

The TINA Trial: Progress of a phase 3 randomised placebo-controlled trial of mirtazapine as a pharmacotherapy for methamphetamine (“ice”) dependence

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Introduction: Methamphetamine use is a significant public health concern. There are no TGA approved pharmacotherapies for methamphetamine use disorder. Two Phase 2 clinical trials in the USA found that mirtazapine, an antidepressant medication, significantly reduced methamphetamine use relative to placebo. These findings indicate the need for a larger Phase 3 trial to confirm benefits in routine clinical practice. The Tina Trial aims to assess whether take home oral mirtazapine can be used safely and effectively in routine clinical care to help people reduce their methamphetamine use.

Methods: This is a phase 3 multi-site randomised double-blind placebo-controlled trial (N = 340). Participants are randomised (1:1) to receive either 12 weeks of take-home oral mirtazapine (30 mg/day) or equivalent placebo. Participants must have a moderate to severe methamphetamine use disorder, be aged between 18-65 years, and not currently taking prescribed antidepressant medication (see trial protocol for full inclusion/exclusion criteria: ACTRN12622000235707).

Results: Recruitment commenced in October 2022. To-date (23/05/2023), 170 participants have been screened for eligibility. Sixty-three participants have been randomised across four sites (Brisbane=30, Geelong=11, Perth=16, Wollongong=6). At baseline, participants used methamphetamine on a median of 21 days in the previous 4 weeks, 66% injected methamphetamine, and 51% screened positive for major depression. The current follow-up rate is 81% (up to week 12).

Discussions and Conclusions: We have initiated a Phase 3 trial to determine whether mirtazapine can be used in practice to help people reduce their methamphetamine use. There has been substantial interest in the Tina Trial, allowing us to successfully recruit and retain participants.

Implications for Practice or Policy: The Tina Trial has the potential to provide evidence for mirtazapine to be a safe and effective pharmacotherapy option for methamphetamine use disorder. Mirtazapine could be prescribed as a PBS Schedule 4 medication, providing a potentially scalable and relatively low-cost intervention.

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