



## Introduction

**Background:** Neuropathic pain is one of the most common, distressing, and treatment-resistant symptoms associated with spinal cord injury (SCI). While cannabidiol (CBD) has been shown to produce limited analgesic effects in chronic pain populations, there is a lack of research examining the impact of a single dose of CBD on electrocortical activity reflected by abnormalities in electroencephalography (EEG) spectral power among those with SCI-related neuropathic pain. The primary purpose of this study is to: 1) evaluate the effect of CBD on neuropathic pain symptoms, momentary pain intensity and unpleasantness, and thermal pain thresholds and 2) assess the effect of CBD on brain electrocortical activity measured during resting-state EEG by conducting EEG power spectrum analysis across theta, alpha, and beta rhythms.

**Methods:** In this randomized, double-blind, placebo-controlled pilot study, fifteen (N=15) men and women with an incomplete or complete traumatic SCI and who also experience continuous neuropathic pain will receive a single dose of CBD (250mg) or a single dose of a placebo in a cross-over design. During the two study visits, resting brain activity will be recorded for 10 minutes, 30 minutes before and after CBD or placebo administration. Participants will also be assessed for momentary neuropathic pain symptoms severity, pain intensity, and state anxiety symptoms, followed by quantitative sensory testing to measure thermal pain thresholds and the presence of allodynia in the painful area.

## Design

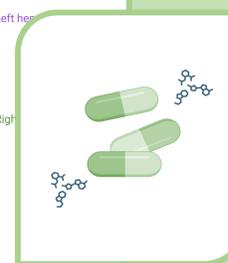
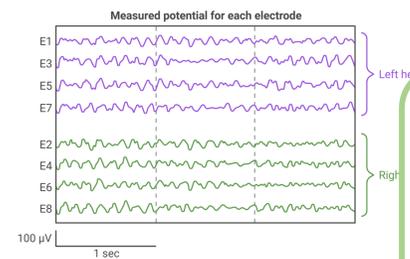
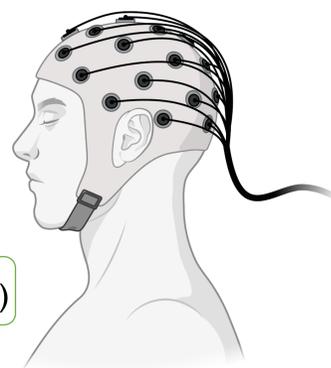
**Primary Outcome 1:** Ratings of momentary pain Intensity and unpleasantness

Baseline

- Neuropathic Pain Symptoms
- Quantitative Sensory Testing
- State Anxiety



Cannabidiol (250mg)



Placebo

**Primary Outcome 2:** Resting-state EEG analysis across theta, alpha, and beta rhythms

Post Assessment

- Neuropathic Pain Symptoms
- Quantitative Sensory Testing
- State Anxiety

## Timeline

Funding Notification

IRB Submission

IRB Requests IND

Contact First CBD Provider

Provider Declined Participation

Secured CBD From New Provider

FDA Request for CMC Clarification Protocol Placed on "Clinical Hold"

Submitted IND

Awaiting CMC For Resubmission

July

August

September

October

November

December

January

February

March

April

May

## Findings

**Results:** Unforeseeable regulatory issues have led the study team to submit an investigational new drug application to the FDA before IRB approval is granted. We have secured a CBD source and are in the process of submitting the necessary documents to the FDA. **Discussion:** The data collection for the study has been significantly delayed. \*Funded by the Consortium for Medical Marijuana Clinical Outcomes Research. CBD to be provided by Groff North America.