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



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This **open-label pilot study** will examine the **safety and feasibility** of a combination tablet of **oral naltrexone/bupropion** for adults with **methamphetamine use disorder (MAUD)**, in an outpatient setting

A recent USA study (1) suggests that combination naltrexone-bupropion might be an effective treatment for MUD. The injectable depot formulations of naltrexone studied are not currently available in Australia, meaning these results are not immediately translatable to the Australian context, however a combination tablet is available

- 1.1 Safety **Primary**
 - Adverse events
- 1.2 Feasibility
 - Medication adherence by smartphone app
 - Retention rate at Week 12
 - Recruitment rate
 - Proportion of ineligible participants

Secondary

2.1 Changes in psychological wellbeing and quality of life2.2 Acceptability of the intervention2.3 Changes in methamphetamine use patterns

Outcomes

Methods 20 participants will be recruited to this open-label study at one inner-city Australian specialist stimulant treatment service

Medication Period

Week 1	Weeks 2-12	Week 13	Week 16
Induction Period		Taper-down Period	Follow-Up Period
5 day induction starting at: naltrexone 8mg / bupropion 90mg once daily	Naltrexone 40mg/ bupropion 450mg in divided doses (2 capsules morning, 3 capsules afternoon) daily	5 day taper- down	No dose

Discussion

- This will be the first study to examine **orally administered** combination naltrexone-bupropion for methamphetamine use disorder
 - May enhance **translatability** of previous findings which used a depot naltrexone injection
 - Will inform a randomised controlled trial to identify a pharmacotherapy which can be incorporated into **local clinical practice**

Anticipated **challenges** include acceptability and adherence:

- How **acceptable** will participants find the combination oral tablets?
- **Recruitment** and **retention** to outpatient trials of MAUD are expected to remain challenging

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