

**Wayne State Warriors Marijuana Clinical Research Program: Investigating the Impact of Cannabinoids on Veterans' Behavioral Health**

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Project Aims:

In this randomized, controlled clinical trial we are recruiting veterans with PTSD who report using cannabis. **We are conducting two studies that are complementary and linked via their aims and methodology.** In **Study 1**, a minimum of 200 veterans will be randomized into one of four different THC:CBD dose conditions (THC; CBD; THC+CBD, and placebo) for a 12-week treatment phase. In **Study 2**, 150 veterans will be randomized into *one of two groups*: a THC reduction group (n=75), tailored across THC products that are approximately 50% lower in THC than the products participants currently use; or a THC reduction + 1:1 THC:CBD group (n=75), also including tailored THC concentrations as in the first group but with CBD added in a 1:1 THC:CBD ratio. Within each Study 2 treatment group, participants will be randomly assigned on a 1:1 basis to either start the 12-week treatment after a 2-week baseline or a 6-week baseline so we can examine participant naturalistic cannabis use before introducing the new product. **Both studies** involve assessments weekly and bi-weekly throughout a 12-week treatment phase, and at 3- (post-treatment), 6-, 9, and 12-months post-baseline. **Primary outcomes** include clinical assessments of PTSD symptom severity, mood and anxiety symptoms, and suicidality. **Secondary measures** include (1) neurocognitive function; (2) overall health, sleep quality, pain, healthcare utilization, and quality of life; (3) individual differences in fear learning and extinction associated with PTSD symptom severity; (4) saliva for DNA analysis to examine genetic and epigenetic markers associated with the endocannabinoid system; and, (5) urine, blood, and saliva samples to quantify levels of endocannabinoids and their metabolites (e.g., anandamide [AEA] and 2-AG), as well as THC and CBD and their metabolites, to examine whether these levels vary as a function of THC:CBD dose mixtures and differentially affect outcomes. Data will be analyzed to determine which dose conditions might be associated with the outcome measures. These data will be used to (1) develop a predictive algorithm that will help determine personalized profiles of patients who may be at increased risk for suicide; and, (2) develop a profile of who might most benefit from cannabinoid therapeutics.

**1). Project Milestones**

Study 1 and Study 2 Protocols have been revised and finalized in accordance with discussion with CRA/LARA.

- **Project Progress**

**Study Procedures and Protocol Development**

- Finalized internal procedures for screening visits.
- Created internal procedures for baseline visits, treatment phase visits (weeks 1-12), and follow-up visits (i.e., 1-week, and 1-, 3- 6- and 9-month post-treatment).
- Created internal procedures for 12-week treatment visits.
- Created internal procedures for 1-week, 1-month, 3-, 6-, and 9-month post-treatment follow-up visits.
- Reviewed REDCap surveys for inconsistencies and formatting discrepancies; made changes according to FDA feedback and resulting IRB-approved documents.
- Finalized safety protocols and automated notification for clinical staff for participants in need of immediate intervention.

- Set up automatic randomization of questionnaire/survey blocks for baseline visits.
- Created randomization table for treatment group assignments during baseline visits.
- Established tracking system for collaboration with other Warrior C.A.R.E. studies.
- Assembled study-focused committees to facilitate study procedures.
- Maintained physical and digital records of protocol changes and IRB amendment submissions.
- Completed DSMB Committee review and addressed feedback from committee members.
- We have begun the process of preparing and packaging cannabis doses in anticipation of participant delivery.

### **Staff Recruitment, Training, and Certification**

- Onboarded 6 volunteer Research Assistants who have received training in standard laboratory procedures, study operations, and institutional guidelines and policies.
- Trained volunteers to contact local organizations/businesses using established recruitment strategies.
- All staff members have received formal training on conducting phone screens according to study eligibility criteria, and on conducting informed consent procedures for screening visits.
- Research Assistants have begun training on data collection procedures for screening, baseline, and treatment phase visits.
- Staff have received training on standardized saliva, urine, and blood collection procedures.
- Three staff members (Coordinator and two Research Assistants) completed phlebotomy training and received certification.
- We have begun training clinical staff on all clinical assessment and diagnostic tools.

### **Participant Recruitment and Outreach**

- Generated 75+ participant recruitment ideas (clinics, Veteran organizations, Veteran/PTSD events, etc.).
- Posted IRB-approved study flyers in Detroit and metro-Detroit locations.
- Created and managed study social media accounts to post the flyers and information about the studies (LinkedIn, Instagram, Facebook).
- Posted recruitment materials on social media.
- Addressed inquiries from Veteran organizations and explored collaborations.
- Updated phone screener on Qualtrics and integrated website screener on warriorcare.net.
- Purchased domain rights for warriorcare.net and updated the website with study information and personnel.
- Identified local community events and resource fairs geared toward Veterans where staff can engage directly with potential participants.
- Started drafting a recruitment-oriented press release.

### **Equipment, Facilities, and Operations**

- Designed SOPs for study equipment (vitals monitor, thermometer, -80 °C freezer, etc.).
- Designed SOPs for van operations and maintenance.
- Confirmed van operations and maintenance on weekly basis.
- Explored ADA-compliance options for van-based visits during treatment phase.
- Explored wireless/non-local alarm system options for -80 °C freezer.

- Purchased materials for blood, saliva, and urine collection.
- Restocked essential office and study supplies.
- Set up study visit rooms and staff offices for improved functionality and accessibility.

### **Institutional Coordination and Logistics**

- Coordinated with Wayne State University to establish participant rideshare procedures using Uber for Business.
- Developed and maintained communication and operational alignment with other institutional and Warrior C.A.R.E. study teams.
- Updated the study protocol on ClinicalTrials.gov, which also provides contact information to enhance referral efforts. Study 2 is in the process of being listed.

### **Plan for Next Quarter**

- We will begin training staff in cannabis administration procedures.
- We will pilot and refine safety protocols regarding participant self-report of symptom escalation.
- We will continue to expand our list of referral sources and identifying additional venues where recruitment materials can be distributed.

### **• Noteworthy Accomplishments – Identify and describe any milestones reached or noteworthy accomplishments completed during the period.**

We initiated recruitment for Study 1.

We are continuing set up for Study 2. Given the challenges of obtaining FDA approval for Study 1, Drs. Ledgerwood and Lundahl continue to strategize possible Study 2 amendments to ensure procedures are consistent with FDA and DEA requirements.

Our website, [WarriorCARE.net](http://WarriorCARE.net), has been updated and includes links to an online screening questionnaire and a form to submit contact information.

We recently submitted the annual IRB Study Continuation and anticipate receiving approval shortly. All WSU IRB approvals are up-to-date.

### **2). Delays – Brief description of problems or delays, real or anticipated, which should be brought to the attention of the Grant Administrator.**

Now that we are actively recruiting participants, we increased salary support for some staff but do not plan to reach salary levels to those outlined in the original budget until we are making consistent progress with study activities.

### **3). Statement concerning any significant deviation from previously agreed-upon Statement of Work.**

N/A

### **4). Financial expenditures of grant money and other contributions to the project, in-kind and/or direct funding.**

All financial information is being provided through Wayne State University Sponsored Programs Administration and is being sent under separate cover.

**Attachments and Other Materials – Provide project materials developed and implemented during the reporting period (e.g. newspaper articles, newspaper advertisements, forms, brochures, announcements, studies, reports, analyses, audits, etc.).”**

We updated study brochures and flyers to reflect the increase in participant compensation due to the FDA’s requirement of additional safety assessments. Currently we are preparing press releases to announce that participant recruitment has begun.

Respectfully submitted,



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October 15, 2025