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## WHITE PAPER

### NOVEL COMBINATION OF HEMP OIL, OMEGA-3, AND BROCCOLI IMPROVES QUALITY-OF-LIFE AND REDUCES REACTIVE OXYGEN SPECIES (ROS) PRODUCTION

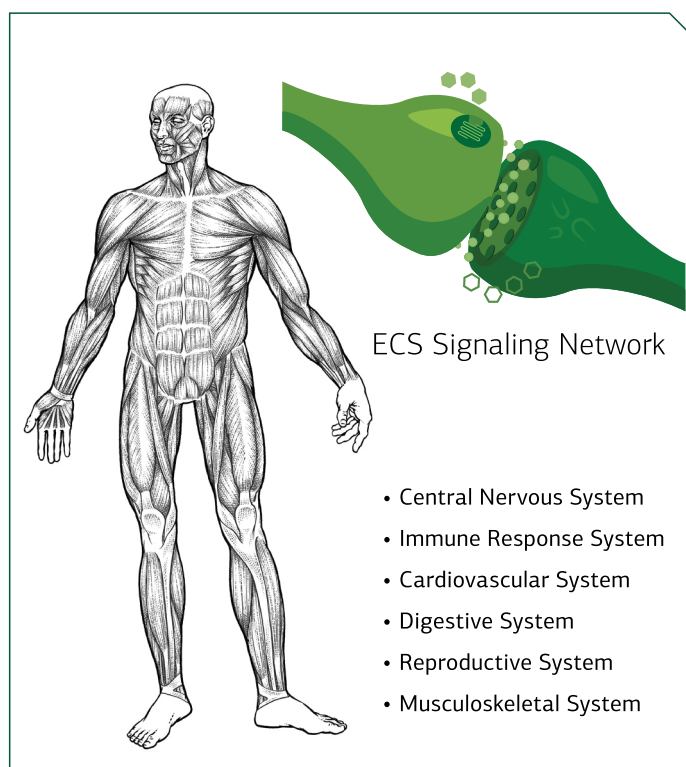
The Endocannabinoid System (ECS) consists of cannabinoid receptors, (CB1 and CB2), endocannabinoid molecules, and metabolic enzymes. All three parts work together to maintain the body's homeostasis and regulate biological processes (Figure 1). Any plant-derived natural product capable of signaling with cannabinoid receptors are called 'phytocannabinoids'.<sup>1</sup>

The ECS supports different functions in the body system. These range from basic ones, such as eating, sleeping, and relaxing, to more complex functions like neuroplasticity, metabolism, and the healthy inflammatory process response.<sup>2-5</sup>

CB1 receptors participate in processes such as energy metabolism, and psychoactive outcomes including emotional wellbeing, while CB2 receptors lack psychoactive effects and instead support the natural body's inflammatory and immune processes\*.<sup>6</sup>

The human body utilized polyunsaturated fatty acids (PUFAs) as a precursor for endocannabinoids. The two major classes of PUFAs are omega-3 and omega-6 fatty acids, and they are not synthesized in the body and must be obtained from dietary sources.<sup>7</sup>

In addition to serving as precursors to endocannabinoids, PUFAs also exhibit strong



**Figure 1.** The Endocannabinoid System (ECS) is a major lipid signaling network comprised of endogenous, lipid-based, physiological ligand molecules (endocannabinoids) that plays a pro- homeostatic role in peripheral organs besides the central nervous system (CNS).

inflammation-modulating properties and regulate several metabolic processes.<sup>8,9</sup>

Broccoli is a cruciferous vegetable rich in Glucosinolates, which are compounds associated with antioxidant capacities.<sup>10,11</sup>

When combined, hemp oil, omega-3, and broccoli becomes a unique formulation that supports the ECS and the whole-body balance.\*

## CLINICAL SUMMARY

This was a randomized, double-blind, parallel-group, placebo-controlled trial describing the role of a dietary supplement containing a novel combination of hemp oil, omega-3 fatty acids, and broccoli in supporting the body's natural inflammation response resolution pathways, over 12 weeks.

Twenty-five adults seeking improvement of quality of life through chiropractic care participated in the study in North Carolina. Participants (men and women, aged  $52.24 \pm 13.16$  years) were randomly assigned to 1 of 2 groups: Group A (Hemp Oil Complex+Chiro,  $n=12$ ) received 1 serving size of Hemp Oil Complex, a novel combination of phytocannabinoids (15 mg), from hemp oil, also containing a proprietary blend of omega-3 and organic broccoli and

broccoli extract (TruBroc®), daily. Group B (Placebo+Chiro,  $n=13$ ), received 1 serving of the placebo (no active properties), daily.

The rationale for this design came from the perspective that individuals experiencing physical and /or emotional stress would benefit from a wholistic approach<sup>16</sup>, combining chiropractic care and a nutritional supplement designed to provide a 3-in-1 benefit for the whole body by supporting the ECS, the body's natural inflammatory response, and its antioxidant pathways\*.

Ethical considerations were reviewed and approved by the Institutional Review Board (IRB) Advarra Inc. (IRB#: Pro00032192)

## ASSESSING PATIENT COMFORT

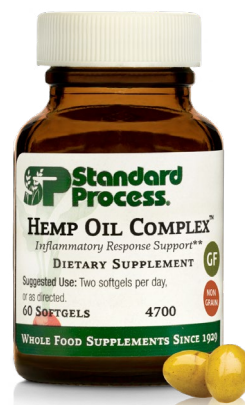
The patient's perspective method, such as the use of self-reported health information, is considered an important tool when providing patient care. It allows healthcare providers to gather information directly from their patient's perspectives regarding their own general well-being.<sup>12,13</sup>

In this trial, the subject's physical comfort level and well-being were measured at baseline (week 0), after 6 weeks, and after 12 weeks, using two validated self-reported questionnaires.<sup>14</sup>

These questionnaires are widely used in clinical trials and patient care, and allow health care professionals and scientists to directly ask patients and participants, their perceptions about their discomfort, wellbeing, and quality of life.<sup>15</sup>

Focusing on the last 24 hours, participants were asked to self-report how their body's comfort level was interfering with their wellbeing and quality of life from 0 to 10 (0 represented "does not interfere" and 10 represented "completely interferes").

The impact of the holistic approach, combining Hemp Oil Complex and chiropractic care improving patients' physical comfort and quality of life are presented in figures 2-3.



\*These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

## IMPACT OF HEMP OIL COMPLEX ON PHYSICAL AND EMOTIONAL WELLBEING AND QUALITY OF LIFE

Physical and emotional stress are related to an individual's well-being.<sup>17,18</sup>

Repeated episodes of physical and emotional stress, combined with their unpredictability or lack of control represent significant challenges in individuals' quality of life.<sup>19</sup>

Participants that received the holistic approach with the combination of Hemp Oil Complex and chiropractic care, self-reported 44% less discomfort at the end of the study, as compared to only 28% less discomfort reported by the participants in the Placebo+Chiro group (Figure 2). The results shown in this study may be due to the role of the endocannabinoid system in physical and emotional manifestations.<sup>20</sup>

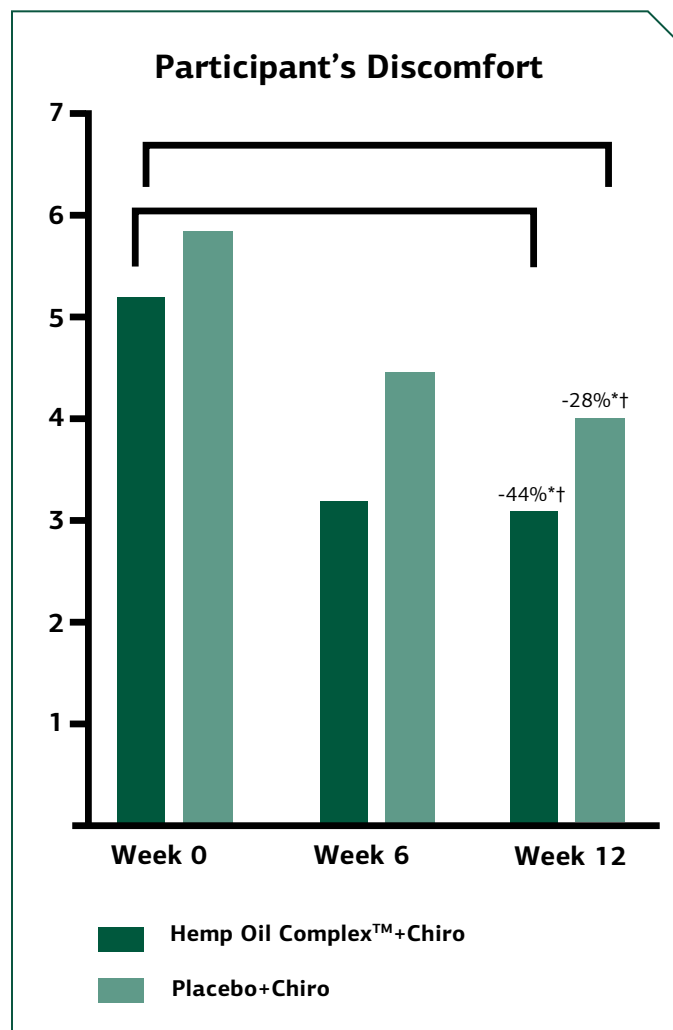
Specifically, CB1 receptors, found in the CNS, are associated with neurotransmitters that regulate neuronal excitability, maintain homeostasis, supporting the regulation of an individual's perception of comfort.<sup>21,22</sup>



### Together, We Can Change Lives

Changing lives is our passion and has been since our company's inception in 1929. This passion is what drove our founder, Dr. Royal Lee, to develop and pioneer the first whole food-based supplement on the market, the revolutionary Catalyn®.

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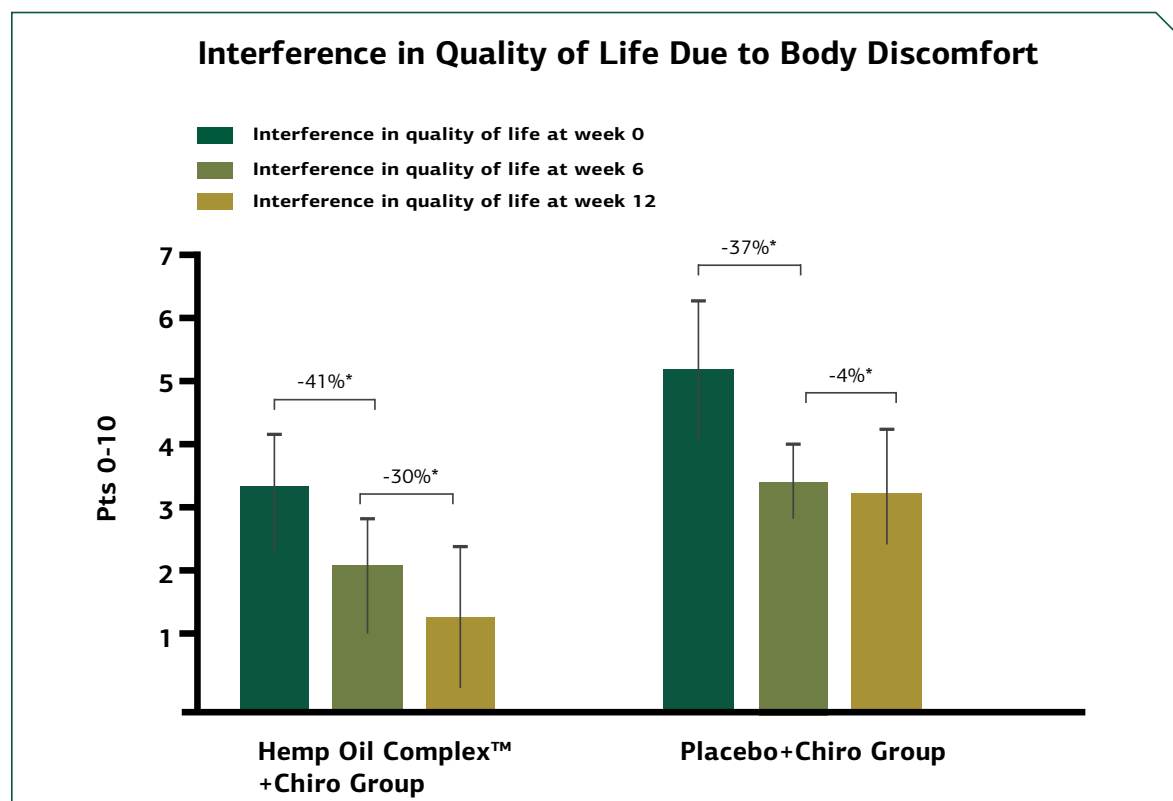
**Figure 2.** Impact of a holistic approach of nutritional supplementation (Hemp Oil Complex) and chiropractic care versus chiropractic care alone in patient's discomfort\*. North Carolina, 2022.

†  $p = \leq 0.0005$

Similarly, after 6 weeks of the combined approach of Hemp Oil Complex and chiropractic care, participants in the Hemp Oil Complex+Chiro group self-reported significantly less interference in their quality of life due to body discomfort (-41% p= 0.0001), as compared to the participants that received only chiropractic care, who reported 37% less interference in quality of life due to their body's discomfort.

Because participants were eager to be a part of the clinical trial and may experience excitement at the prospects of a new approach to improve their quality of life,<sup>23</sup> it was hypothesized that participants would report a decline in their perception of interference in quality of life due to body's discomfort, in the initial phase of the trial (as shown in figure 3).

However, in the second phase of the trial (from weeks 6 to 12), participants in the Hemp Oil Complex+Chiro group self-reported an additional decrease of 30% in their perception of interference in quality of life due to body discomfort\*. Participants in the group that received only chiropractic care (Placebo+Chiro) reported a reduction of only 4% less interference in quality of life over the same period (Figure 3). One explanation for this finding might be the proximity of GABA (γ-aminobutyric acid) receptors to CB1 receptors.<sup>24</sup> GABA terminals are found in key locations in the brain and are associated with mood regulation and emotional wellbeing, both of which contribute to the quality of life.<sup>24-26</sup>



**Figure 3.** Impact of a holistic approach of nutritional supplementation (Hemp Oil Complex) and chiropractic care versus chiropractic care alone in Interference in Quality of life due to body discomfort \*. North Carolina, 2022\*.

† p= ≤0.0005

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## HEMP OIL COMPLEX SUPPLEMENTATION AND THE BODY'S NATURAL INFLAMMATORY RESPONSE FUNCTION\*

During a healthy inflammatory response, the release of pro-inflammatory mediators such as cytokines and kinins (activate nociceptors), can contribute to a patient's perceived body discomfort.<sup>4,27-30</sup> In normal circumstances, the natural inflammatory process will be regulated and efficient, and the inflammation will resolve.<sup>31,32</sup>

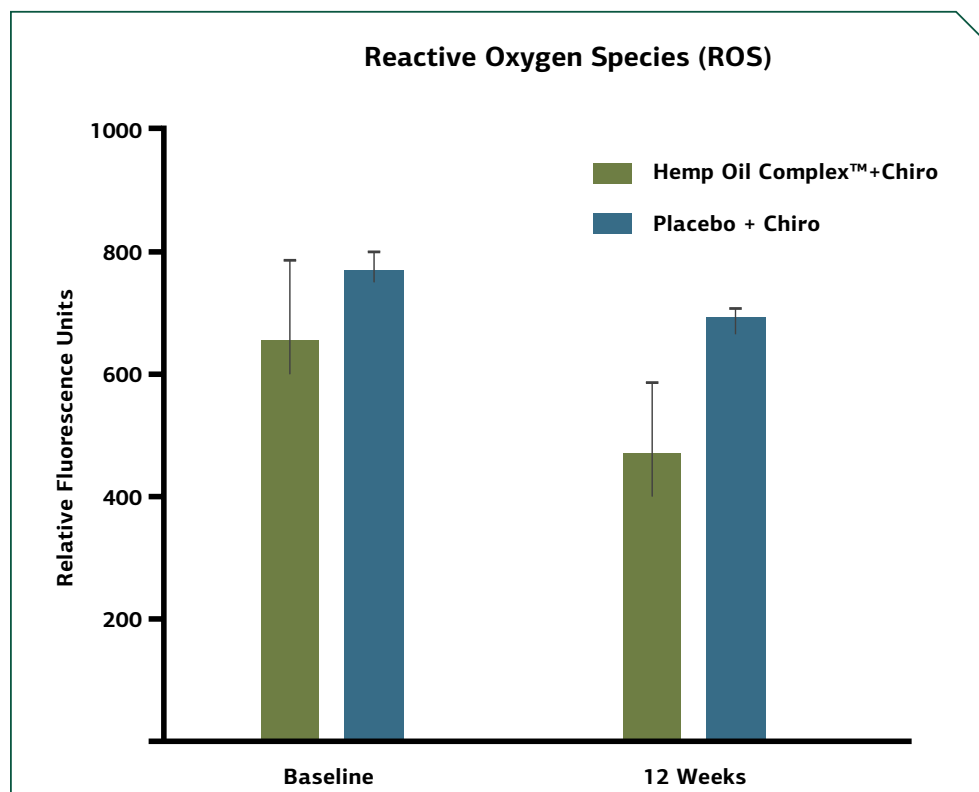
However, persistent stressors can initiate a cascade of pro-inflammatory responses, triggering the accumulation of reactive oxygen species (ROS), which are reactive molecules that are byproducts of metabolism and various endogenous sources.<sup>33,34</sup> The increase in ROS will recruit more inflammatory immune cells leading to the release of more ROS, further contributing to what is called "oxidative stress".<sup>33,34</sup>

In this study, participants' oxidative stress was measured using a laser-based technology (flow cytometry-fluorescence)<sup>35,36</sup> to demonstrate the impact of Hemp Oil Complex in supporting the body's healthy inflammatory response function and individual's endogenous antioxidant pathways.<sup>37</sup>

After 12 weeks, participants that received the combined approach of Hemp Oil Complex and chiropractic care demonstrated a significant improvement in their natural antioxidant pathway (-29% ROS), as compared to the placebo group (-9% ROS) [Figure 4].\*

This result might be related to Hemp Oil Complex's key ingredients with its unique formulation of hemp oil, calamari oil, broccoli powder, and TrueBroc®.

Combined, Hemp Oil Complex™ contains phytonutrients known for supporting the body's natural inflammatory response function and antioxidant activity.\*<sup>37</sup>



**Figure 4.** Impact of Hemp Oil Complex Supplementation in supporting natural antioxidant pathway.\* North Carolina, 2022.

Hemp Oil Complex+Chiro Group=  $p=0.013$

Placebo+Chiro group = $p=0.036$

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## CONCLUSION

This study aimed to investigate the impact of a novel combination of hemp oil containing 15 mg of phytocannabinoids, EPA/DHA, and broccoli supplementation in combination with weekly chiropractic care in individuals seeking improvement of quality of life.

After the intake of Hemp Oil Complex and chiropractic care for 12 weeks, participants in this self-reported more physical comfort and improved quality of life, and showed improvement in their natural antioxidant capacity by reducing ROS activity (as shown in figure 4).

The results of this study demonstrated that Hemp Oil Complex:

- Supported the Endocannabinoid System, by providing PUFAs, which function as precursors for endocannabinoids
- Supported healthy Inflammatory Processes, by supporting the Endocannabinoid System through PUFAs, known to support available lipid mediators in the body involved in healthy inflammation processes.
- Supported the endogenous Antioxidant Pathways, probably through phytonutrients from TrueBroc® known for activating Nrf2/ARE pathways.

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