Learnings from the implementation of a Consumer Advisory Group for a nation-wide Randomised Placebo-Controlled Clinical Trial investigating a pharmacotherapy for methamphetamine withdrawal

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Background: Involvement and leadership of community and people with lived-living experience (LLE) in the Alcohol and Other Drugs sector has been integral to the success of clinical program implementation, improving service provision and advising on drug and health policy. However, guiding principles for the meaningful inclusion of people with LLE in the context of AOD medical research, and particularly, clinical trials, is not well documented in the literature.

In 2024, the National Centre for Clinical Research on Emerging Drugs (NCCRED) received NHMRC funding for a randomised, placebo-controlled multi-site clinical trial investigating lisdexamfetamine as a treatment for acute methamphetamine withdrawal over a seven-day inpatient admission (the OLAM trial). A portion of this funding was allocated to establish a Consumer Advisory Group (CAG) for the lifetime of the study, led by consumer investigator Jack Nagle. We describe here the process of development, continuing implementation and future evaluation of a CAG for a multi-site, national RCT in the AOD sector.

Three aligning priorities were developed to guide methods of recruitment, group formation and implementation: **(i)** diverse representation of people with LLE of methamphetamine-use across organisational representatives, community peers and LLE as a support person; **(ii)** transparency and accountability of research processes and operations to the CAG, and **(iii)** direct bank payments for renumeration. CAG members agreed on overarching aims of the CAG to give ongoing advice an expert LLE perspective, to advocate for participants and to ensure meaningfulness of OLAM study results to the community.

Consumer involvement in research is a dynamic and evolving process. A detailed and ongoing evaluation of the OLAM CAG, in partnership with the Australian Injecting & Illicit Drug Users League (AIVL), will contribute valuable learnings to disrupt the way clinical trials are currently run, guiding the development of peer involvement principles in clinical trial research to the wider AOD sector.

Description of Model of Care/Intervention: <*Insert text here*>

Effectiveness/Acceptability/Implementation: <*Insert text here*>

Conclusion and Next Steps: <*Insert text here*>

Implications for Practice or Policy: <*Insert text here*>

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