

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

Carl I Moller¹, Krista Siefried^{1,2}, Brendan Clifford^{1,2}, Liam Acheson^{1,2}, Jonathan Brett², Adrian Dunlop³, Paul Haber^{4,5}, Michael Christmass⁶, Nick Lintzeris⁷, Kirsten Morley⁸, Steve Shoptaw⁹, Madhukar Trivedi¹⁰, Nadine Ezard^{1,2}

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

Primary

1.1 Safety

- Adverse events

1.2 Feasibility

- Medication adherence by smartphone app
- Retention rate at Week 12
- Recruitment rate
- Proportion of ineligible participants

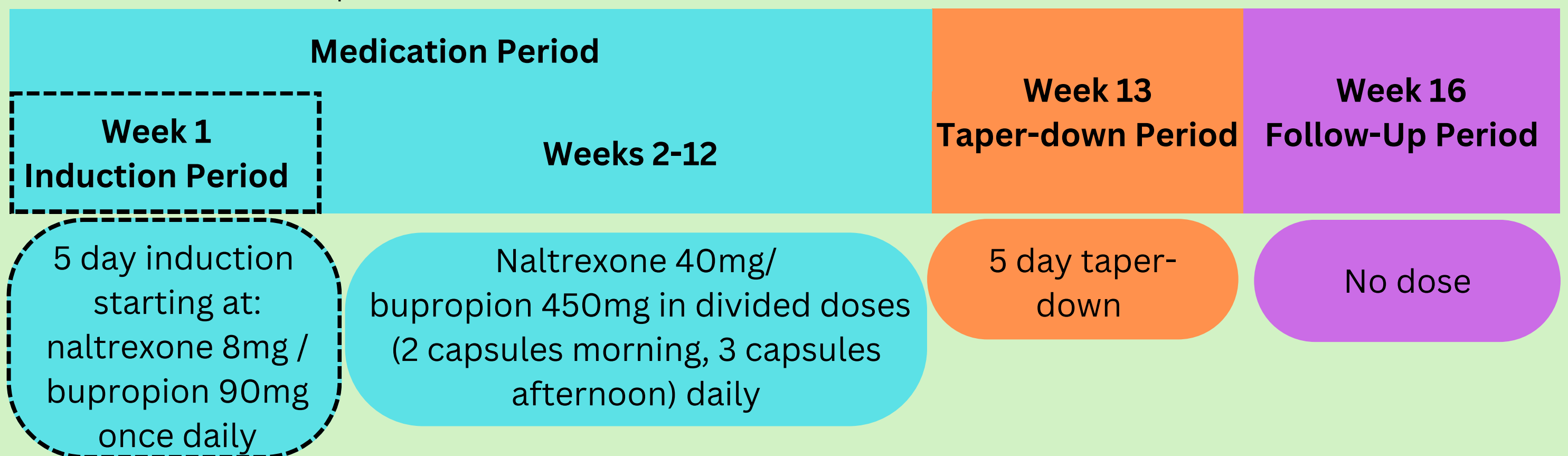
Secondary

- 2.1 Changes in psychological wellbeing and quality of life
- 2.2 Acceptability of the intervention
- 2.3 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



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