

Title: Treating comorbidities in cannabis dependent patients with nabiximols: findings of a placebo controlled RCT.

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Introduction: There is much interest in the use of medical cannabis to treat chronic pain, mood, PTSD and sleep conditions. However, most medical cannabis RCTs exclude patients who regularly use cannabis, such that our evidence for medical cannabis in patients with cannabis use disorder (CUD) is extremely limited, despite this group representing a considerable target population for medical cannabis. This paper examines outcomes for a range of comorbidities in participants enrolled in an RCT of nabiximols for CUD.

Methods: A double blind placebo-controlled RCT comparing safety and efficacy in a multisite outpatient study. 137 treatment-seeking cannabis dependent participants were randomised to 12-weeks of nabiximols (Sativex®) or placebo, in combination with psychosocial services. Whilst participants with acute or severe health comorbidities were excluded from the study, considerable proportions of patients reported chronic pain, sleep and mental health problems at baseline. Outcomes for participants reporting these comorbidities over the 12-week period are reported.

Key findings. 128 participants received allocated treatment, of which 53% reported clinically significant pain (BPI), 48% reported moderate/severe insomnia (ISI), 20% reported moderate/severe depression (DASS-21), 31% moderate/severe anxiety (DASS-21) and 17% met PTSD cut-offs (PC-PTSD), with no significant between-group baseline differences. Treatment outcomes (pain, mental health, sleep) for participants with these comorbidities are presented.

Conclusions: Patients with CUD and comorbidities benefited from nabiximols treatment. Whilst they needed high doses of THC/CBD, treatment appeared safe and well tolerated in this group.

Implications for Practice or Policy: This study suggest patients with CUD and other comorbidities can benefit from medical cannabis treatment and they should not be excluded from such treatments.

Disclosure of Interest Statement:

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nabiximols and placebo at no cost – but had no other role in the study. NL has received funding from NSW Health and Office Medical Cannabis for consultancies and research related to medical cannabis. NL has received funding for consultancies and research from Mundipharma, Indivior and Braeburn for unrelated work.