VF Hemp Oil

Standard Process VETERINARY FORMULAS™

Efficacy of Standard Process Full Spectrum Veterinary Formula (VF) Hemp Oil in enhancing Canine Quality of Life - A Randomized Blinded Cross-Over Trial

WHITE PAPER

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INTRODUCTION

Pet owners and veterinary professionals prioritize the well-being of companion animals. Dogs commonly experience discomfort and inflammation due to joint health challenges. Improving the quality of life for canine patients is a top priority. The objective of this clinical study was to evaluate the impact of hemp-derived phytocannabinoids, specifically Cannabidiol (CBD) on various quality of life endpoints in dogs, including body discomfort, proinflammatory markers in serum, gait/mobility, and activity levels.

BACKGROUND

The endocannabinoid system (ECS) is a vital biological system in dogs that helps regulate physiological processes and maintain balance. It consists of endocannabinoids, receptors, and enzymes.[1] Dogs naturally produce endocannabinoids like anandamide (AEA) and 2-arachidonoylglycerol (2-AG), acting as signaling molecules that bind to ECS receptors.[2] The ECS has CB1 and CB2 receptors located throughout the body, where CB1 influences pain, mood, memory, and appetite, while CB2 regulates the immune system and inflammation.[3] Exogenous cannabinoids, such as those in hemp oil, can interact with the ECS, offering therapeutic benefits.

Hemp oil, with cannabinoids like CBD, has shown promise in alleviating discomfort and inflammation without psychoactive effects through indirect modulation of the ECS.[4,5] This can be particularly helpful in dogs with joint health challenges and inflammation, which can limit mobility and activity levels.[6,7] The Full Spectrum hemp oil used in this study contains a diverse array of compounds, including cannabinoids, terpenes, and flavonoids, providing a comprehensive approach to well-being. Sourced from Standard Process, this VF Hemp Oil is known for its purity, potency, and organic certification.[8] Each 1 mL serving of Hemp Oil delivers a consistent dosage of 15 mg of phytocannabinoids, ensuring standardized formulation.

METHODS

In a 16-week trial consisting of two phases, this study employed a randomized, placebo-controlled, double-blind, cross-over design. The trial involved thirty-seven dogs of varying breeds and sizes, aged between three and twelve years. These dogs were randomly assigned to receive either VF Hemp Oil or a placebo product (organic extra virgin olive oil) during the first phase, which lasted eight weeks (W1 - W8). Subsequently, they switched to the alternate product (VF Hemp Oil or placebo) for the second phase (W9 - W16). The dosage of VF Hemp Oil administered was calculated at 2 mg/kg body weight twice daily, based on a recent study that confirmed its safety for both dogs and cats at this specific dosage.[9] Fit Bark accelerometers were utilized to monitor the dogs' daily activity throughout the study.[10] Several assessments were conducted at four time points, including baseline, the end of week 8, week 9, and the end of week 16. These assessments included a blood chemistry panel, evaluation of gait and physical activity, owner's perception of discomfort using the validated Canine Brief Pain Inventory (CBPI) questionnaire, and analysis of serum proinflammatory markers. Additionally, the study aimed to determine the mechanism of action by analyzing the serum bioavailability of phytocannabinoids in these groups as they transitioned through the two phases.

RESULTS

No adverse effects were reported for the duration of the study. There was no significant change in bodyweight of the animals during the study timeline (47.69 ± 3.25 lbs vs. 47.4 ± 3.3 lbs). Asterisks *, **, *** indicate significance levels of $P<0.05$, $P<0.01$, and $P<0.001$, respectively.

SUPERIOR BIOAVAILABILITY OF HEMP-DERIVED CBD WITHOUT ELEVATED LIVER ENZYMES

In this study, we aimed to determine the bioavailability of hemp-derived phytocannabinoids, specifically CBD, while keeping the delta-9 tetrahydrocannabinol (THC) concentration low (see Figure 1). The mean concentration of CBD in serum peaked at the end of Hemp Oil phase for both groups and was found to be 118.4 ± 13.4 ng/mL for group 1 and 106 ± 13.1 ng/mL for group 2. Furthermore, within the study population, the measured THC concentration (11 OH THC and 9 – COOH THC) remained below the predefined threshold for psychoactive effects (≤0.3%), ensuring the safety of the participants and validating the low-THC formulation used in this study.[11] The mean concentration of 11 OH THC and 9 – COOH THC was 2.08 ± 0.28 for group 1 and 1.34 ± 0.21 for group 2.

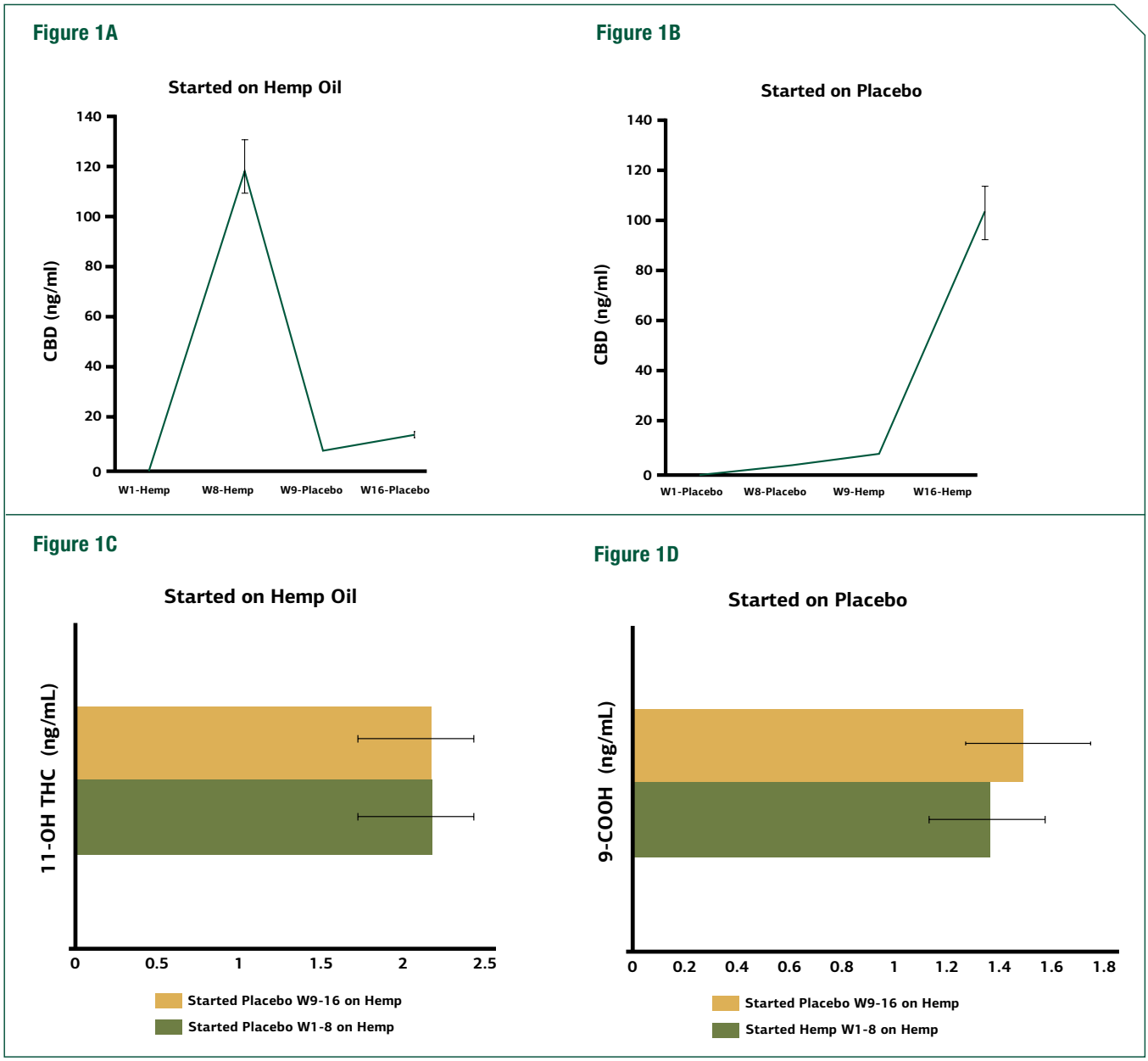


Figure 1. Bioavailability analysis confirms successful absorption and distribution of CBD in dogs' serum, supporting therapeutic potential of hemp-derived phytocannabinoids.

Elevated liver enzymes after consumption of CBD oil are a concern among veterinarians.[12] Considering recent studies indicating potential adverse effects in dogs, we tested the impact of hemp oil on alkaline phosphatase (ALP), alanine aminotransferase (ALT), and gamma-glutamyl transferase (GGT). Our results indicate no significant changes in liver enzymes in both placebo and intervention phases of the study (all P-values > 0.05). No observed adverse effects indicate safety of hemp oil at administered dose for the study duration, agreeing with previous research.[9]

IMPROVED BODY DISCOMFORT IN GROUP RECEIVING HEMP-DERIVED CBD

Dogs experienced notable relief from discomfort, as indicated by the Canine Brief Pain Inventory (CBPI) assessment, highlighting the efficacy of hemp-derived phytocannabinoids in reducing body discomfort. The CBPI assessment is a questionnaire used to evaluate pain levels in dogs.[13] Hemp-derived phytocannabinoids, particularly CBD, target the ECS and demonstrate potential analgesic properties.[14] They reduce pain perception and enhance the well-being of dogs. These findings suggest that hemp-derived phytocannabinoids, at a dose of 2 mg/kg body weight twice daily, effectively alleviated body discomfort between ~42 % – 51 % compared to placebo (28.9 ± 5.34 for group 1 and 25.4 ± 4.46 for group 2). The group receiving hemp oil in the first phase reported increased discomfort by 38.5 % by end of trial when switched to placebo (9.47 ± 3.79 to 13.12 ± 3.23) (Fig 2 B).

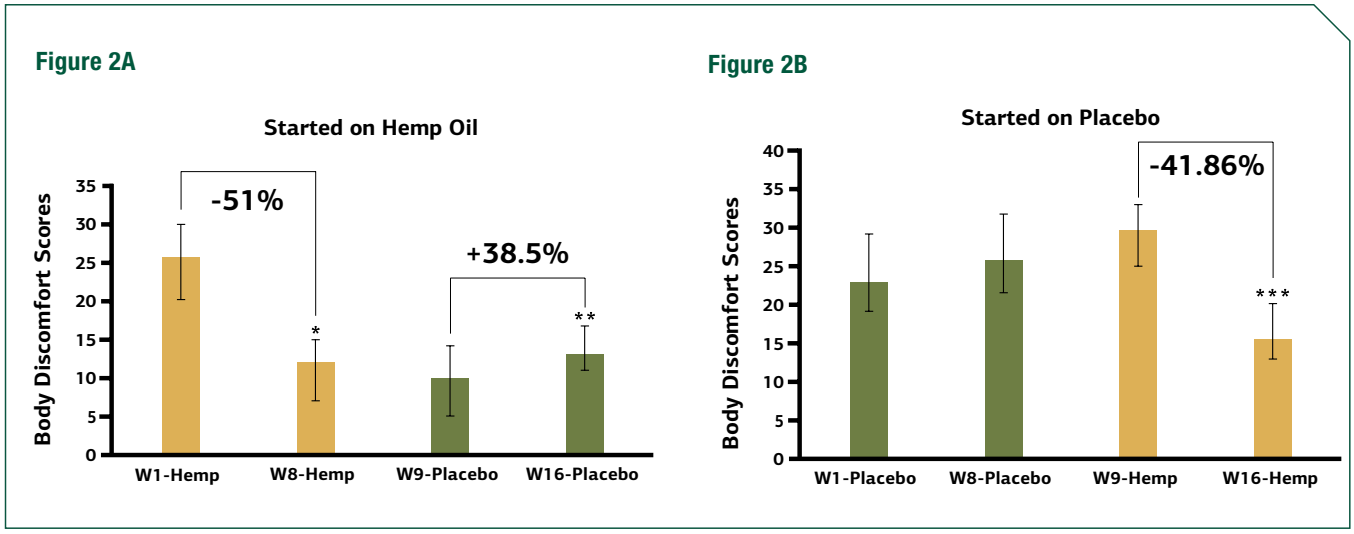


Figure 2. During the intervention phase, the administration of hemp-derived phytocannabinoids resulted in a significant reduction ($p < 0.05$) in body discomfort scores compared to the placebo phase.

REDUCTION IN SERUM LEVELS OF PRO-INFLAMMATORY MARKERS

Consistent with previous reports on immunomodulatory properties of hemp-derived phytocannabinoids in dogs, significant reduction in proinflammatory markers were observed during hemp oil administration (Figure 3), reinforcing the reduction in body discomfort observed during the intervention phase.[15,16] This effect was particularly pronounced when dogs were switched to placebo phase of the trial, where acute inflammation-like signals were noticed again (Fig 3A, 3C, & 3E). By targeting and suppressing inflammatory pathways, CBD-rich VF Hemp Oil at an administered dose of 2 mg/kg body weight twice daily demonstrated the potential to alleviate inflammation-associated symptoms and promote overall canine well-being.

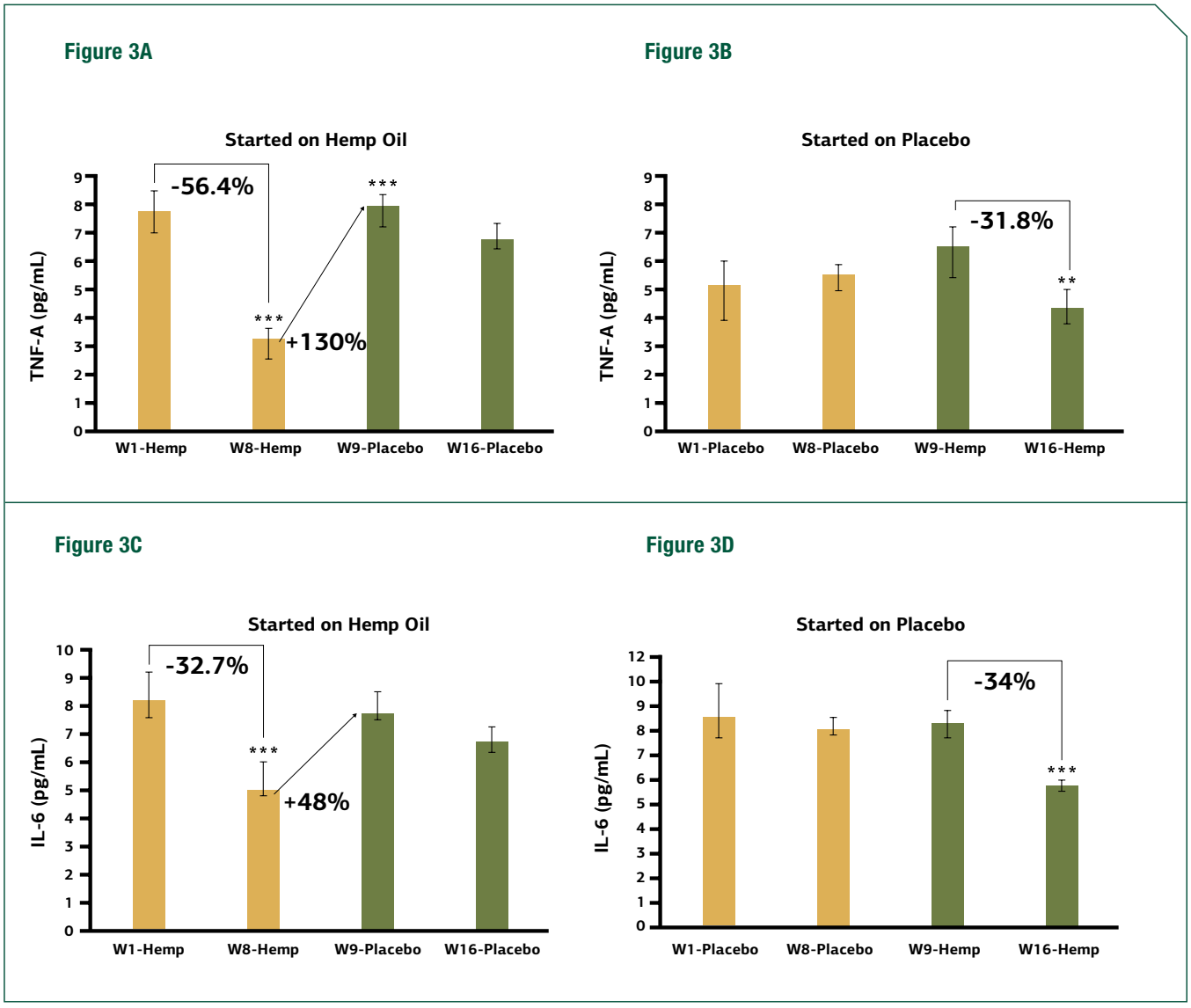


Figure 3. During the intervention phase, the administration of hemp-derived phytocannabinoids resulted in a significant reduction ($p < 0.05$) in proinflammatory markers (interleukin-6, interleukin-8, and tumor necrosis factor-alpha) in dogs' serum compared to the placebo phase.

Figure 3E

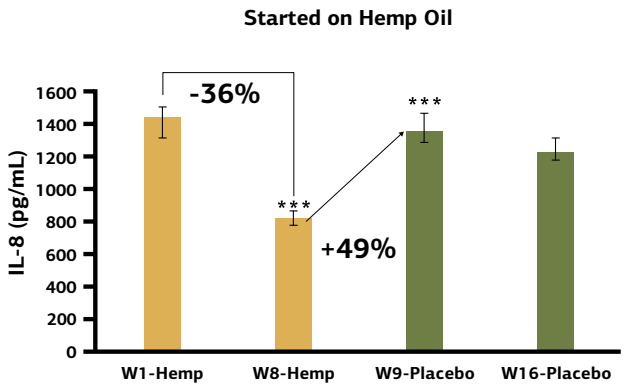
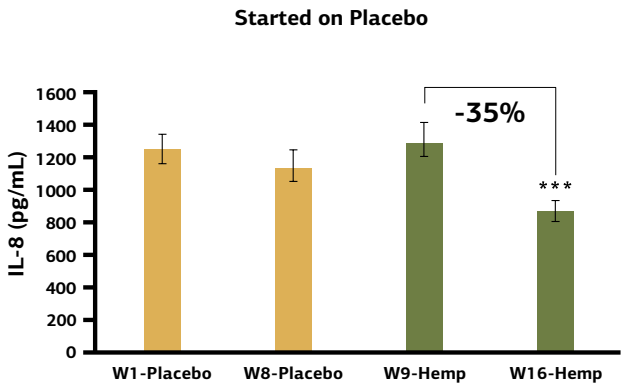


Figure 3F



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IMPROVED OVERALL PHYSICAL ACTIVITY AS MEASURED BY FITBARK ACCELEROMETERS

Hemp-derived phytocannabinoids demonstrated a significant increase in dogs' physical activity levels (18% and 35% in groups 1 and 2, respectively) compared to the placebo phase, as shown in Figure 4 using Fitbark accelerometer data. This increase indicates improved energy levels, motivation, and overall physical engagement. Additionally, the observed 17% decline within the group when switched to the placebo phase highlights the potential efficacy of hemp-derived phytocannabinoids in enhancing dogs' activity and well-being, presenting a promising opportunity to enhance their quality of life.

Figure 4A

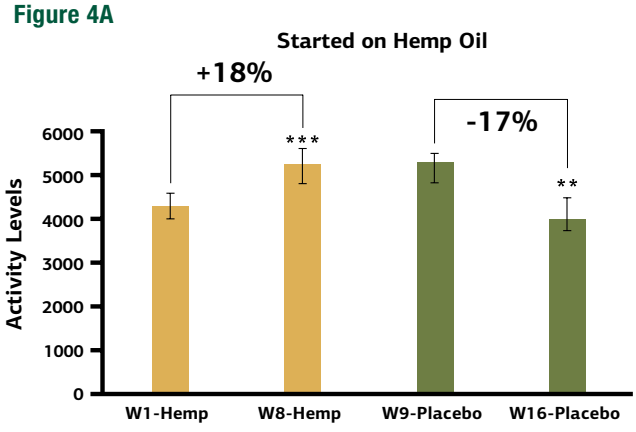

Figure 4B

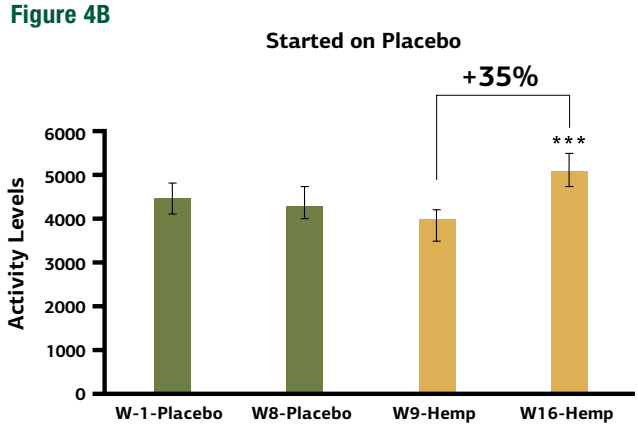

Figure 4. Hemp-derived phytocannabinoids positively impact dogs' physical activity status, as shown by the Fitbark accelerometer data.

IMPROVED GAIT AND MOBILITY

Furthermore, a trend of decreasing Gait Lameness scores over time was observed with hemp oil consumption, indicating an increase in optimal limb function in the intervention group compared to the placebo (Figure 5). On the other hand, both groups reported an increase in lameness scores of 7% to 16% during the placebo phase of the trial (also shown in Figure 5).

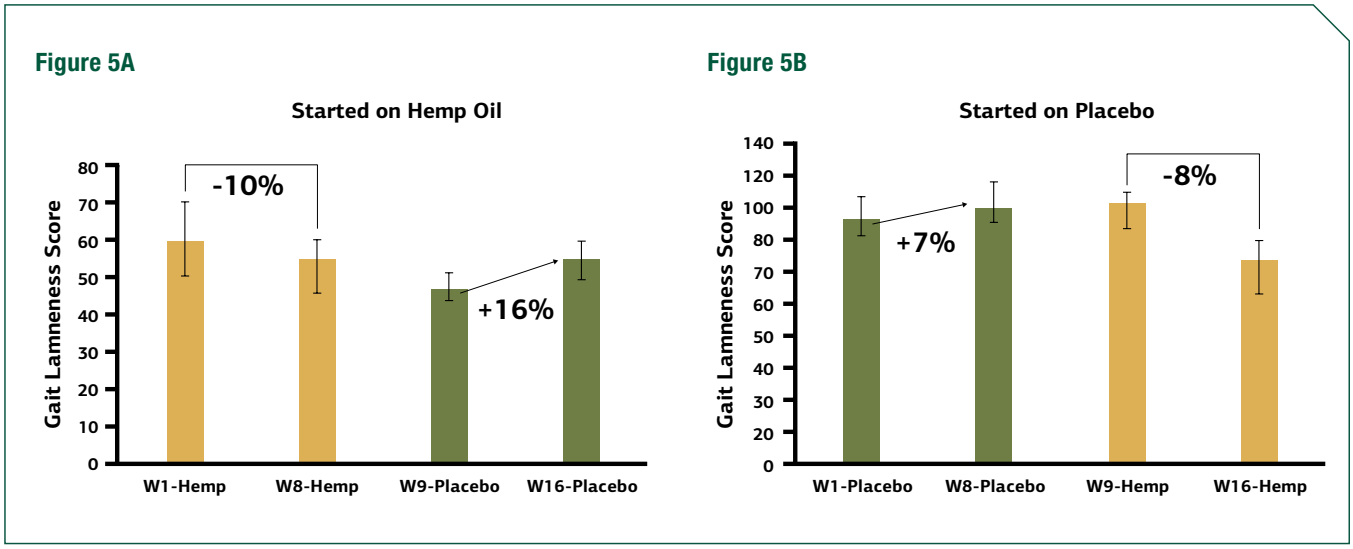

Figure 5. Hemp-derived phytocannabinoids positively impact dogs' gait and mobility.

CONCLUSION:

These findings collectively demonstrate the safety and efficacy of Standard Process® farm-derived VF Hemp Oil in reducing body discomfort, managing inflammation, and potentially improving overall activity, as well as positive trend in gait and mobility in dogs. The administered amount of 2 mg/kg body weight twice daily proved effective in producing these positive outcomes.

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