Can Patients Taper Opioid Medication and Maintain Pain Control? A randomized trial of cannabis added to behavioral pain management among adults with chronic, non-cancer pain

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Background

- Chronic pain affects 50 million adults in the USA¹; 25% are treated with chronic prescription opioids² despite limited long-term efficacy data³ and risk for opioid use disorder and overdose⁴⁻⁵
- It is not known if cannabis can reduce chronic pain and/or aid opioid dose reduction⁶
- Behavioral therapies can improve pain and function, but access and cost limit widespread use⁷

Clinical Trial of Cannabis added to Behavioral Pain Management Intervention (NCT04827992)⁸

Methods

Design

- 24-week pragmatic trial offering behavioral intervention to all subjects at weekly group sessions
- Blocks of 3-6 subjects randomly assigned to voluntary selfinitiation of cannabis use or to a waitlist-control in which they may not use cannabis for the duration of trial
- Participants choose cannabis products, dose, and frequency



Figure 1: Study Timeline

Participants

- Adults ages 18-75, taking \geq 25 morphine milligram equivalents (MME) per day for chronic pain
- Interested in using cannabis to reduce pain and/or opioid dose
- Exclusions include > weekly cannabis use, unstable major medical illness, psychosis, moderate or severe substance use disorder (except OUD, tobacco use disorder)
- Enrolling at MGH, Maine Medical Center (MMC), and Cambridge Health Alliance (CHA)

Outcomes

- 1° outcomes: Pain Intensity/Interference and prescription opioid dose (MME/day), verified by the Prescription Monitoring Program
- Secondary outcomes: Quality of life, depression, anxiety, symptoms of opioid and cannabis use disorders
- Outcomes assessed at monthly visits and via daily surveys.

Baseline and Preliminary Completion Data Intervention: Prescription Opioid Taper Support Prescription Opioid Taper Support (POTS)⁹ to develop pain self-PROMIS-29 Scores at Baseline management skills, provide support for individualized, voluntary 40 taper with goal of 10% reduction from baseline per month Rating .<u>G</u> 30 Draws on CBT, mindfulness practices, and motivational Normal interviewing <u>č</u> 20 Mild Participants identify POTS as helpful for managing their pain Moderate (M=6.9, SD=2.0). 94% agreed or strongly agreed that they learned a 10 -Severe new skills related to pain management in the program. Sample POTS Group Session Content Pain Neurobiology and Pain Gate Theory Intro to Relaxation Techniques and Progressive Muscle Relaxation Improving Sleep Pacing and Activity Scheduling Figure 2: PROMIS-29 Scores (T-score, M=50, SD=10 in general population) Coping with Pain Flare-Ups All subjects report impaired physical function (n=39, 100%). Most Pain Beliefs and Activity Avoidance report worse pain interference (n=38, 97.4%), fatigue (n=26, 66.7%), Setting Pleasurable Activity Goals and ability to participate (n=26, 66.7%) than the general population. Maintaining Gains and Dealing with Setbacks Self-Reported Opioid Dose and Pain Participant Characteristics (0 250 -MMC Measure 14 56.4 (12.2) 60.4 (9.7) MME PEG Score 5 (62.5%) 8 (57.1%) 6 (42.9%) 3 (37.5%) 12 (85.7%) 4 (50%) 0 (0%) 1 (12.5%) 0 (0%) 1 (12.5%) Subject 2 (14.3%) 1 (12.5%) * Reduced Prescription Opioid Dose (n=4, 22%) Figure 3: Self-Reported Opioid Dose (average MME/day) and Pain (PEG Scale, 0-10) At a threshold of ±5% change in MME, 7 (38.9%) decreased their 4 (80%) 6 (85.7%) self-reported dose, 7 (38.9%) increased, and 4 (22.2%) did not 0 (0%) 1 (14.3%) change. 58.2 (33.9) 64.9 (24.2) 6.1 (2.0) 6.8 (1.9) 2.3 (1.0) 2.0 (2.5) Conclusions 54.6 (17.6) 51.4 (18.0) Enrolled participants reflect an older, White sample. Recruitment strategies require modification to broaden age, racial, and ethnic Note. Pain Rating describes pain on a scale from 0-10. Symptoms of Opioid Use Disorder composition to increase generalizability of the findings. (OUD) is a count; ranging from 0-11 symptoms. The Q-LES-Q-SF is the Quality-of-Life Enjoyment and Satisfaction Questionnaire, scored as percentages with 100% being the Acceptability, perceived helpfulness of POTS intervention are high Although participants identify a dose reduction goal, barriers such References as concerns about pain control and low confidence in ability to reduce persist. Lucas J, Zelaya C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001rescription opioid use among adults with chronic pain: United States, 2019. Natl Health Stat Report 2021;162:1 Manchikanti KN, et al. Effectiveness of long-term opioid therapy for chronic non-cancer pain. Pain Physician 2011;14:E133–56. This study will provide the first RCT data on effectiveness of Association between opioid prescribing patterns and opioid overdose-related deaths. saolu IO, Ehiri JE, et al. Medical cannabis for the reduction of opioid dosage in the treatment of non-cancer chronic pain: a systematic cannabis in reducing opioid utilization and pain. Results will guide Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 3):1–95. DOI: Jashinski J, Grossman E, Quaye A, et al. Randomised, pragmatic, waitlist-controlled trial of cannabis added to prescription

	Total	MGH
Consented		
Ν	62	40
Age⁺	57.3 (11.0)	56.5 (11.3
Sex*		
Female	38 (61.3%)	25 (62.5%)
Male	24 (38.7%)	15 (37.5%)
Race*		
White	49 (79.0%)	33 (82.5%)
Black	5 (8.1%)	4 (10%)
Asian	1 (1.6%)	0 (0%)
Missing	4 (6.5%)	3 (7.5%)
Baseline		
Ν	39	27
Cannabis Use*		
Lifetime	34 (87.2%)	24 (88.9%)
Past Year	6 (15.4%)	5 (18.5%)
MME/Day ⁺	84.4 (69.2)	94.8 (79.2
Pain Rating ⁺	6.5 (1.3)	6.6 (1.0)
OUD Symptoms ⁺	2.0 (1.9)	1.9 (1.9)
Q-LES-Q-SF ⁺	50.5 (15.8)	49.2 (15.5
Completed		
Ν	18	17

greatest possible quality of life. * N (%), + M (SD)

adults with chronic non-cancer pain: study protocol. BMJ Open 2022;12:e064457. doi:10.1136/ bmjopen-2022-06445

Sullivan MD, Turner JA, DiLodovico C, et al. Prescription opioid taper support for outpatients with chronic pain: a randomized controlled trial.





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