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.

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The Difference is Research

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.

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 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 >= $1200 per fortnight after tax vs. 25%, p = 0.002) and more likely to smoke (vs. inject) methamphetamine (70% vs. 35%, p = 0.001).

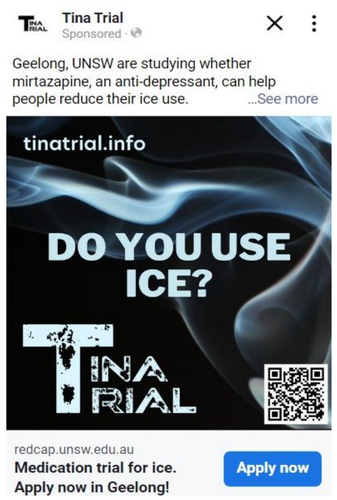

Figure 3. Facebook advertisement

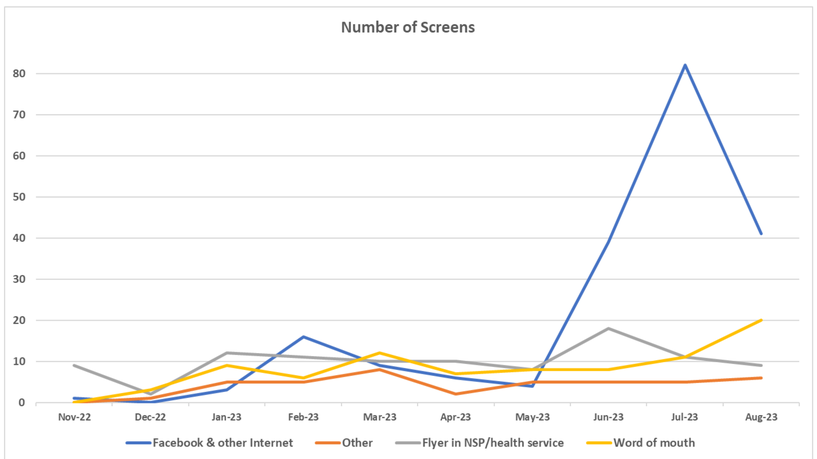

Figure 4. Number of phone screens by recruitment channel over time

Implications

Effective recruitment remains a critical aspect of clinical trials. Facebook advertisements, flyers in NSPs/health services, and word of mouth are the main channels through which most people who were phone-screened had heard about the Tina Trial.

Paid Facebook advertisements have the potential to reach a very large number of people of a broader demographic but are less likely to identify potentially eligible participants.

In contrast, advertising through trusted channels (e.g., NSPs, word of mouth), where peers and familiar health workers (e.g., NSP workers) are present, may reach fewer people than Facebook advertisements, but they have a greater likelihood of capturing potentially eligible participants.

These findings highlight that it is important to implement a range of targeted recruitment strategies for clinical trials.

References

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