Oral Naltrexone-Bupropion Combination Pharmacotherapy for Methamphetamine Use Disorder: Pilot Study Protocol

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Introduction: Australia has one of the highest rates of methamphetamine use disorder in the world, yet there are currently no pharmacological treatment options to help people reduce or stop their methamphetamine use. Recent findings from the USA suggest that combination naltrexone-bupropion might be an effective treatment approach. The formulations of the medications studied are not currently available in Australia. To inform further research into the potential efficacy of this treatment approach in the Australian context, it is necessary to investigate the feasibility and safety of locally available formulations of these medications.

Abstract body text: This open-label pilot study will examine the safety and feasibility of a combination tablet of oral naltrexone 8mg/bupropion 90mg administered twice daily over 12 weeks for adults with methamphetamine use disorder, in an outpatient setting. The primary outcomes are safety (assessed by adverse events) and feasibility (medication adherence, retention rate, time taken to recruit entire sample, and proportion of ineligible participants at pre-screening and screening stages). Secondary outcomes include changes in psychological wellbeing and quality of life from baseline to primary endpoint, acceptability of the intervention (assessed via qualitative interviews), and changes in methamphetamine use from baseline to primary endpoint.

Discussions and Conclusions: This pilot trial will be the first study to examine orally administered combination naltrexone-bupropion for methamphetamine use disorder. Outcomes will inform the development of a randomised controlled trial. Findings will contribute to the effort to identify a pharmacotherapy that can be incorporated into clinical practice for treating methamphetamine use disorder.

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