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## Title

Psychological treatments improve outcomes in opioid-treated chronic low back pain: a pragmatic randomized controlled trial.

## **Priority 1 (Research Category)**

Pain management

## **Presenters**

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## **Abstract**

CONTEXT: Existing therapies for chronic low back pain (CLBP) are suboptimal, and many patients resort to opioid therapy. Cognitive behavioral (CBT) and mindfulness-based (MBT) therapies are safe and evidence-based for chronic pain, but their long-term effects have not been well-studied in opioid-treated CLBP.

OBJECTIVE: To compare the effectiveness of MBT versus CBT in adults with opioid-treated CLBP.

DESIGN/ANALYSIS: This multisite, pragmatic, stakeholder input-informed, randomized controlled trial (RCT) compared CBT and MBT in opioid-treated CLBP. Intention-to-treat, linear mixed effects model analysis compared treatment effectiveness of MBT relative to CBT at 6 and 12 months. Qualitative interviews augmented the quantitative data.

SETTING: Outpatient and community.

POPULATION: Adults with CLBP treated with long-term daily opioids.

OUTCOME MEASURES: Self-reported pain, function (primary), quality of life (QoL) and opioid dose (secondary).

INTERVENTIONS: Each intervention was manual-driven and included eight weekly two-hour group sessions and at-home practice during the study.

RESULTS: After screening 6,024 adults, 770 (385 MBT, 385 CBT) were enrolled; most identified as female (56.4%), non-Hispanic (84.0%), White (81.8%), and middle-aged (57.8±11.3 years old; mean±SD), with

long-standing, impactful CLBP: moderate average pain (Brief Pain Inventory: 6.1±1.6) and functional limitations (Oswestry Disability Index: 47.2±14.0), impaired physical (28.5±8.3) and mental (42.5±11.8) health-related QoL (Medical Outcomes Study Short Form), and high opioid dose (177±1,041 MME/day), without statistically significant between-group differences at baseline. Both interventions were safe. Over time, both groups improved significantly on their primary and secondary outcomes, without statistically significant between-group differences at 6 or 12 months. The non-inferiority analysis confirmed non-inferiority of MBT relative to CBT. Qualitative data largely corroborated the quantitative results of MBT and CBT's safety and usefulness.

CONCLUSIONS: In the largest trial of this type to date, MBT and CBT produced significant improvements in CLBP symptoms (pain, function, QoL), with reduced opioid dose, maintained through 12 months. These interventions should be accessible to patients as a part of 'usual care' for complex, refractory, opioid-treated CLBP as the means for improving lives and health, and reducing the individual and societal burdens of CLBP and opioid-related harm.

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