Original Article

Analgesic Effects and Skin Sensitization of 1% Topical Cannabidiol Oil for Myofascial Pain

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Abstract

OBJECTIVES: To evaluate the analgesic effects and skin sensitization of 1% topical cannabidiol (CBD) oil in participants with myofascial pain.

MATERIALS AND METHODS: This study included 192 participants diagnosed with myofascial pain. Participants applied 1 g of 1% topical CBD oil to the painful area twice daily for 14 days. Pain intensity was assessed using the Numerical Rating Scale (NRS) at baseline and at 30, 60, and 120 minutes and on Days 7 and 14. Analgesic effects were determined by changes in pain scores and percentage of pain relief. Skin sensitization was evaluated using a human patch test consisting of induction and challenge phases, with assessment of local cutaneous reactions.

RESULTS: Among 192 participants, 78 (40.6%) were male and 114 (59.4%) were female. The shoulder was the most frequently reported pain location (32.8%), followed by the leg (29.7%) and back (22.9%). Mean pain scores progressively decreased following treatment, with significant reductions from baseline at all assessment time points ($p < 0.001$). Pain relief increased progressively throughout the 14-day treatment period, reaching approximately 41% on Day 14. No clinically significant cutaneous reactions or evidence of skin sensitization were observed during the human patch test.

CONCLUSION: The findings suggest that 1% topical CBD oil may reduce pain intensity in individuals with myofascial pain and was well tolerated without observable skin sensitization. Further randomized controlled studies are warranted to confirm its efficacy and long-term safety.

Keywords: cannabidiol, analgesic, skin sensitization, myofascial pain

Myofascial pain is a common musculoskeletal condition characterized by localized or referred pain associated with myofascial trigger points within skeletal muscles. It commonly affects the neck, shoulders, back, and extremities and may interfere with physical activity, occupational performance, sleep, and overall quality of life.[1] Management of myofascial pain generally involves a combination of pharmacological and non-pharmacological approaches, including oral analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), topical analgesic preparations, physical therapy, stretching, and massage.[2] However, conventional pharmacological treatments may be associated with adverse effects, particularly when used repeatedly or for prolonged periods. Consequently, there is increasing interest in topical therapeutic agents that may provide localized pain relief while minimizing systemic exposure.

Cannabidiol (CBD) is a major non-intoxicating phytocannabinoid derived from *Cannabis sativa L*. Unlike Δ9-tetrahydrocannabinol (THC), CBD does not produce the characteristic psychoactive effects associated with cannabis. Preclinical and emerging clinical evidence suggests that CBD may possess analgesic and anti-inflammatory properties through multiple mechanisms. CBD interacts directly or indirectly with several molecular targets involved in nociception and inflammation, including components of the endocannabinoid system, transient receptor potential

channels, serotonin receptors, and other signaling pathways associated with pain modulation and inflammatory responses.[3, 4] These pharmacological properties have led to growing interest in the potential application of CBD for the management of musculoskeletal and localized pain.[5, 6]

Topical administration represents a potentially useful route for CBD delivery in patients with localized myofascial pain. Application directly to the painful area may facilitate local exposure to CBD while limiting systemic absorption and systemic adverse effects.[5] An oil-based preparation may additionally facilitate massage of the affected muscles. Massage itself may contribute to temporary pain relief by reducing muscle tension, promoting local circulation, and providing mechanical stimulation to painful or hypersensitive areas. Therefore, the topical application of CBD oil combined with gentle massage may provide complementary effects for relieving myofascial pain. A 1% topical CBD oil formulation represents a relatively low-concentration preparation intended for direct application and massage over painful areas. Nevertheless, despite increasing availability and use of topical cannabinoid-containing products, clinical evidence regarding their analgesic effectiveness remains limited, and the optimal concentration and application regimen have not been clearly established. Evaluation of a standardized 1% CBD oil formulation under controlled clinical conditions is therefore necessary to determine whether topical application can produce measurable pain relief in individuals with myofascial pain.

In addition to therapeutic effectiveness, dermatological safety is an important consideration for any product intended for repeated topical application. CBD formulations contain not only the active compound but also carrier oils and other formulation components that remain in direct contact with the skin. Repeated exposure may potentially cause local adverse reactions such as erythema, pruritus, irritation, or allergic contact dermatitis in susceptible individuals. Assessment of skin sensitization is therefore important for determining whether repeated application of 1% topical CBD oil induces signs or symptoms suggestive of an allergic or sensitization response.

Accordingly, this study was designed to evaluate both the analgesic effects and skin sensitization of 1% topical cannabidiol oil in individuals with myofascial pain. The CBD oil was applied directly to the painful area and gently massaged into the skin to investigate its potential for reducing pain following topical administration. Pain intensity and pain relief were assessed following treatment to determine the analgesic response, while local skin reactions were evaluated to identify potential sensitization associated with repeated topical exposure. By simultaneously assessing effectiveness and dermatological safety, this study may provide clinically relevant evidence regarding the potential use of 1% topical CBD oil as a complementary topical intervention for the management of myofascial pain.

Materials and Methods

Highly purified cannabidiol (CBD) isolate powder (99.99% purity) was provided by Cannex Lab Co., Ltd. The 1% topical CBD oil formulation used in this study was prepared in-house using the purified CBD isolate. The study was conducted in two phases. The first phase evaluated the analgesic effects of 1% topical CBD oil in participants with myofascial pain, while the second phase assessed the potential for skin sensitization following topical application of the CBD oil in human participants. The study was conducted in accordance with the protocol approved by the Human Research Ethics Committee of Phichit Province, Thailand (Approval number: 38/2569). The target population consisted of individuals diagnosed with myofascial pain who met the predefined eligibility criteria.

Sample size calculation

The minimum required sample size was calculated using the N4Studies application based on the estimation of a single population proportion. Assuming an expected proportion of 50% and a 95% confidence level, the target sample size was set at 210 participants, including an allowance of approximately 10% for potential dropout.

Inclusion criteria

Participants were eligible for inclusion if they met all of the following criteria:

1. Male or female participants aged ≥ 20 years.
2. Clinically diagnosed with myofascial pain by a physician or qualified healthcare professional.
3. Presence of localized musculoskeletal pain associated with myofascial pain at the time of enrollment.
4. Baseline pain intensity of at least 3 on the 0–10 Numerical Rating Scale (NRS).
5. No use of systemic or topical corticosteroids or non-steroidal anti-inflammatory drugs (NSAIDs) within 2 weeks prior to enrollment.
6. No use of other topical analgesic preparations, including counterirritants or cannabinoid-containing products, on the affected area within 14 days prior to enrollment.
7. Intact skin at the intended application site, without open wounds, active dermatitis, infection, or other clinically significant skin lesions.
8. Able to understand the study procedures, follow the treatment instructions, and reliably report pain intensity using the NRS.
9. Willing to comply with the study protocol, including the application of 1% topical CBD oil twice daily for 14 consecutive days.
10. Willing and able to provide written informed consent prior to participation in the study.

Exclusion Criteria

Participants were excluded if they met any of the following criteria:

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1. Pregnancy or breastfeeding.
2. Known hypersensitivity or history of allergic reactions to CBD, cannabis, cannabis-derived products, or any component of the study formulation.
3. Presence of active dermatological conditions at or near the intended application site, including dermatitis, eczema, psoriasis, skin infection, open wounds, or significant skin irritation.
4. Presence of acute musculoskeletal injury, fracture, or other clinically significant conditions that could account for pain in the treatment area.
5. Diagnosis of other chronic pain disorders that could substantially interfere with the assessment of myofascial pain.
6. Use of systemic or topical corticosteroids, NSAIDs, or other analgesic medications during the prohibited period before enrollment or during the study, unless specifically permitted by the study protocol.
7. Current use of topical CBD, cannabis-containing preparations, or other topical analgesic products on the treatment area.
8. History of a clinically significant adverse reaction to topical oils or similar dermatological preparations.
9. Presence of a medical or dermatological condition that, in the investigator's judgment, could interfere with the evaluation of analgesic effects or skin sensitization.
10. Inability or unwillingness to comply with the treatment regimen, study assessments, or follow-up procedures.

Assessment of analgesic effects

A total of 192 participants diagnosed with myofascial pain were included in the analgesic-effect assessment. Before initiation of the intervention, demographic and clinical characteristics, including age, sex, location of pain, characteristics of pain, and baseline pain intensity, were recorded. Baseline pain intensity was assessed before the first application of the study product using the Numerical Rating Scale (NRS).

Each participant received 1 g of 1% topical cannabidiol (CBD) oil per application. The study product was applied directly to the affected painful area into the skin. Participants were instructed to apply the CBD oil twice daily, in the morning and evening, for 14 consecutive days. The amount of CBD oil, frequency of application, and application technique were standardized according to the study protocol to minimize variability among participants.

Pain intensity was evaluated using the 11-point NRS, a commonly used self-reported instrument for the assessment of pain intensity. Participants were asked to rate their current pain intensity on a scale ranging from 0 to 10, where 0 represented "no pain" and 10 represented the "worst imaginable pain." NRS scores were categorized as follows: 0, no pain; 1-3, mild pain; 4-6, moderate pain; and 7-10, severe to worst possible pain.

To evaluate the short-term analgesic response following the initial application, pain intensity was assessed at baseline (before application) and at 30 minutes, 1 hour, and 2 hours after topical application. To determine the analgesic effect following repeated administration, pain intensity was subsequently evaluated on Days 7 and 14 of treatment. The same NRS assessment method was used at each time point to ensure consistency in pain evaluation. The primary assessment of analgesic effectiveness was based on changes in NRS pain scores from baseline to each post-treatment assessment. The mean NRS score at each time point was compared with the baseline value to determine the magnitude and temporal pattern of pain reduction following topical CBD oil application. The change in pain intensity was calculated as the difference between the baseline NRS score and the NRS score at each post-treatment assessment:

$$\textbf{Change in NRS score} = \textbf{Baseline NRS score} - \textbf{Post-treatment NRS score}$$

The percentage reduction in pain intensity was calculated relative to the baseline NRS score using the following equation:

$$\textbf{Pain reduction (\%)} = \frac{\textbf{Baseline NRS score} - \textbf{Post treatment NRS score}}{\textbf{Baseline NRS score}} \times 100$$

A greater reduction in the NRS score indicated a greater analgesic response. Changes in pain intensity across the assessment time points were analyzed to characterize both the onset and progression of the analgesic response during the 14-day treatment period. Throughout the study, participants were also monitored for local adverse events associated with topical application, including erythema, pruritus, burning sensation, irritation, rash, or other unexpected cutaneous reactions. Any adverse events reported by participants or observed during follow-up were documented and evaluated for their potential relationship to the study product.

Human patch test for skin sensitization

Skin sensitization to 1% CBD oil was evaluated using a human patch test consisting of an induction phase, a rest period, and a challenge phase. The test product was applied under a patch to a defined area of intact skin during the induction phase. The application site was examined after patch removal for local cutaneous reactions. Following the induction phase, participants underwent a rest period without exposure to the study product, followed by a challenge application to a previously untreated skin area.

Skin reactions were assessed after the challenge application for clinical signs of delayed hypersensitivity, including erythema, edema, pruritus, papules, vesicles, bullae, and other clinically significant cutaneous reactions. The onset, severity, and duration of any observed reactions were documented. The absence of clinically significant reactions following the challenge was interpreted as no observable evidence of skin sensitization, whereas the development of a

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delayed inflammatory response following re-exposure was considered suggestive of a potential sensitization reaction. All adverse skin reactions were recorded and evaluated throughout the study.

Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 25.0. Descriptive statistics were used to summarize participants' demographic characteristics, pain locations, and pain characteristics. Continuous variables were presented as means with standard deviations (SD) or standard errors of the mean (SEM), as appropriate, while categorical variables were summarized as frequencies and percentages. Paired t-tests were used to compare mean pain scores at baseline with those measured at 30 minutes, 60 minutes, 120 minutes, 7 days, and 14 days after the application of 1% topical CBD oil. A p-value of < 0.05 was considered statistically significant.

Results

A total of 192 participants with myofascial pain were included in the study. As shown in Figure 1, the shoulder was the most frequently reported site of pain, accounting for 63 participants (32.8%), followed by the leg in 57 participants (29.7%) and the back in 44 participants (22.9%). Posterior neck pain was reported in 19 participants (9.9%), while combined neck and shoulder pain was the least frequently reported pain location, occurring in 9 participants (4.7%).

Regarding pain characteristics, throbbing pain was the most commonly reported type of pain, occurring in 63 participants (32.8%), followed by cramping pain in 57 participants (29.7%) and sharp pain in 44 participants (22.9%). Dull pain was reported in 19 participants (9.9%), whereas radiating pain was the least common, reported in 9 participants (4.7%) (Figure 2).

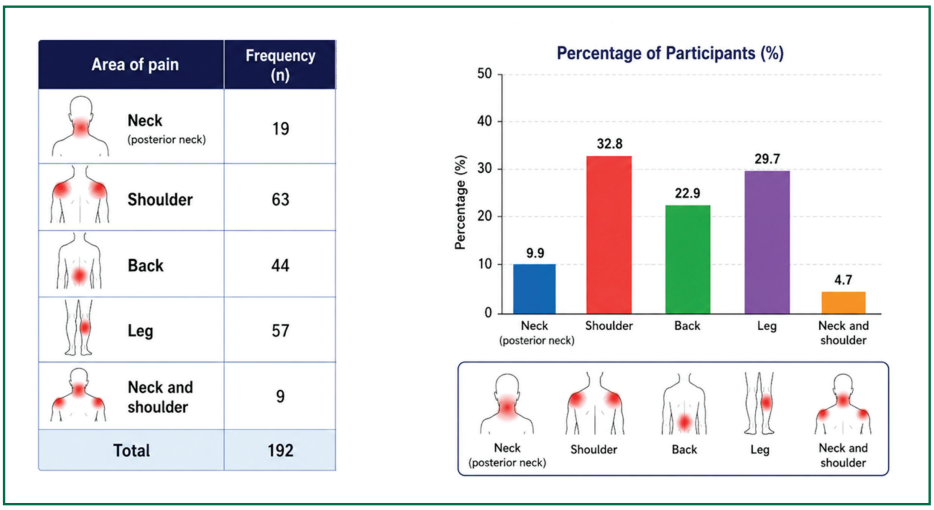


Figure 1: Distribution of pain by body region among 192 participants.

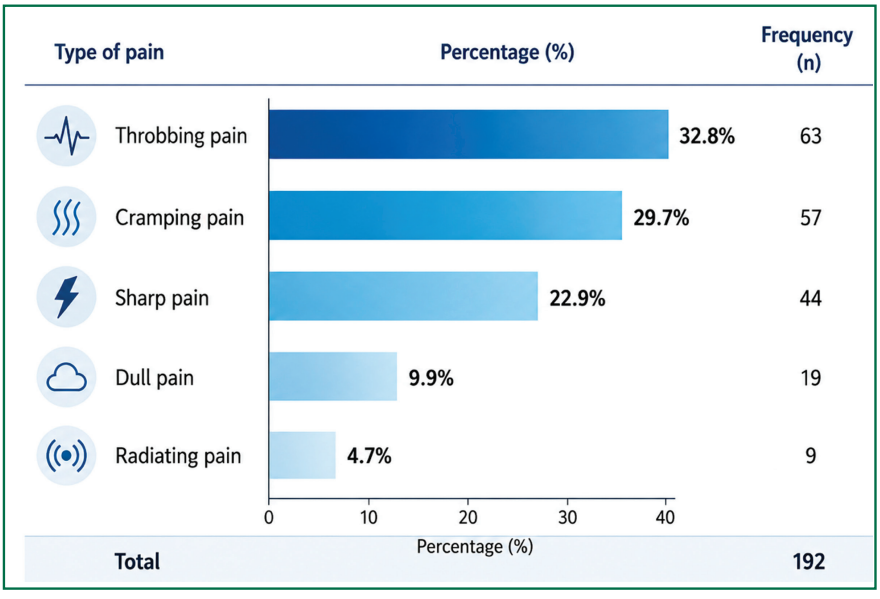


Figure 2: Distribution of pain characteristics among participants (N = 192).

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A total of 192 participants with myofascial pain were included, comprising 78 males (40.6%) and 114 females (59.4%). The mean age was 50.9 ± 15.2 years in males and 56.7 ± 15.0 years in females. Most participants were aged 60–79 years (41.1%), followed by 40–59 years (35.9%) and 20–39 years (19.8%). The shoulder was the most commonly reported site of pain (32.8%), followed by the leg (29.7%), back (22.9%), neck (9.9%), and combined neck and shoulder (4.7%), respectively. Among males, leg pain was the most frequently reported (n = 27), whereas shoulder pain was the most common among females (n = 37) (Table 1).

As shown in Figure 3, the mean pain score progressively decreased following treatment with 1% topical cannabidiol (CBD) oil. Compared with the baseline pain score, significant reductions in mean pain scores were observed at 30, 60, and 120 minutes after the initial application, as well as on Days 7 and 14 following treatment (all $p < 0.001$). Pain scores continued to decrease throughout the treatment period, with the greatest reduction observed on Day 14. These findings demonstrate a progressive reduction in pain intensity following topical application of 1% CBD oil over the 14-day treatment period.

As shown in Figure 4, the percentage of pain relief progressively increased following treatment with 1% topical CBD oil. Pain relief was approximately 13% at 30 minutes, increasing to 22% at 60 minutes and 27% at 120 minutes. A greater analgesic response was observed after repeated application, with pain relief reaching approximately 37% on Day 7 and 41% on Day 14. The greatest percentage of pain relief was observed on Day 14, indicating a progressive improvement in pain relief over the 14-day treatment period.

Table 1: Comparison of baseline characteristics between male and female participants

Demographic characteristic	Male, n (%)	Female, n (%)	Total, n (%)
Sex	78 (40.6)	114 (59.4)	192 (100.0)
Age, years,			
Mean ± SD	50.9 ± 15.2	56.7 ± 15.0	54.3 ± 15.3
Range	23–87	20–88	20–88
Age group, years			
20–39	24 (12.5)	14 (7.3)	38 (19.8)
40–59	24 (12.5)	45 (23.4)	69 (35.9)
60–79	29 (15.1)	50 (26.0)	79 (41.1)
≥80	1 (0.5)	5 (2.6)	6 (3.1)
Area of pain			
Neck	7 (3.6)	12 (6.3)	19 (9.9)
Shoulder	26 (13.5)	37 (19.3)	63 (32.8)
Back	14 (7.3)	30 (15.6)	44 (22.9)
Leg	27 (14.1)	30 (15.6)	57 (29.7)
Neck and shoulder	4 (2.1)	5 (2.6)	9 (4.7)

Regarding sensitization, no clinically significant skin reactions were observed during the induction or challenge phases of the human patch test. None of the 192 participants developed erythema, edema, pruritus, papules, vesicles, bullae, or other signs of delayed hypersensitivity following exposure to 1% CBD oil. These findings indicated no observable evidence of skin sensitization to 1% CBD oil under the study conditions.

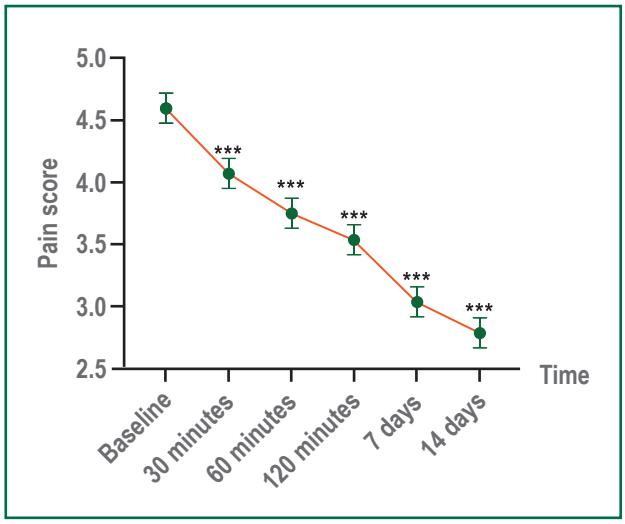


Figure 3: Changes in pain scores following application of 1% topical cannabidiol (CBD) oil. Pain intensity was assessed using the Numerical Rating Scale (NRS) at baseline and at 30, 60, and 120 minutes, and on Days 7 and 14 following treatment. Data are presented as mean ± standard error of the mean (SEM), ***Significant $p < 0.001$.

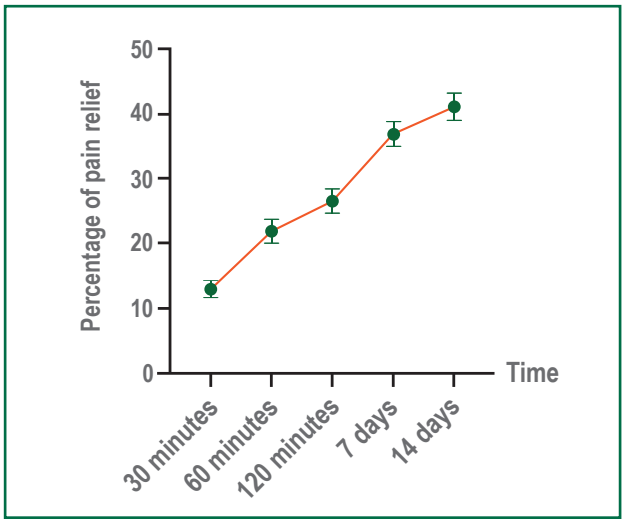


Figure 4: Percentage of pain relief following application of 1% topical cannabidiol (CBD) oil. The percentage of pain relief was assessed at 30, 60, and 120 minutes, and on Days 7 and 14 following treatment. Pain relief progressively increased over the treatment period, with the greatest percentage of pain relief observed on Day 14. Data are presented as mean ± standard error of the mean (SEM).

Discussion

The present study demonstrated that 1% topical cannabidiol (CBD) oil was associated with a progressive reduction in pain intensity among participants with myofascial pain. The present findings are consistent with previous clinical studies suggesting a potential analgesic effect of topical CBD. Nitecka-Buchta et al. reported that transdermal CBD applied twice daily for 14 days significantly reduced pain intensity and masseter muscle activity in patients with myofascial pain associated with temporomandibular disorders.[7] Similarly, Xu et al.[8] demonstrated that topical CBD significantly reduced pain and discomfort in patients with symptomatic peripheral neuropathy. A randomized controlled trial in patients with thumb basal joint arthritis also demonstrated improvements in pain-related outcomes following twice-daily topical CBD treatment without treatment-related adverse events.[9] Collectively, these findings support the potential role of topical CBD in the management of localized musculoskeletal and neuropathic pain, although differences in CBD concentrations, formulations, pain conditions, and study designs should be considered when comparing outcomes across studies.

The analgesic effects observed in the present study may be related to the multimodal pharmacological actions of CBD. CBD interacts with several molecular targets involved in nociceptive and inflammatory signaling, including transient receptor potential vanilloid 1 (TRPV1), serotonergic 5-HT1A receptors, and components of the endocannabinoid system.[10, 11] Modulation of these pathways may contribute to analgesic and anti-inflammatory effects and may partly explain the progressive reduction in pain observed following repeated topical administration. Nevertheless, the precise mechanisms underlying the analgesic effects of topical CBD in humans remain incompletely understood, and the extent of CBD penetration through the skin may depend on the formulation and delivery system.[12]

Importantly, no clinically significant cutaneous reactions or evidence of skin sensitization were observed during either the induction or challenge phases of the human patch test. No erythema, edema, pruritus, papules, vesicles, bullae, or other signs of delayed hypersensitivity were identified. This finding is consistent with previous clinical studies in which topical CBD formulations were generally well tolerated.[9,13] However, systematic reviews have emphasized that available safety data for topical and transdermal CBD remain limited because of small sample sizes, heterogeneous formulations, and differences in CBD concentrations and exposure periods.[12] Therefore, the absence of sensitization in the present study should be interpreted as evidence of tolerability under the specific conditions and duration of this study rather than definitive evidence of long-term dermatological safety.

Several limitations should be considered. The absence of a placebo or vehicle-control group limits the ability to attribute the observed reduction in pain exclusively to CBD, particularly because massage, the oil vehicle, natural fluctuations in pain, and placebo effects may have contributed to the observed response. In addition, pain intensity was assessed using a self-reported numerical rating scale, and the study duration was limited to 14 days. Further randomized, double-blind, placebo-controlled studies with longer follow-up periods and standardized CBD formulations are warranted to confirm the efficacy, optimal concentration, and long-term safety of topical CBD for myofascial pain.[12,14]

Overall, the findings suggest that 1% topical CBD oil may provide short-term and progressive pain relief in individuals with myofascial pain and was well tolerated without observable evidence of skin sensitization during the study period. These findings support further controlled clinical investigation of topical CBD as a potential complementary approach for the management of myofascial pain.

Limitations

This study has several limitations. First, participant dropout resulted in a smaller final sample size than initially planned, which may have affected the statistical power of the study. Second, pain intensity was assessed using a self-reported numerical rating scale (NRS), which may be influenced by individual differences in pain perception and tolerance. In addition, potential confounding factors, such as massage, stretching, physical activity, and other non-pharmacological pain-relieving measures, could not be completely controlled during the study period. Furthermore, the absence of a placebo or control group limits the ability to attribute the observed reduction in pain exclusively to 1% topical CBD oil. Finally, the relatively short 14-day follow-up period limits conclusions regarding the long-term analgesic effects. Further randomized, placebo-controlled studies with larger sample sizes and longer follow-up periods are warranted to confirm these findings.

Conclusion

The findings of this study suggest that 1% topical cannabidiol (CBD) oil may be effective in reducing pain intensity in individuals with myofascial pain, with progressive pain relief observed over 14 days of treatment. The formulation was well tolerated, with no clinically significant skin reactions or evidence of skin sensitization. These findings support the potential use of 1% topical CBD oil as a complementary option for myofascial pain management. Further randomized controlled studies are warranted to confirm its efficacy and long-term safety.

Conflict of interest

The authors declare no conflict of interest.

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