Cannabidiol (CBD) and Quality of Life in Retired Elite Athletes Pilot Study

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I. Purpose

Sports injuries come in different forms. Injuries from single incidents such as torn ligaments or broken bones generally have a known standard of care and recovery arc. Others are more nebulous and may develop sequelae that are chronic and linger long past the end of sports participation. These conditions can serve as a detriment to these individuals quality of life. Prior research has highlighted Cannabidiols (CBD) receptor-mediated neuro-protective and analgesic properties, as well as its effects on sleep, mood and other aspects of mental health. This study considered those effects as part of overall quality of life in retired athletes.

Primary Objectives:

1) Evaluate the feasibility of various supplemental CBD products and dosing regimens for future research.
2) Evaluate the feasibility of recruitment, screening and retention of the proposed study population.
3) Evaluate the feasibility of study assessment surveys, cognitive testing and diagnostic imaging for future research.

Secondary Objective:

1) Identify areas for training and/or supportive materials needed for Investigators and study staff.

II. Methods

Screening and Protocol

A pre-screening questionnaire was utilized to select appropriate candidates for study enrollment. Potential subjects were provided the questionnaire via email. Qualifying subjects were referred to either the Miami or Denver clinic location to schedule the Screening Visit. Non-qualifying subjects received a standardized response informing them of their status. None of the non-qualifying subject information was retained.

At the Screening Visit, informed consent was administered, and enrollment criteria reviewed to ensure the subject met all entry criteria. The Screening Visit provided a baseline measurement for all study assessments, in addition to collecting information about current medical conditions and medications. After baseline assessments were performed, subjects received a 2-week supply of product and were instructed in its use. The product assigned to the subject was determined in a randomized manner.

The subject returned to the same health professional every two weeks for a follow-up visit, repeat of the tests, and a new supply of product for a total of eight weeks actively using study products. At Visit 5 (Week 8), no further product was dispensed. Four weeks later, following the washout at Week 12, all study procedures will were repeated.

Visit #	Visit Procedures and Assessments	Est Time	Week #
Pre-screening	Pre-Screening Questionnaire	10 minutes	----
Visit 1 Screening	Informed Consent; Review of entry criteria. Vital Signs, Medical History/Concomitant Medications WAVi EEG, Pain/Sleep Survey, Roberto Cognition Test, Current Conditions Survey. Study supplement 14 day initial supply dispensed at 25 mg per day or placebo.	2 hours	Week 1
Visit 2	Study supplement and Adverse Event review. Vital Signs, Review of changes to medical conditions or medications WAVi EEG, eDiary review, Roberto Cognition Test. Study supplement 14 day supply dispensed at 50 mg per day or placebo.	1 hour	Week 3
Visit 3	Study supplement and Adverse Event review. Vital Signs, Review of changes to medical conditions or medications WAVi EEG, eDiary review, Roberto Cognition Test. Study supplement 14 day supply dispensed at 75 mg per day or placebo.	1 hour	Week 5
Visit 4	Study supplement and Adverse Event review. Vital Signs, Review of changes to medical conditions or medications WAVi EEG, eDiary review, Roberto Cognition Test. Study supplement 14 day supply dispensed at 100 mg per day or placebo.	1 hour	Week 7
Visit 5	Study supplement and Adverse Event review. Vital Signs, Review of changes to medical conditions or medications WAVi EEG, eDiary review, Roberto Cognition Test/ Current Conditions Survey. No further supplements given.	1 hour	Week 9
Visit 6	Adverse Event review. Vital Signs, Review of changes to medical conditions or medications WAVi EEG, eDiary review, Roberto Cognition Test, Current Conditions Survey.	90 mins	Week 12

III. Results

Subject Overview

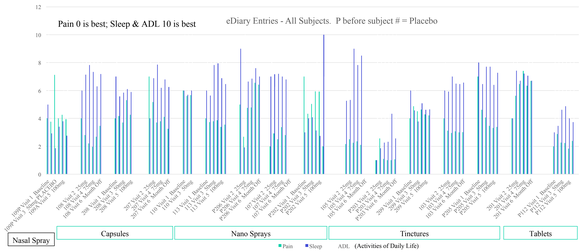
The final 23 qualifying subjects consisted of 20 men and 3 women from 8 different sports. All had participated from college on.

- Age range: 29-70 years Average age: 47
Years of play range: 1-15 years Average years played: 7.7
Years since retirement: 4-34 years Average years retired: 16.4
- Sports played:

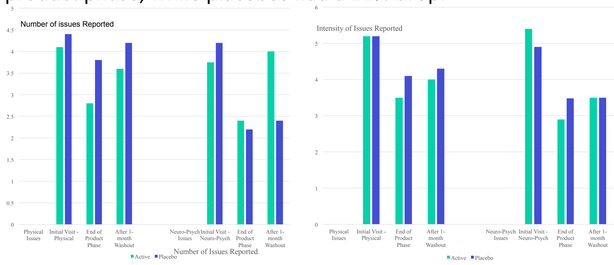
Football 14	Hockey 2	Basketball 2	US Ski Team 1
Soccer 1	Baseball 1	Tennis 1	Mountaineer 1

Results By Study Assessment Tools

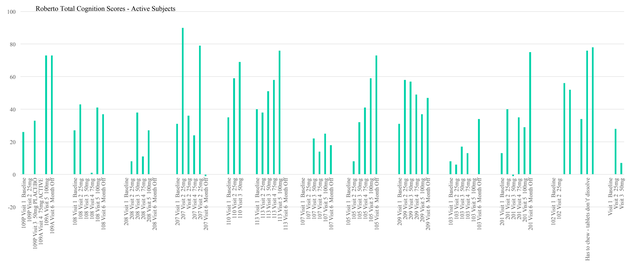
E-Diary – Worked well to help keep subjects engaged and in compliance with protocol. Emoji-based responses easy to use. A few application tweaks are needed, such as forcing push notifications even if the subject's phone in Battery Saver mode. Subjects requested a Comments line so they could add in special qualifiers such as "traveling this week, didn't sleep" or "had the flu".



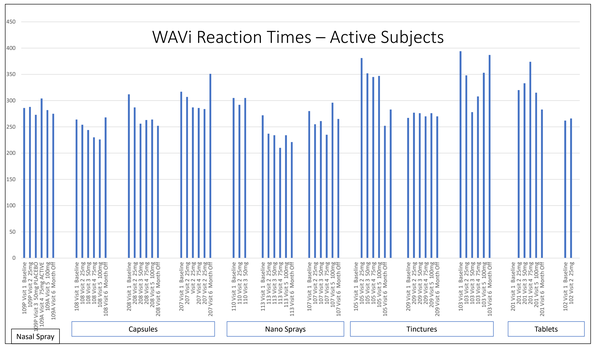
Clinical Data – Subjective assessment questions were asked at baseline, end of trial, and washout. For full study, will ask at every encounter for better granularity. Active subjects reported a 32% drop in physical symptoms at the end of the product phase, while placebos had a 21% drop.

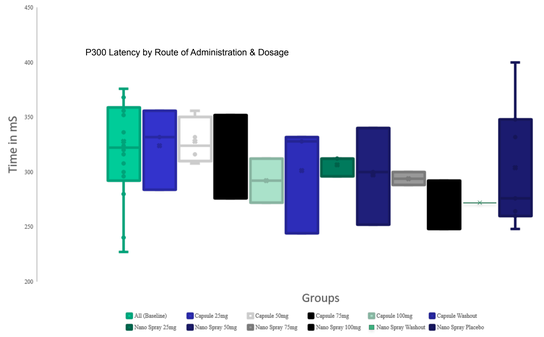


Roberto Cognition App - The app is designed for the subject to use it 5-6 times over the course of a week to establish a baseline. Unfortunately, we only used it 6 times total over 3 months, and only in a clinical setting. Lack of a baseline may have affected data relevance. For a full study, we would use it as designed.



WAVi QEEG – This formed the bulk of the objective data Some subjects who reported "feeling nothing" or "no change" in symptoms showed improvements in WAVi voltages, P300 scores, and reaction times nonetheless. Reaction time data may be a promising measure for finding appropriate doses. P300 data shows capsules and nanoemulsified sublingual sprays to merit further study. As study cohorts were on average over a decade from playing days, recruiting subjects with more recent injuries might allow us to better use WAVi concussion and brain health protocols.





IV. Conclusions

Three routes of administration were well tolerated by subjects: capsules, nanoemulsified sublingual sprays, and tinctures. However, WAVi and subjective data were weaker on tinctures. In a long-term study we would concentrate on capsules and nano-sprays only. The graduated dosing demonstrated well on the WAVi and shows promise as a tool to find optimal dosing for subjects. Subject recruitment was unexpectedly hampered by the high amounts of CBD many retired athletes were already taking. Access to a larger study population may help mitigate this finding.

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