4 consent forms approved thus far, with the most recent change approved under the PISC on 7/17/2023. Both LSIs (Puget Sound and Portland) have site-specific versions adapted from the 7/17/2023 PISC ICF approved.

Refine eligibility criteria and screening protocols: Eligibility criteria is discussed regularly within the study executive team for consistency between sites. Established specific cut off for AUDIT-C scores for men and women participants. Some case-by-base exceptions may be granted depending on the circumstances and documented on site specific enrollment logs. Created separate letter recruitment logs to track recruitments be letter vs referrals/self-referrals. Established successful procedures for screening process via a consent visit checklist. Established successful process to document determination of eligibility prior to randomization.

Design Case Report Forms: All CIRB approved case report forms within Qualtrics are functional. Administered 1st round of case report forms to 1st cohort (currently in treatment phase). Created database for data corrections.

Submit amendments, adverse events, and protocol deviations: PISC amendment 04 included opening and closing statements which removed generic Qualtrics language and added protocol specific language to inform veterans of next steps/ what to expect. PISC amendment 05 included changes to informed consent language to reflect approved status of Certificate of Confidentiality. PISC amendment 06 included a sample phone script and opt-in/out letters for both LSI sites. The most recent PISC Amendment (07) includes a protocol amendment (protocol version 4; 5/22/23) allowing for direct referrals, changes to the AUDIT-C questionnaire and an amended HIPAA waiver 7-5-23 that were approved by CIRB on 7-13-2023, effective 6-02-2023. One serious adverse event experienced by subject in this study was determined by VACIRB to not meet criteria for UPIRTSO and therefore not reported to the VACIRB or DoD. One protocol deviation was reported to VACIRB due to impermissible disclosure of information to a VA employee not yet onboarded to the research study; a PSET was created but this event was determined by privacy officers to be not reportable.

Coordinate with sites for annual IRB and ORD continuing review: PISC and both LSIs (Puget Sound and Portland) completed annual IRB continuing reviews in a timely manner, next CR due 22Sep2024. DoD OHRO approved project on 10/6/2023 until next CR due 22Sep2024.

Study registration with the National Institutes of Health (NIH) clinical trial registry www.clinicaltrials.gov: Study is now listed as active and enrolling on clinicaltrials.gov.

Hire Study Coordinators for both sites: The primary site Study Coordinator is hired and fully onboarded. For the LSI Portland Study Coordinator is hired and fully onboarded.

Hire Statistician: Confirmed with PVARF that hiring a statistician out of state is possible. Currently, we are in the process of reallocating funds from SIBCR (PISC grant management) to PVARF (Portland site grant management) to officially hire statistician as a consultant for this study.

Train staff on study procedures: PISC has implemented procedural checklists to maintain consistency between sites and adherence to protocol. Study team members conducting study procedures meet weekly to discuss study related tasks on a granular level (i.e. inclusion/exclusion, recruitment, obstacles, etc.). Both site coordinators continue to successfully recruit and consent participants.

Train group leaders on the provision of Warrior Renew and Wellness Control groups: All clinicians are trained on their relevant study interventions. All group leaders have received in their possession handouts for both interventions: all subject facing handouts and slide decks, SI SOP, schedule of events, and Warrior Renew sample scripts for integrated exercises. Clinicians are participating in ongoing weekly recurring meetings to practice and further solidify knowledge of interventions. Established training process for clinicians onboarding to the study after the study investigators kick-off meeting.

Establish inter-rater reliability
Conducted training on how to administer assessments and developed operating procedures to promote inter-rater reliability. Internal procedure checklists exist for consenting visits, randomization, tracking recruitment efforts, etc. Research coordinators from both sites meet separately from study team and once weekly to promote consistency in study procedure implementation.

Ongoing, regular research meetings of study staff to ensure adherence to the protocol and group treatment fidelity: Clinicians continue to meet weekly at the previously agreed upon time. Clinicians are updated regularly on recruitment numbers and when to expect the next cohort.

Prepare recruitment and informational materials: Version 2 of recruitment flyers and tri-fold brochures are approved under PISC. LSI Puget Sound has site specific recruitment material under Version 2 approved and is pending printing to be distributed at both American Lake and Seattle campuses. LSI Portland is pending CIRB approval of site-specific recruitment materials under Version 2.

Create database: VA BOX has been created, which serves multiple functions for storage of data. There is a folder within BOX containing exported data from the Qualtrics platform, which updates with survey responses each day. Pending statistician hire to create a database for data analyses. Confirmed data collection method from Qualtrics is successful and automatically being transferred to VA BOX.

Create enrollment logs, including database for participant's address where they will be receiving virtual group therapy and direct number for local emergency response in case of emergency: The following logs have been created and are actively being used: master subject visit tracker, training, delegation, recruitment/ no-call, master randomization schedules, site specific enrollment/ letter referrals/ compensation trackers, etc. Logs are continually refined once needs are identified. The current processes are functional and easily understood.

Prepare slide presentations and participant handouts for each session of the Warrior Renew and Wellness Control groups: All slide presentations and participation handouts for both interventions have been created and approved by VACIRB. A second version of WR slides and WR handouts were approved by VACIRB and implemented prior to starting the first cohort. Both sites have supply of printed handouts ready to be disbursed for each cohort.

Identify appropriate venues for publicizing the study and hold informational sessions: Both sites have been regularly presenting the study to various mental health clinics at each site. Puget Sound has study information published in the monthly informational emails informing providers of research opportunities available to veterans at their site. Portland has started distributing study information and recruitment materials/updates via email to mental health providers at their site.

Identify potential participants through referrals for MST services: Research coordinators at both sites now have access to the VSSC Report Viewer which identifies and provides information about veterans that have referrals for MST. Portland and Puget Sound research coordinators have pre-screened and sent out VACIRB approved opt-in/out letters to eligible veterans. Due to the limited amount of MST referrals in Portland compared to Puget Sound, Portland has put in a DART request to further screen for eligible veterans.

Identify potential referring clinicians and provide information about the study: Now that this study is able to accept direct referrals, both LSI sites are working to meet one-on-one with clinicians that have been identified as being in managerial or roles that may produce MST referrals, such as women's clinic supervisor, etc. The current direct referrals process has dramatically increased recruitment numbers in Puget Sound. Portland is still heavily relying on self-referrals and in the process of getting the primary care clinics informed about this study and how to refer interested veterans.

Make recruitment materials available in waiting rooms and other public VA spaces: Puget Sound and Portland have recruitment materials available in waiting rooms of women's clinics, general clinics, laboratory waiting areas, etc.

Respond to referrals by pre-screening and contacting appropriate Veterans for consent: New referrals are documented into our recruitment logs, pre-screened and contacted regardless of eligibility. Only eligible veterans are scheduled for consent visits and proceed to screening if they sign consent.

Meet with Community Advisory Board (CAB) on ongoing basis for advice and consultation on recruitment and study implementation: Study team continues to regularly meet with Community Advisory Board. Next meeting scheduled for 11/30/2023.

Perform screening procedures on consented participants: Screening procedures are easy to follow and resulted in successful randomization of the first women's cohort. It became apparent that group meeting times need to be determined prior to starting consent for that specific cohort in order to determine whether the meeting times work for prospective participants. Currently, study team is working on consenting and screening the first men's cohort, expected to start the week of 10/30/2023.

Randomize participants into Warrior Renew or Wellness Control groups (16 groups total: 8 Warrior Renew; 8 Wellness Control; evenly divided between men's and women's groups): Randomization procedures are functional and effective. To date, the first women's cohort has been randomized into Warrior Renew and Health & Wellness. Study is planning to randomize the first men's cohort in October 2023. Current results suggest most potential subjects prefer afternoon times, meanwhile a handful prefer morning times. Study team established a process to determine group meeting times prior to consenting for that cohort in order to reduce the amount of early drop outs due to schedule conflicts.

Conduct group therapy (active and control): Currently, 1 (women's) cohort is undergoing group therapy and is expected to finish therapy the first week of November 2023. The first men's cohort is expected to start group therapy the week of 10/30/2023.

Collect outcome measures at baseline, 8-weeks, and 16-weeks: The current process for administering assessments has been effective. At this point, we have only collected data for 1 cohort's baseline assessments and expect to have their 8-weeks assessment by mid-November 2023. Our next set of baseline assessments will be sent out end of October prior to the next group start (week of 10/30/2023).

Continuous double-data entry and data cleaning: So far, a database was created for obvious data discrepancies (incorrect date format, etc.) and provides explanations/corrections after clarifying with veterans. A database was created for screening measures, which requires both coordinators to upload non-identifying source documents to verify with data entered into the database.

What opportunities for training and professional development has the project provided?

This project has provided professional development to clinicians in the area of advancing skills to provide Warrior Renew group therapy, which is currently a treatment offered at the VA. The clinicians receive intensive weekly training and feedback by the Warrior Renew creator, Dr. Lori Katz. Additionally, as the study onboards interns, this study provides a source of professional training as interns help co-facilitate groups and document therapy sessions as outlined in the research protocol.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

By the next annual reporting period, we plan to have started/completed therapies for 2-3 more cohorts (or 4-6 more groups; 2 groups per cohort) to have randomized about 85% of target enrollment; and to have a mid-term data analysis in process.

4. IMPACT:

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

This RCT for the Warrior Renew treatment may not only provide support for an effective treatment tailored to the unique needs of MST survivors but also further understanding of the specific variables related to clinical outcomes in men with MST. This proposed study will target two target areas: 1) Treatment: This is a proposed randomized clinical trial (RCT) of a novel group treatment for military sexual trauma (MST) delivered in a virtual format to reduce barriers to care; 2) Understand: This research will evaluate potential mediators on severity of PTSD symptoms and treatment outcomes in understudied male survivors of MST.

What was the impact on other disciplines?

MST is a significant problem within active military and Veteran populations, leading to psychiatric sequela and disability. Manualized virtual Warrior Renew treatment is ready to be rolled out for larger scale implementation trials and clinical care settings to improve outcomes for sexual trauma survivors. If efficacious, this cost-effective, highly-versatile virtual-format Warrior Renew group intervention could be used to significantly improve mental health outcomes and quality of life for Veterans and active-service members who have experienced MST.

What was the impact on technology transfer?

Given this study is administered in a 100% virtual format that allows veterans from a one local VA site to connect with therapists from a different local VA site for therapies given under this protocol, the study team has developed strategies to make groups possible with current technologies while remaining compliant to VA regulations that does not allow access to information (such as charts) between VA health care systems. It is possible that this study could lead to adoption of new practices in situations where one VA site could get access to care from another VA site as needed.

What was the impact on society beyond science and technology?

Access to care is a critical issue for MST treatment as there are multiple barriers to in-person care, including emotional barriers of stigma/embarrassment, fear of re-traumatization, increased sense of vulnerability, as well as structural barriers such as rural or resource-limited environments, time constraints, lack of childcare, and transportation issues. Additionally, by 2030 demand for mental health services are projected to outstrip supply of psychiatrists by 12,530 clinicians, necessitating new approaches to expand the reach of the workforce to improve access to care. Thus, an effective virtual, group treatment for MST may help overcome these barriers to care in a modality that is cost and resource effective. Reviews of studies examining the use of telehealth, found that PTSD treatment provided via virtual formats was as effective as face-to-face therapy and may increase access to care. Patient satisfaction and quality of doctor-patient relationship remained high, while costs and drop-out rates were lower for telehealth interventions. Early findings are promising, but studies such as the one proposed are needed to better understand how virtual interventions can be applied effectively, particularly with a population of those who experienced MST.

5. CHANGES/PROBLEMS:

Nothing to report.

Changes in approach and reasons for change

Nothing to report.

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

Anticipated problems include the recruitment of male MST survivors. Currently, LSI Portland is establishing a relationship with the primary care clinic in order to publicize the study and ramp up recruitment of interested male veterans for future cohorts. LSI Puget Sound continues to present the study on a regular basis to the clinics to inform clinicians that the study is still open and enrolling.

Changes that had a significant impact on expenditures

Nothing to report.

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

NO SIGNIFICANT DEVIATIONS, UNEXPECTED OUTCOMES OR CHANGES IN THE APPROVED PROTOCOL TO REPORT. BELOW IS A LIST OF THE CURRENTLY APPROVED MINOR MODIFICATIONS.

SUBMITTED TO AND APPROVED BY: VA Central IRB, PISC

- **PISC Amendment 01 Submitted 2-23-2023; Approved 4-07-2023:** Protocol (Amendment 1) Version 2-23-2023, PISC ICF Version 2-23-2023, Recruitment Surveys/Flyers/Trifold Brochures, Columbia Suicide Screening version 2-23-2023
- **PISC Amendment 02 Submitted 3-30-2023; Approved 4-07-2023:** Both interventional subject handouts (H&W v1 3-22-2023, WR v1 3-22-2023), PowerPoint Slides (H&W Sessions 1-8 v1, WR Sessions 1-8 v1) and Warrior Renew sample scripts v1.
- **PISC Amendment 03 Submitted 4-10-2023; Approved 4-14-2023:** Updated Renew Study Recruitment Survey v2 4-10-2023, PISC Informed Consent v3 4-10-2023, Protocol (Amendment 2) v3 4-10-2023, and a new measure (Mental Health Treatment Questionnaire v1.0)
- **PISC Amendment 04 Submitted 4-24-2023; Approved 5-02-2023:** Opening and Closing Statements on Qualtrics per Timepoint V1, Certificate of Confidentiality approval
- **PISC Amendment 05 Submitted 4-26-2023; Approved 5-08-2023:** PISC Informed Consent V3.1 with updated language regarding CoC approval
- **PISC Amendment 06 Submitted 5-24-23; Approved 6-5-23:** Renew Study Sample Phone Script v1.0, Puget Sound Renew Opt-in/out letter v1.0, Portland Renew Opt-in/out letter v1.0
- **PISC Amendment 07 submission 5-31-23; Approved 7-13-23:** Protocol (Amendment 3) Version 4.0, clinician-to-clinician letter v1.0, ERDSP revised 5-31-2023, AUDIT-C v2.0, HIPAA waiver amendment, ORD Cold Calling approval letter
- **PISC Amendment 08 Submitted 7-18-23; Approved 7-18-23:** PISC Informed Consent Form/HIPAA version 3.2
- **PISC Amendment 09 Submitted 8/17/23; Approved 9/12/2023:** Puget Sound Opt-in-Out Letter v2.0; Portland Optin-Out Letter v2.0, PISC trifold brochure v2.0 8-3-2023; PISC Puget Sound Fler v2.0 8-3-2023; Demographics questionnaire v2.0 8-2-23; ERDSP revised 9-7-2023
- **PISC Amendment 10 Submitted 8/28/2023; Approved 9/5/2023:** WR Slides Sessions 2-8 v2.0; WR Subject handouts v2.0
- **PISC Reportable Events Submitted 9/21/2023; Acknowledged 10/16/2023:** Impermissible release of information to VA employee – VACIRB determined not serious, unanticipated and related. PSET0178669 placed on 10/12/2023.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

  Journal publications.

Nothing to report.

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

Nothing to report.

  Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Amanda Wood, PhD
Project Role:	PI / LSI VA Puget Sound
Researcher Identifier (e.g. ORCID ID):	000-0002-4398-3225
Nearest person month worked:	3.0 (25% for 12 months)
Contribution to Project:	Dr. Wood has served as the PI and is responsible for all aspects of the project development, regulatory processes, and overall development of study procedures and implementation.
Name:	Belle Zaccari, PsyD
Project Role:	LSI VA Portland
Researcher Identifier (e.g. ORCID ID):	0000-0003-2260-6620
Nearest person month worked:	2.4 (20% for 12 months)
Contribution to Project:	Dr. Zaccari has served as the LSI for the VA Portland and is responsible for all aspects of the project development, regulatory processes, and overall development of study procedures and implementation within the VA Portland.
Name:	My Crooker (formerly Myduyen Nguyen), BS
Project Role:	Lead Study Coordinator (PISC); Local Site Study Coordinator, Puget Sound
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	9.0 (100% for 9 months)
Contribution to Project:	Ms. Crooker is the primary Study Coordinator for the Renew study and is responsible for conducting regulatory processes, recruitment, study implementation, consent and data capture, and overall study coordination at the PISC and local site levels.
Name:	Miles Evanisko, BA
Project Role:	Local Site Study Coordinator, Portland
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	5.0 (100% for 5 months)
Contribution to Project:	Mr. Evanisko is the primary Study Coordinator for the Renew study and is responsible for conducting regulatory processes, recruitment, study implementation, consent and data capture, and overall study coordination at the local site level.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Lori Katz is now a Sub-Investigator and interventionist at the Portland local site (VAPORHCS). Dr. Rosamond Smith has been removed as a Sub-investigator at the Puget Sound local site, but remains on the study as a clinician for referrals.

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

Please see Quad Chart in Appendix A.

9. APPENDICES:

Appendix A: Quad Chart.

Efficacy of Virtual Warrior Renew Therapy for Veterans Who Experienced Military Sexual Trauma

Proposal Log Number: TP210603 PAIR

Award Number:

PI: Amanda Wood, PhD **Org:** VA Puget Sound Health Care System **Award Amount:** $749,962

Study Aims

- The primary aim of this study is to test the effectiveness of virtual Warrior Renew compared to virtual wellness control group on PTSD symptoms related to MST.
- The secondary aim is to test the effectiveness of Warrior Renew on psychiatric symptoms, negative cognitions, and positive factors compared to a wellness control group.
- The third aim is to further the understanding of the unique needs and perspectives of male MST survivors and gender differences on presenting symptoms and potential mediating factors related to treatment outcome.

Approach

This randomized control 16-week trial will compare virtual Warrior Renew treatment to a wellness control group in Veterans who have experienced military sexual trauma (MST). Veterans will be assessed at baseline, at 8-weeks after the completion of the group treatment, and at a 16-week follow-up. The primary outcome is symptoms of PTSD.

Recruitment per VA site	Warrior Renew Group		Wellness Control Group		Totals
	Men	Women	Men	Women	
VA Puget Sound	2 groups of 8-9 participants	2 groups of 8-9 participants	2 groups of 8-9 participants	2 groups of 8-9 participants	67
VA Portland	2 groups of 8-9 participants	2 groups of 8-9 participants	2 groups of 8-9 participants	2 groups of 8-9 participants	67
Totals	32-36	32-36	32-36	32-36	134

Recruitment goals per study site.

Timeline and Cost

Activities CY	22	23	24	25
Major Task: Study Preparation				
Major Task: Study recruitment				
Major Task: Study implementation				
Major Task: Complete Study				
Estimated Budget ($K)	**$60**	**$250**	**$260**	**$200**

Updated: 10/23/2023

Goals/Milestones

CY22 Goals – Study Preparation

☑ Regulatory IRB and R&D approvals obtained, primary study coordinator hired, train study staff, & prepare to initial clinical trial

CY23 Goals – Recruit Participants and Perform Study Procedures

☑ Recruit study participants and conduct group intervention, with the goal of enrolling 67 participants

CY24 Goals – Recruit Participants and Perform Study Procedures

☐ Recruit study participants and conduct group intervention, with the goal of enrolling 67 participants, for a total enrollment of 134

CY25 Goals – Data analysis and Reporting

☐ Conduct statistical data and report results through papers and presentations

Comments/Challenges/Issues/Concerns

- None

Budget Expenditure to Date

Projected Expenditure: $749,962 (total study)

Actual Expenditure: $134,388