

Setting up a Medical Cannabis Vaporizing Study in a Drug and Alcohol Clinic in Australia – Issues and Key Learnings



Health
South Eastern Sydney
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Background

Given recent changes to cannabis legislation in Australia, interest has grown in conducting research on the substance's effects beyond its therapeutic use. Here we report on the procedure of setting up two cannabis research projects at two NSW Drug and Alcohol (D&A) Service sites (The Langton Centre and Royal Prince Alfred Hospital), and the unique challenges that came up in this particular setting.

Both studies were randomized placebo-controlled trials with healthy volunteers, who were occasional users of cannabis. Study endpoints were driving performance (Trial A), and memory and cognition (Trial B). In Trial A, the study drug (Tilray T100: 11% THC, <1% CBD; Tilray T200: 11% THC, 11% CBD, dose: 125mg) and placebo were administered to participants via a Mighty Medic vaporizer (image 1). In Trial B, the study drug (Bedrobinol: 13.5% THC, <1% CBD, dose: 300µg THC/kg bodyweight) and placebo were administered via a Volcano Classic vaporizer (image 2).

Issues & key learnings

Several issues were raised in terms of governance, ethics, and the study site.

Ethics/Governance:

- Safety concerns (e.g. side effects, risks for work or roadside testing, travel considerations, risk of adverse reaction, duration of intoxication and detection of cannabis metabolites in the body)
- Participant protection (e.g. admission of illegal activity, confidentiality)

Site:

- Formalising an agreement with pharmacy regarding licensing and storage of the study drug
- Training of staff (e.g. handling intoxicated participants in research)
- Administrative issues (e.g. registration of healthy volunteers at a D&A site)
- Staff and consumer perceptions regarding vaping in a D&A setting (e.g. concerns about smell of cannabis, see also image 3)

Setup process

Setting up involved the following steps:

- Obtain ethics approval from the Human Research Ethics Committee (HREC)
- Submission of Clinical Trial Notification (CTN) to the Therapeutic Goods Administration (TGA)
- Obtain local governance approval from research sites (SSA)
- Formalise Clinical Trial Research Agreement (CTRA) between sponsor and clinical site
- Apply to NSW Health for Authority to Possess and Prescribe
- An import permit for an S9 drug is no longer required and there are now companies stocking medical cannabis products in Australia (e.g. Novachem)

More information can be found via

<https://www.tga.gov.au/import-and-export>



Conclusion and next steps

Although a challenging task, setting up trials involving vaporized cannabis in these settings was a worthwhile experience, as a process is now in place for future studies. The vaporizer has shown to be a safe and effective method for the administration of medicinal cannabis. Although uncommon, mild adverse events associated with THC (such as nausea) may still persist in a small proportion of participants.



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