A Wellness Rx Report:

Observational CBD Cream Study

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Abstract

In an attempt to evaluate the effects of it's new Homeopathic CBD Cream on patients diagnosed with chronic pain, *Wellness Rx* tested the effects on sleep, muscle and joint pain, pain management, mobility, and stress. A total of four individuals were given jars of the cream, along with a questionnaire and were asked to fill it out for a period of 30 days to test for effectiveness. Results showed that the cream reduced pain, increased mobility, and demonstrated a decrease in pain-related stress. Patients reported that the cream worked fast, allowed for a more comfortable sleep and provided better pain-related stress coping skills. To further confirm these results, *Wellness Rx* also interviewed four other patients that had become repeat purchasers of the cream. In both groups, it was found that the cream applied to pain areas worked fast and provided patients sustainable benefits equal to or better than pain relief products used in the past. Overall, it can be shown that the *Wellness Rx* Homeopathic CBD Cream had substantial effects on managing chronic pain and provided patients with a tool to return to their daily lifestyle pain-free.

Introduction

Hemp Oil has become a mainstream market rage across the United States. Hemp Oil is extracted from the hemp plant and contains over eighty compounds or cannabidiols, with the most commonly extracted being CBD Oil. CBD does not contain the cannabidiol THC or the psychoactive ingredients that are known to produce the altered state of consciousness. The source of the extracted hemp plant is important to know, especially if pesticides have been used in the growth. The final product makeup of the extract will determine the bioavailability, or the amount of active ingredients that enter the bloodstream. The higher the bioavailability, the less product is needed to achieve results.

CBD Oil works primarily to calm down the brain and spinal cord, working to stabilize any neuroinflammation in the brain and reduce over neuroinflammation in the body. This reduction in inflammation improves the immune system, increases body and mind detoxification, and reduces pain. This is why when CBD Oil first hit the market it was originally targeted for individuals diagnosed with two epilepsy disorders, Dravet syndrome and Lennox-Gastaut

syndrome. Today, goals for CBD Oil treatments range from reduced sickness, improved relaxation and sleep quality, improved clarity of thought, enhanced energy, reduced body pain, reduced addictive urges, and treatment of chronic conditions such as epilepsy, ADHD, manic depression, Alzheimer's Disease, and certain cancers. CBD Oil does hold promise in helping patients remove or reduce daily use of both prescription (i.e. benzodiazepines, sleep medications, and opioids) and over-the-counter medications (i.e. ibuprofen, acetaminophens).

The World Health Organization (WHO) recognizes CBD as being safe, non-toxic, and with little to no side effects, thus making CBD a safe alternative to synthetically derived options. Although the central nervous system is linked to the crucial processes run by the brain and spinal cord, CBD has no effect on the regions of the brain that control heart and lung function. This is why fatal overdoses related to cannabidiols are virtually impossible¹.

CBD Oil can be taken into the body in multiple ways, including the inhalation of smoke or vapor, as an edible, as a sublingual tincture (under the tongue), in capsule form, or applied topically to an affected area. Products can be pure CBD Oil (isolate) or a mixture of CBD Oil with other extracted cannabidiols (full spectrum oil). While CBD Oil is usually well-tolerated, and serious adverse effects are rare, it should be avoided or used with caution by high-risk groups such as pregnant women, nursing mothers, infants, or patients at risk of psychosis. CBD Oil is also a potent inhibitor of certain enzymes that metabolize certain drugs²

¹ Greenspoon, Peter. (August 2018). Cannabidiol (CBD)-What we know and what we don't. *Harvard Health Publishing*

https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476

²According to the FDA, CBD Oil may increase serum concentrations (make the medication more potent) of macrolide antibiotic (azithromycin; erythromycin; clarithromycin), heart medications (calcium blockers and beta blockers), cyclosporine, sildenafil (Viagra), antihistamines, antiretrovirals, some statins (atorvastatin and simvastatin), mental health medications (benzodiazepines; SSRIs & tricyclic antidepressants, haloperidol & antipsychotics) and opioids (including codeine, hydrocodone & oxycodone).

Although, there are multiple studies done on the effects CBD tinctures and edibles have on anxiety, mental health, sleep quality, etc; there are little to no studies done on the effects of a CBD cream applied topically on a specific area that experiences chronic muscular or joint pain. This observational study was an attempt to address this lack of information.

Methods

Patients of *Wellness Rx* in Tannersville, NY were selected based upon starting symptoms of chronic pain in the muscles and/or joints. A team of eight carefully selected individuals were chosen to participate in the thirty day study with an age range of 49-89 years old.³ Each individual was given an initial oral pre-assessment interview (Appendix A), a *Wellness Rx* questionnaire to fill out each evening (Appendix B), as well as a one ounce jar of the *Wellness Rx* Homeopathic CBD Cream. Individuals were asked to return to the pharmacy at the end of every week for a check-in, a new jar of cream, and another questionnaire, as well as to complete a post-study interview after completion of the four weeks (Appendix C). To compensate for the four patients that began the study but dropped out in the early stage of investigation, four other patients that were repeat purchasers and had been using CBD Cream for an extended period of time were added to the study for investigation.

The topical cream is a unique blend of CBD Oil isolate, curcumin essential oil, which is primarily used to reduce inflammation, and a special homeopathic base cream which includes arnica, belladonna, and diluted snake and lizard venom, used to reduce inflammation, and break up fluid within the pain area.

³ Participants that stopped the use of the cream within days (i.e. afraid of drug testing, didn't feel comfortable, potential drug interaction, started using an internal prednisone medication) or did not feel effects within one week of use (one individual used the cream for 7 days but did not feel any change due to irreversible muscle damage).

Finding the right patient frequency & correct application was crucial for the success of the cream, we considered this a patient's "sweet spot". The CBD Cream should have effects on a patient within five to ten minutes after application with the majority of effects being shown after one day of use. Study participants were initially asked to apply the cream twice a day (every twelve hours, i.e. morning and night) and in a six inch circumference around the target area. Once cream benefits were realized, daily dosages & frequency were adjusted to meet the individuals needs.

Based on starting symptoms, some individuals were given a placebo cream to use every other day to show the positive effects of the CBD cream. The placebo was placed in an identically labeled jar, the only difference being a letter "B" written on the top as opposed to the "A" written on the actual study CBD cream. The contents of the placebo were "Palmer's Cocoa Butter Formula with Vitamin E." This specific cream was used due to the color match of the cream with the CBD formula, the lack of smell, as well as the lack of pain reducing effects. Individuals who were given both the placebo and the study cream had the placebo removed from the study after one week of use.

Observations/Results

All patients reported liking the design of the jar, the color and the scent of the cream, as well as the *Wellness Rx* logo and packaging. It seemed that the one ounce jar of cream provided was sufficient for the individuals for two weeks with the dosage each was given. The number one observed benefit reported by patients was the decrease in pain from initial pain ratings, the increase in mobility, and the decrease in pain-related stress.

Patients reported that the use of the cream allowed them to find better pain-related coping skills. This is a good indicator of trial success, whether the skills be "real" or "perceived," both lead to overall good outcomes (stress reduction, better sleep, more energy, better decision-making, and improved confidence). Individuals also stated that the cream gave temporary relief to life-long pain and that for the first time in years they were able to sleep, exercise, and enjoy daily activities without the fear of heightening their pain.

Overall the CBD cream had high success. Most first time cream users had positive results with the exception of a few individuals who reported no change in sleep (due to use of sleeping medications, as well as lifelong insomnia). Our best results showed patients that reported that chronic pain was now manageable due to the addition of the CBD cream into their lifestyle (Case Studies can be found in Appendix D).

Individuals who had previously purchased the cream were interviewed and asked how the cream had worked in their daily life and what made them purchase the cream multiple times. Almost all of the patients stated that the cream supplied "immediate relief with the most relief of any other pain-related cream." They stated that they had clear discomfort when the cream was not used and that the daily implementation of the cream into their daily life has improved their overall wellbeing. These patients included a correctional officer who comes home at night to swollen legs with major discomfort, she stated that the application of the cream at night before going to bed provides her relief to sleep; an artist and fisherman that has received excellent results managing his body pain during the day and upon awakening. This patient also reported experimenting with the cream by diluting it with Witch Hazel to successfully relieve his scalp's itching and redness. Another patient who purchased the cream has reported multiple diagnoses

and has suffered from chronic pain for over thirty years, the cream has helped relieve her back pain. Lastly, another patient purchased the cream for use on her neck and back pain, but has experimented with it on her resistant adult acne, which she was unable to eradicate for twenty years. Amazingly, she reported that the cream opened up her pores and removed the trapped dead bacteria in two nights. Other individuals who have frequently purchased the cream from *Wellness Rx* have reported the positive changes that have occurred and the benefits the cream has had on their lifestyle, but no testimonials were taken from these individuals to be reported in this study.

Conclusion

As CBD use becomes more widespread and objective research increases, the benefits of reduced body inflammation and body detoxification could start to demonstrate expanded therapeutic benefits for patients. These benefits could include the broad field of wellness and prevention (improved immune systems, decrease in sleep deprivation, lower cortisol levels), chronic diseases (Crohn's disease; diabetes: by allowing more insulin to enter the cells to reduce glucose levels; improve management of high blood pressure; reduce episodes of chronic migraines; dementia), mental and behavioral challenges (ADHD; obsessive-compulsive disorder; PTSD; autism; depression; addiction), public health challenges (technology induced anxiety; COVID-19 related anxiety), and also has possible benefits for reducing challenges due to Lyme Disease as well as certain cancers.

The use of the high-quality CBD cream by motivated patients clearly did produce positive benefits in a short amount of time, with little to no adverse side effects. With patient

compliance and experimentation we were able to find the correct frequency and application for individuals which then allowed for optimal therapeutic use of the cream on their chronic pain areas.

Results of the study showed that a high percentage of patients reported a decrease in pain, an increase in mobility, and an increase in pain management techniques. Frequent buyers of the cream have felt similar effects with the long term use of the cream, with most of the individuals claiming that the CBD Cream would be added into their daily lifestyle. Overall this observational study showed the positive effects of CBD Cream and a future study would assist in furthering our results.

Study Group Investigators:

Ed Ullmann R.PH, MPA is the owner and pharmacy manager of *Wellness Rx L.L.C*, an independent pharmacy in Tannersville, NY that blends traditional medicine with natural medicine. Mr. Ullmann is a member of the President's Advisory Council at Albany College of Pharmacy & Health Services and he serves as an Adjunct Experimental Faculty member for the school. Mr. Ullmann has developed over 30 start-up companies and for over 16 years served as an HMO founder & CEO. He has also been a Pharmacy District Manager, a mental health director, county legislator, and was owner/operator of the world-renowned Warm Mineral Springs in Florida. Mr. Ullmann holds a B.S. degree in Pharmacy from Albany College of Pharmacy & Health Services, an MPA degree from Maxwell School of Citizenship and Public Affairs at Syracuse University, and was a National HMO Fellow at Georgetown Medical School.

Michelle Thorpe is a pharmacy intern at *Wellness Rx L.L.C.* Ms. Thorpe was born and raised in Tannersville, NY. She has her undergraduate degree from The University of Tampa where she received her Bachelor of Science in General Biology. She plans on obtaining her Master of Science in Physician Assistant Medicine in the coming year. Michelle would also like to thank fellow intern, Angelia Benjamin for her assistance on the study.

Patient Name: DOB: What are your current medications? What type of chronic pain are you experiencing? (Muscular? Joint?) When do you experience the most pain? (Morning? Night? All Day?)	APPENDIX A	: Pre-Assessment Interview
What are your current medications? What type of chronic pain are you experiencing? (Muscular? Joint?) When do you experience the most pain? (Morning? Night? All Day?)	Patient Name:_	
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When do you experience the most pain? (Morning? Night? All Day?)		
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• When do you experience the most pain? (Morning? Night? All Day?)	0	
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Freatment Plan:	Γreatment Plan	:

APPENDIX B: Weekly Questionnaire					
Wellness Rx	CBD Cream Study				
Patient name:	DOB:	Week:			
Wellness RX Representatives:					
Contact Phone Number:					

Sleep Quality	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Hours of Sleep							
Was Sleep Interrupted? How Many Times?							
What Awakened You?							
How Rested Do You Feel? (1-10, low to high)							
Rate Your Energy Level (1-10, low to high)							
Stress Level/ Coping Skills (1-5, low to high)							
Pain Health (1-10, low to high)							
Muscular							
Joints							
Mobility (1-5, low to high)							
Muscular							
Joints							

Starting	
Symptoms:	
APPENDIX C: Post-Study Interview	
Patient Name:	
DOB:	
Date:	
Do you feel that the addition of the CBD Cream increase.	ased your health and wellness over
the 30 days?	
0	
Do you experience any chronic pain? If so, where and	when?
o	
Do you think that you will add the CBD Cream into you	our daily lifestyle when the onset of
pain occurs?	
0	
 Would you recommend this product to family and frie 	nds for chronic pain management?
0	

APPENDIX D

Patient A:

A 86 year old woman presented with joint pain in the knees, hands, and spine due to osteoarthritis and spinal stenosis. Patient stated that the pain was worse in the morning upon awakening. She rated her knee pain at a 9/10 in the morning and an 5/10 in the evening, her spine pain at a 8/10 for both times of day, and her hands as a 9/10 in the morning and a 5/10 in the evening. The treatment plan provided included a placebo. Patient was asked to apply cream A (CBD Cream) in the morning to her problem areas 4 out of 7 days, and to apply cream B (placebo) in the same dosage 3 out of 7 days.

Patient reported in the 1st week that days the placebo was used her pain health and mobility were all relatively high (8/10 and 6/10, respectively). Days the CBD cream was used pain health and mobility were affected (4/10 and 5/10, respectively). After week 1, the placebo was removed from the study and the CBD cream was used 7 days of the week applied to the hands, spine, and knees in the mornings. Use of the cream showed that the patient's pain health decreased, her mobility ratings were high and the ability to cope with stress related pain had risen from a 1/10 to a 7/10.

Patient reported that during the study she had experienced sciatica pain in her right hip daily, but the pain temporarily felt relief after the application of the cream everyday. Patient reported consistent results with the cream application for the 4 week period.

Patient B:

A 56 year old woman presented with right knee pain due to a hyperextension as well as arthritis of the knee and right wrist pain due to a cyst that was scheduled to be removed, but has since been postponed due to COVID-19. Patient stated that she usually experienced more pain at night, but it depended on her daily activities, ranking this pain as 6/10. The treatment plan provided did not include a placebo. Patient was asked to apply cream to the whole knee (on and around) and to the wrist twice a day.

Patient reported that with use of the cream her muscular and joint pain had decreased and that her pain health had decreased to a 4/10. Patient stated that the arthritis in the right knee was relieved after the use of the cream and that she had experienced more mobility than she had in years. The wrist mobility was not as high, and that is due to the cyst. Patient also reported that

her sleep schedule was not affected by the use of the cream at night, this is due to her use of Ambien to sleep.

Overall consistent results were reported and the patient stated that she is considering adding the cream to her daily life, especially on days where her activity level is high.

Patient C:

A 65 year old woman presented with right and left knee pain due to osteoarthritis (bone-on-bone), as well as arthritis in her right ankle. Patient stated that the pain is persistent in both morning and night, but after movement pain tends to subside. She rated her knee pain at an 8/10 both in the morning and at night. The treatment plan provided included a placebo. Patient was asked to apply the cream two times a day from the ankle up the leg to the calf on both legs. Cream A (CBD Cream) to be used 4 out of 7 days and Cream B (placebo) 3 out of 7 days. Patient reported that before the use of the cream her pain health was a 6/10 for both muscular and joint health and after the addition of the cream pain health had dropped to a 3/10 with some days reporting a 2/10. The placebo was removed from the study after week 1. Patient reported that sleep was not a good indicator of pain, as she has been a lifelong insomniac. Following up with the patient at the end of the study she stated that she used the cream on her right ankle in the morning and at bedtime. The cream provided immediate pain relief especially the intensity of the pain. Prior to taking the cream, the patient reported that she couldn't get comfortable at night while in bed, but after applying the cream this discomfort went away. Patient reported however that she has been an insomniac for many years and the cream had no effect on this disorder, but her awakening at night was no longer pain related.

Patient D:

A 67 year old man presented with moderate muscular pain in the back and shoulders due to years working as a carpenter. Patient stated that the pain is persistent, all day pain, especially after exercising or stressing those muscles. The treatment plan provided did not include the use of a placebo. Patient was asked to apply the cream two times per day to the back and shoulders in a 6 inch diameter.

Patient reported that during week 1 of the study most nights he was awakened by pain. As the week went on his pain health was seen to decrease from a 5/10 to a 3/10 with the addition of the cream. Entering week 2 the patient reported that his pain health had remained steady and that his mobility had increased to a 5/5. As the patient entered week 3, he stated that the cream really seemed to be helping, his pain health reached a 1/10 with his mobility remaining a 5/5 with some days dropping to a 4/5 due to an increase in activity to the area. Week 4 the patient reported that

his pain health was a consistent 1/10 and his mobility varied from a 4/5 to a 5/5, this was due to the lack of pain and the increase in activities such as kayaking and exercising.

During the post study interview, the patient stated that the cream really worked for him, by the end of the month he no longer had interrupted sleep due to pain, he was able to increase activities and exercise and that his chronic pain was now manageable due to the addition of the cream into his daily lifestyle.