Experimental and Clinical Psychopharmacology

Manuscript version of

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Funded by:
- National Center for Complementary and Integrative Health
- National Institutes of Health, National Institute on Drug Abuse

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Looking Beyond Traditional Pain Outcomes to Better Evaluate Cannabis's True Potential and Limitations in Chronic Pain Management

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Figure: 0; **Table**: 0

Running title: Cannabis and pain outcomes

Abstract

Cannabis is increasingly used for managing chronic pain, despite the low quality and inconsistency of most evidence from randomized controlled trials, and the divergent expert opinions and guidelines issued by academic societies. In this perspective piece, we suggest a way forward. The clinical trials have focused on traditional chronic pain outcomes (such as pain severity and interference, as well as physical and emotional functioning). However, qualitative studies suggest that many individuals perceive cannabis as beneficial not because it directly reduces pain, but because it alters their psychological responses to it and improves other important outcomes, such as role and social functioning, sleep quality, and opioid substitution, which are largely overlooked in clinical trials of cannabis for chronic pain. We contend that the true clinical potential and limitations of cannabis for pain management may be fundamentally misunderstood if research continues to prioritize conventional chronic pain outcomes alone. We call for the integration of perspectives from people with lived experience in identifying meaningful clinical outcomes for future clinical trials on cannabis and chronic pain. Such a shift would clarify cannabis's true benefits and limitations, ultimately guiding more nuanced, evidence-based, and personalized treatment approaches for chronic pain.

Keywords: Cannabis; Cannabinoid; Pain; Outcomes; Clinical Trial.

Public Significance Statement

Cannabis is increasingly used for chronic pain management, even though research findings and expert opinions are mixed. This article discusses the need to reconsider what constitutes meaningful treatment outcomes in clinical trials on cannabis and chronic pain by incorporating perspectives from people with lived experience. This would help clarify the true benefits and limitations of cannabis and develop clearer clinical guidelines.

Looking Beyond Traditional Pain Outcomes to Better Evaluate Cannabis's True Potential and Limitations in Chronic Pain Management

The medicinal use of cannabis has been legalized in numerous states in the U.S., as well as in countries such as Canada, Israel, Germany, and Australia. One of the primary reasons for the use of medicinal use of cannabis, cannabis-based products (e.g., edibles, patches, topicals, etc.), and synthetic cannabinoids (hereafter referred to collectively as "cannabis") is the management of chronic pain (Bonn-Miller et al., 2014; Fales et al., 2019; Garcia-Romeu et al., 2022). In fact, it is estimated that approximately 78% of people who use medical cannabis report pain relief as their main reason for usage (Romero-Sandoval et al., 2018). Hence, cannabis has garnered significant attention from both the scientific community and the public, especially in the context of the ongoing opioid crisis, as a non-opioid treatment for both cancer-related and non-cancer chronic pain.

Over the past two decades, numerous randomized-controlled trials (RCTs) have assessed cannabis's therapeutic potential for chronic pain. The results have been synthesized in a substantial number of systematic reviews and meta-analyses (Aviram & Samuelly-Leichtag, 2017; Fisher et al., 2021; Gazendam et al., 2020; Häuser, Finnerup, et al., 2018; Häuser, Finn, et al., 2018; Moore et al., 2024; Moore et al., 2021; Rice et al., 2021; Stockings et al., 2018; Wang et al., 2021; Wong et al., 2020). Findings are usually reported to be inconclusive or to reflect statistically significant but small, clinically questionable benefits for pain outcomes (e.g., pain severity, pain interference, and emotional and physical functioning), generally characterized by low-quality evidence, except for chronic neuropathic pain, where more consistent and higher-quality evidence of benefits has been observed (Aviram & Samuelly-Leichtag, 2017; Barakji et al., 2023; Fisher et al., 2021; Gazendam et al., 2020; Häuser, Finnerup, et al., 2018; Häuser, Finn,

et al., 2018; Moore et al., 2024; Moore et al., 2021; Petzke et al., 2022; Rice et al., 2021; Stockings et al., 2018; Wang et al., 2021; Wong et al., 2020). Many studies also report greater adverse effects with cannabis compared to placebo, most of which are mild (e.g., transient cognitive impairment, nausea, vomiting, and drowsiness) (Aviram & Samuelly-Leichtag, 2017; Barakji et al., 2023; Stockings et al., 2018; Wang et al., 2021).

While there is a collective call for rigorous methodological improvements in future RCTs, recommendations by experts and national and international societies vary dramatically, reflecting the controversial nature of cannabis as a therapeutic option for chronic pain management. For example, a comprehensive 2017 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that there is substantial evidence that cannabis is effective for treating chronic pain in adults (National Academies of Sciences, Engineering, and Medicine et al., 2017). The European Pain Federation (EFIC), German Pain Society, and Canadian Pain Society also endorsed cannabis as a third-line or off-label treatment option for chronic neuropathic pain (Fitzcharles et al., 2021; Häuser, Finn, et al., 2018; Petzke et al., 2022). In contrast, the International Association for the Study of Pain (IASP), Multinational Association of Supportive Care in Cancer (MASCC), National Institute for Health and Care Excellence (NICE) in the UK, and the French Society of Neurology, advise against cannabis use for pain management (including neuropathic pain) due to the low quality of the evidence (Fitzcharles et al., 2021; Petzke et al., 2022; Rice et al., 2021; To et al., 2023). Such contradictory stances have been causing confusion among patients, clinicians, and the public.

The reality is that, despite cautions from clinical researchers against using cannabis as a first-line treatment for chronic pain, and growing concerns regarding the risks associated with high-potency THC (the primary psychoactive and intoxicating compound of cannabis) and THC

analogue products, such as psychosis (D'Souza, 2023), cognitive impairment (Wieghorst et al., 2022), cardiovascular problems (Page et al., 2020), and cannabis use disorder (Hasin et al., 2023), cannabis use continues to rise substantially for both medical and nonmedical purposes. Reflecting this trend, the global cannabis market, valued at $57 billion USD in 2023, is projected to soar to approximately $444 billion USD by 2030 (*Cannabis Market Size & Growth | Forecast Report [2030]*, 2025). Therefore, it is imperative to establish clearer and more scientifically rigorous frameworks to better understand cannabis's actual benefits and harms, as has been repeatedly emphasized by cannabis research communities (Aviram & Samuelly-Leichtag, 2017; Barakji et al., 2023; Fisher et al., 2021; Gazendam et al., 2020; Häuser, Finnerup, et al., 2018; Häuser, Finn, et al., 2018; Moore et al., 2024; Moore et al., 2021; Petzke et al., 2022; Rice et al., 2021; Stockings et al., 2018; Wang et al., 2021; Wong et al., 2020).

High-quality evidence requires studies with large sample sizes, long-term follow-ups, well-defined patient populations with specific diagnoses, detailed evaluations of drug-by-drug and drug-by-disease interactions, and comparisons of doses, cannabis formulations, and routes of administration that more accurately reflect real-world use (Haroutounian et al., 2021; Moore et al., 2021; Thrul & Vandrey, 2024). But one crucial aspect of high-quality evidence has often been overlooked: the selection of target outcomes that reflect patient priorities. Currently, most RCTs investigating cannabis for chronic pain primarily focus on core patient-reported outcomes recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), which was established by researchers (Dworkin et al., 2005; Turk et al., 2003). These outcomes include pain severity, physical functioning, and emotional functioning. Experimentally-induced pain responses (e.g., thermal, mechanical, or electrical stimuli) are also often assessed as outcomes to examine cannabis-induced analgesia (Mun et al., 2020). While all

these measures are important and should continue to be assessed, they may not fully capture the true therapeutic potential of cannabis in chronic pain management.

As recently highlighted by the IASP Presidential Task Force on Cannabis and Cannabinoid Analgesia as one of the key research priorities in clinical trials, we strongly advocate for integrating outcome measures that reflect what matters most to patients (Haroutounian et al., 2021). For instance, a recent clinical guideline proposed by Busse and colleagues used input from a panel of three people with lived experience of chronic pain to identify important outcomes for clinical trials evaluating the effects of cannabis for chronic pain, and the panel's recommendations included not just the IMMPACT core pain outcomes, but also outcomes reflecting role functioning, social functioning, sleep quality, and opioid substitution (Busse et al., 2021), which are often overlooked in clinical trials of cannabis for chronic pain. In addition, it is important to note that many consumers report that cannabis helps them cope with their conditions by enhancing their ability to manage and tolerate any given level of discomfort (Bigand et al., 2019; Bourke et al., 2019; Coomber et al., 2003; Ng et al., 2022; Piper et al., 2017; Warner et al., 2024). Specifically, consumers frequently describe feeling less reactive to pain, experiencing a shift in pain perception, or finding it easier to distract themselves from the pain when using cannabis (e.g., "*Marijuana doesn't really help with the pain, but it sorta helps you put on some rose-colored glasses so you can ignore it a little bit better,"* (Warner et al., 2024) *"[Cannabis] changes perception and experience of my chronic pain"* (Piper et al., 2017) and "*Well, when it [cannabis] was effective it felt calmer, felt more relaxed and felt less pain."* (Coomber et al., 2003)). These insights suggest that other meaningful outcomes for patients interested in using cannabis to manage chronic pain may include psychological constructs such as, *pain catastrophizing* (a maladaptive cognitive process characterized by magnifying pain-

related stimuli, ruminating on pain, and feeling helpless during actual or anticipated pain; Sullivan et al., 2001) and *pain acceptance* (acknowledging the presence of pain without attempting to reduce or avoid it, and committing to engaging in life activities despite the pain; McCracken et al., 2004). Many of these outcomes can be readily and effectively assessed by psychometrically well-validated, sensitive to change self-report instruments, such as the 36-item Short Form (SF-36) Survey (Mchorney et al., 1993), Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989), Pain Catastrophizing Scale (PCS: Sullivan et al., 1995), and Chronic Pain Acceptance Questionnaire (CPAQ; Vowles et al., 2008). In addition, these outcomes can be assessed more intensively with ecological momentary assessment (EMA) or daily diary methods which can substantially reduce retrospective recall bias (Shiffman et al., 2008). For sleep quality, more objective methods, such as wrist actigraphy and/or a wireless sleep EEG device may also be used. However, these potentially important outcomes, which seem to directly reflect patients' perspectives on how cannabis may help them manage pain, remain largely outside the primary outcomes in RCTs evaluating cannabis's effects for chronic pain.

If current research paradigms continue to focus solely on traditional pain outcomes exclusively, even with improved scientific rigor, we risk fundamentally misinterpreting true clinical potential of cannabis. Hence, it is crucial to reassess target outcomes in cannabis-related pain research by actively integrating the perspectives of people with lived experience, particularly those who have faced stigma due to cannabis's historical legal complexities. One particularly useful approach for achieving this is the *Community-Based Participatory Research* (CBPR) framework (Wallerstein & Duran, 2006), which fosters equitable partnership between researchers and people with lived experience to ensure that knowledge gained from research directly benefits the community and meet their needs (Israel et al., 2005). A practical and

achievable next step is to collaborate with people with chronic pain who use cannabis, using qualitative methods such as Q-methodology, which combines qualitative insights with quantitative analysis to rank people's priorities (Herrington & Coogan, 2011). For instance, a recent study with youth experiencing depression used similar methods to uncover outcomes beyond expert-recommended core outcomes for clinical trials in this population (Krause et al., 2023); that work could be one model for next steps in cannabis research. Also, evaluation of patients' priorities should be accompanied by a thorough assessment of the burden that outcome measurement places on patients. To support this process, future studies should begin by compiling a comprehensive list of potential outcomes in collaboration with an interdisciplinary team, including community advisory boards with people who have lived experience. The board should be involved from the outset and play an active role in study design and decision-making throughout the process. Given CBPR's cyclical and iterative nature, outcome priorities identified should not be treated as fixed but should be periodically reassessed and refined over time through continued collaboration with the community (Israel et al., 2005).

Overall, our call to action is not to lower the threshold for what counts as a benefit for cannabis; rather, it is likely to offer critical insights into the functional drawbacks inherent in cannabis's effects on mentation. Understanding cannabis's specific strengths and limitations would ultimately enable more informed and personalized clinical decisions. For instance, if cannabis's primary therapeutic value lies in modulating cognitive and emotional responses to pain rather than directly reducing pain severity, and a patient's goal is to enhance resilience and improve their ability to cope with pain while minimizing risks, clinicians can guide them toward evidence-based psychological interventions. These may include cognitive behavioral therapy for

chronic pain, mindfulness-based therapy, or acceptance and commitment therapy (Kerns et al., 2011; McCracken et al., 2022)—approaches that may better align with the patient's needs.

One limitation faced by any study of cannabis for pain is the contribution of placebo and expectancy effects, especially given the difficulty of maintaining blinding if patients are randomized to active and placebo conditions. This issue is not unique to patient-rated outcome measures; robust placebo and expectancy effects have also been observed in ostensibly objective physiological markers. These include pain studies examining C-reactive protein and erythrocyte sedimentation rate (Vollert et al., 2020), as well as other contexts such as bronchial hyperreactivity in asthma, blood pressure, and polysomnographically-assessed sleep (Kemeny et al., 2007; Muench et al., 2023; Wilhelm et al., 2016). Longitudinal burst designs could help determine whether benefits are transient or sustained, but may not rule out expectancy and placebo effects, because those effects can be enduring (Tuttle et al., 2015). From a practical perspective, it may be necessary to accept placebo and expectancy effects as a component of what makes any pain treatment effective. In any case, this issue is one that affects all pain research, regardless of the outcome measure. Hence, this should not be used as a justification for sidelining measures that are meaningful to patients.

In conclusion, while the evidence regarding cannabis's efficacy for traditional pain outcomes remains limited, we cannot simply dismiss the experiences of thousands of people who report meaningful benefits from using cannabis for managing their pain—nor, for that matter, those whose outcomes have been unsatisfactory to them. Research priorities must evolve to incorporate outcomes that are relevant to patients, while continuing to evaluate core pain outcomes to achieve a more comprehensive understanding. The CBPR framework, which has been largely underutilized in cannabis and pain due to longstanding stigma associated research

with cannabis use, offers a promising pathway for integrating the voices of those with lived experiences. To achieve this, researchers should conduct qualitative studies that involve a diverse group of people with chronic pain who use cannabis, and establish partnerships with community advisor boards from the outset of study design. Ultimately, broadening our understanding in this way can mitigate existing confusion, foster nuanced clinical decision-making, strengthen patient advocacy, and promote personalized treatment strategies.

Author Contributions Statement

Chung Jung Mun played a lead role in conceptualization, writing–original draft, and writing–review and editing. Johannes Thrul played a lead role in writing–review and editing. David Epstein played a lead role in conceptualization and writing–original draft and a supporting role in writing–review and editing.

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