

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

- Pre-screen eligibility data and recruitment site information from Qualtrics and/or Excel files uploaded to RIPPLE Scientific software.
- Developed comprehensive training videos documenting standard procedures across study visits, providing staff with accessible reference materials to support training and maintain consistency.
- Created the Visit Prep Committee for 2 experienced volunteers to assist Research Assistants in preparing all materials (e.g., gathering paper documents, cleaning the visit room) needed to run an in-lab visit.
- Created Volunteer Lab Manual to provide clear guidelines on volunteer expectations, study procedures, and recruitment tasks.

Staff Recruitment, Training, and Certification

- Four new student (undergraduate and graduate) volunteers completed all lab wide training, study-specific trainings, and recruitment training.
- Interviewing for additional Research Assistant to assist with mobile lab (van) visits.
- Appointed one Research Assistant “Volunteer Coordinator” to delegate and review volunteer tasks.

Participant Recruitment and Outreach

- Purchased BuildClinical (also known as OpenClinica) to assist with recruitment efforts and increase study retention.
- Attended Veterans’ events:
 - Vet-To-Vet on 2/5/26 and 4/8/26 (The War Memorial Grosse Pointe)
 - Veteran Resource Fair on 2/12/26 (The War Memorial Grosse Pointe)
 - Warrior Workshop on 3/17/26 (Detroit VA Hospital)
 - Salute To Service Nights on 3/20/26 and 3/21/26 (USA Hockey Arena, Plymouth)
 - Downriver Food Drives on 1/30/26, 2/27/26, 3/27/26 (Downriver For Veterans)
- Dr. Ledgerwood (Co-Investigator) gave first of several invited talks on “PTSD in Veterans” at an event hosted by the Colonel Gregory Gadson Office of Military and Veterans Academic Excellence at Wayne State University. Drs. Lundahl and Marusak are scheduled to speak on related topics over the next several months to continue building this alliance.
- Site partnership: Met with staff at the John D. Dingell Department of Veterans Affairs Medical Center in Detroit to coordinate recruitment support through the VA – a key channel for reaching the study population. Through this connection we were approved to attend monthly VA workshops with potential participants
- We set up Ripple Science (DBA: EnrollNow) software, which is a HIPAA-compliant, web-based platform for managing clinical trial recruitment, patient tracking, and participant retention. Ripple will assist with streamlining staff tasks, increasing efficiency of participant recruitment, and tracking participant progress throughout the trial.
- Records of all previously recruited participants have been logged into RIPPLE.
- Continued to post IRB-approved study flyers in Detroit and metro-Detroit location (186 approved locations: local businesses, Veteran organizations, clinics, community centers, community colleges, trade schools, universities, gyms, gas stations, grocery stores)
- Continued virtual recruitment outreach through the WarriorCARE social media accounts (LinkedIn, Instagram, Facebook, Academia)
- Expanded our virtual recruitment outreach by starting to post recruitment materials on Craigslist.
- Collaborated with several Veteran organizations to explore different ideas on recruitment outreach
- Continued to identify Veteran-related local community events and resource fairs where staff can engage directly with potential participants
- Have received nearly 150 potential participant inquiries since launching recruitment (*+51 since last report*)
 - Completed 104 eligibility pre-screenings (*+36 since last report*)
 - 79 Phone Pre-Screens

- 25 Website Pre-Screens
- 10 Screening Visits completed
- 4 Screening Visits in progress

Equipment, Facilities, and Operations

- Continued weekly van operations and maintenance
- Purchased centrifuge for biological sample collection in the mobile lab
- Purchased air purifiers to be used for filtering and clearing the air during cannabis administration in our study visit rooms.
- Purchased portable Sploofy air purifiers which will be assigned to participants during the 12-week treatment phase to use when smoking the treatment cannabis at home.

Plan for Next Quarter

- Invited to appear on BunkerBros Veterans Mental Health podcast series in May to discuss the VMR studies
- Continue to expand our list of referral sources and identifying additional venues where recruitment materials can be distributed
- Generate recruitment materials with BuildClinical (which will need to be IRB approved before we run the recruitment campaign).
- Attend Veteran-specific Memorial Day events.
- Continue recruiting and enrolling eligible participants into the study.
- Onboard new research assistant hires and new student volunteers.

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

Study 1 recruitment and participant enrollment is ongoing

We are continuing set up for Study 2

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.).”

Respectfully submitted,



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