

The Tina Trial: Strategies for recruiting people who use methamphetamine in a randomised double-blind placebo-controlled clinical trial of mirtazapine for methamphetamine use disorder.

Keygan J¹, Palmer L¹, Degan T¹, Saunders L¹, Morrison C², Wrobel A², Kontogiannis A³, Thomas T³, Hatton E³, Turner A², Dean O², Kelly P³, Sinclair B⁴, Reid D⁴, Cordaro F⁴, Hayllar J⁵, Christmass M⁶, Berk M², Hill H⁷, Lundin R⁷, Arunogiri S⁸, Colledge-Frisby S^{1,9}, Dore G¹⁰, Shoptaw S¹¹, Goodman-Meza D¹², Clare P¹², Koeijers J¹, Farrell M¹, Degenhardt L¹, McKetin R¹.

Background

Recruitment is a major challenge in methamphetamine pharmacotherapy trials. The mean sample size for trials reported in the most recent systematic review of pharmacotherapies for methamphetamine use disorder was 90 (range 19 to 229) [1]. Small sample sizes, which are often coupled with poor retention [2], means that many trials are unable to robustly detect the potential benefits of pharmacotherapies. Therefore, strategies to enhance recruitment to clinical trials are essential to building the evidence base for effective pharmacotherapy options.

We describe different recruitment strategies that we have used to recruit participants for the Tina Trial, a phase 3 trial of mirtazapine (an antidepressant medication) for methamphetamine use disorder. We need to recruit 340 participants across Australia within the next two years. Due to the nature of the Tina Trial's exclusion and inclusion criteria, as well as participation requiring a 5-month commitment, effective recruitment strategies are integral to the success of the trial.

Aims

- Document the strategies used to facilitate recruitment in the Tina Trial.
- Highlight the most effective recruitment strategies for engaging people who go on to show genuine interest and commitment to participate in the trial.
- Explore the demographic characteristics associated with various recruitment channels.



Figure 1. Needle and Syringe Program equipment with Tina Trial stickers



Figure 2. Water bottles with Tina Trial stickers

Methods

Design: A double-blind randomised placebo-controlled trial (ACTRN12622000235707).

Intervention: Mirtazapine (30 mg/day x 12 weeks) or matched placebo.

Recruitment Target: 340 participants, with 60 participants being recruited from each of the four primary sites (Geelong, Brisbane, Wollongong, and Perth) and the balance from added sites in 2024.

Recruitment rate: The anticipated recruitment rate is approximately 1 participant per week per site.

Eligibility criteria: DSM-5 moderate-to-severe methamphetamine use disorder, currently using methamphetamine, not taking prescribed antidepressant medication, not pregnant/lactating, and no contraindications for mirtazapine.

Recruitment channels:

- Flyers in Needle and Syringe Program (NSP)/health services (Figure 1 and Figure 2)
- Facebook (e.g., paid advertisements) or other internet advertising (e.g., tinatrial.info)
- Word of mouth (e.g., peers)
- Other (e.g., news story; flyer on community notice boards)

Analysis: We compared the characteristics of participants recruited via Facebook and other internet advertising to participants recruited via other methods of using Pearson's Chi Square tests.

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Progress

Recruitment for the Tina Trial commenced in November 2022. As of 30/08/2023, 422 people had been phone-screened for eligibility. People who were phone-screened for eligibility had heard about the study through Facebook (40%) or other internet advertising (7%), flyers in NSPs or health services (23%), word-of-mouth (20%), or other flyers/elsewhere (6%).

Targeted paid Facebook advertisements for the Tina Trial (Figure 3) were introduced June 20, 2023, which increased the number of phone screens, superseding NSPs/health services and word-of-mouth as the primary recruitment method (Figure 4).

Of the 422 people phone-screened, 302 were potentially eligible (72%), 129 of whom were recruited via Facebook or other internet sites. People recruited from Facebook or other internet sites were less likely to be eligible on the phone screen compared to people recruited via other channels such as NSP flyers and word of mouth (65% vs. 78%; $p = 0.004$). They were less likely to be eligible because they did not live within the recruitment area (10% vs 2%, $p = 0.001$).

Of people who were potentially eligible, 153 were consented into the study to complete a face-to-face eligibility assessment (50 of whom were recruited from Facebook or other internet sites). Participants recruited via Facebook and other internet sites were less likely to be unemployed (38% vs. 66%), on a higher income (50% earning $\geq$ \$1200 per fortnight after tax vs. 25%, $p = 0.002$) and more likely to smoke (vs. inject) methamphetamine (70% vs. 35%, $p = 0.001$).



Figure 3. Facebook advertisement

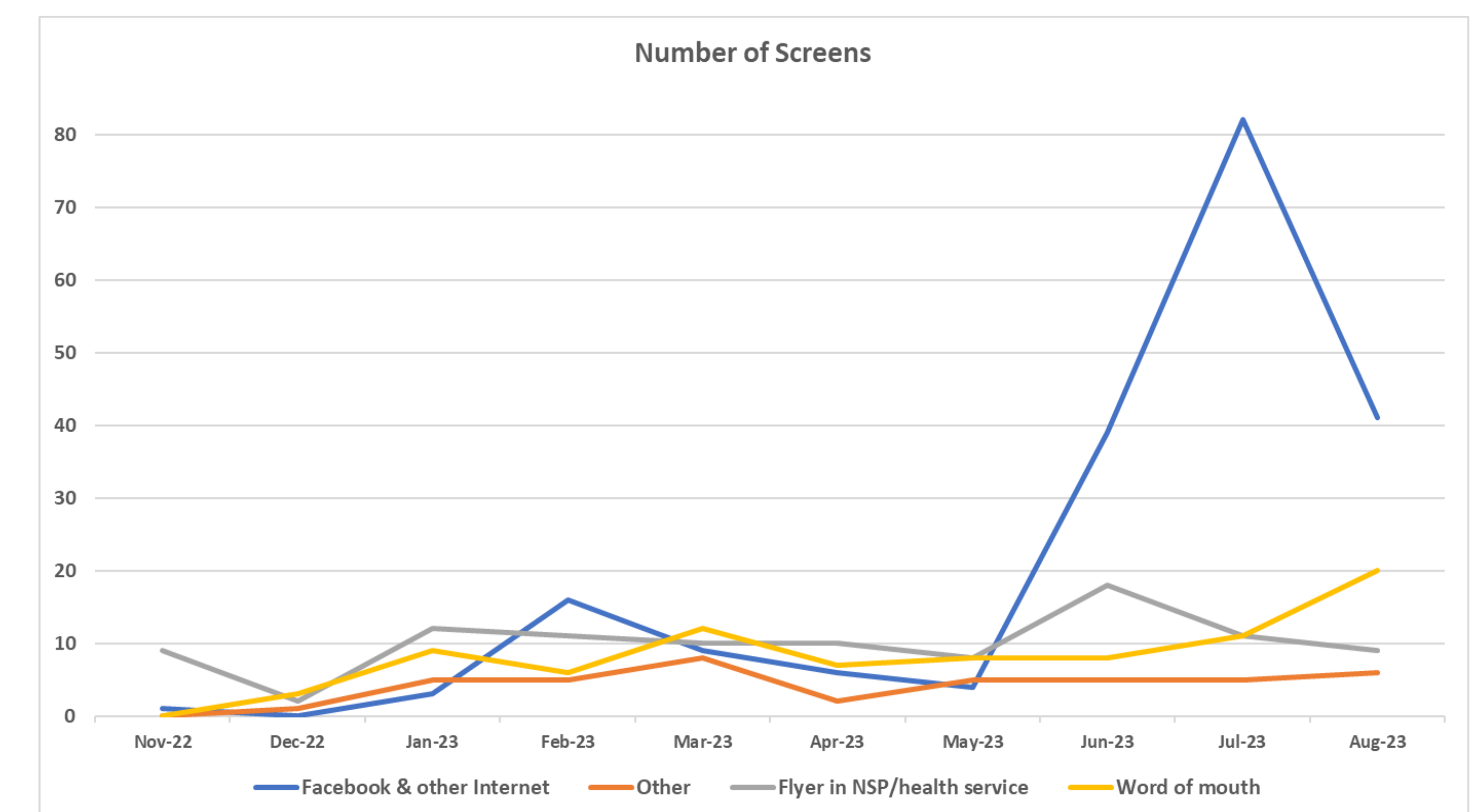


Figure 4. Number of phone screens by recruitment channel over time

References

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