Acceptability of oral naltrexone and bupropion for treatment of methamphetamine use disorder

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Acknowledgements

Acknowledgement of Country

This presentation was prepared on Gadigal land, and I would like to pay my respects to elders past and present and extend that to any Aboriginal and Torres Strait Islander peoples here today.

Acknowledgement of Community

I acknowledge the contributions of people with lived and living experience to this project. Through focus group participation, as a consumer investigator, as participants in the trial, and in qualitative interviews, they brought knowledge and wisdom along with a commitment to altruism through research

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Conflicts of interest

I am employed by the National Centre for Clinical Research on Emerging Drugs (NCCRED) and hold affiliations with the University of New South Wales and St Vincent's Hospital Sydney

This study was funded by NCCRED

NCCRED is funded by the Australian Government Department of Health, Disability and Aging

I have no other conflicts to declare

Acceptability of potential treatments in clinical trials

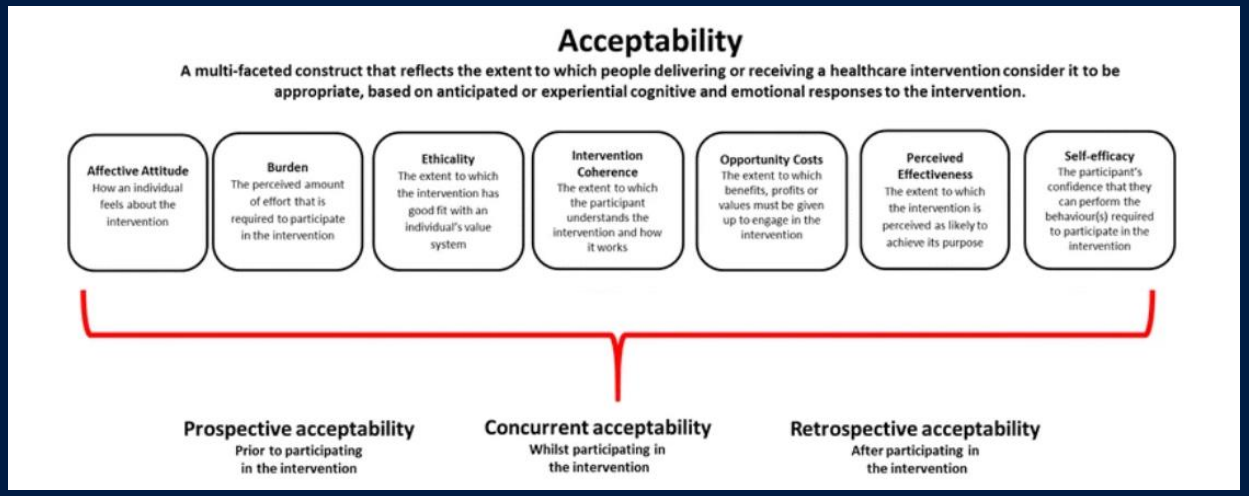
Treatment acceptability is an intrinsic aspect of treatment effectiveness

- A **necessary, but not sufficient** condition for effectiveness
- Dependent on:
  - Content
  - Context
  - Quality
- If acceptable, patients are **more likely to adhere to treatment** and **benefit from improved clinical outcomes**
- Particularly important in treatments of substance use disorders

Approach

Qualitative sub-study within a pilot clinical trial of oral naltrexone/bupropion for the treatment of methamphetamine use disorder

- Participants were invited to contribute to a semi-structured interview after completing the intervention
- Interviewer had no other role in the trial
- Data analysed thematically and applied to the *Theoretical Framework of Acceptability in Healthcare*
  - Affective attitude
  - Burden
  - Ethicality
  - Intervention coherence
  - Opportunity cost
  - Perceived effectiveness
  - Self-efficacy



Visualisation of the framework, Sekhon et al 2017

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Affective Attitude, Intervention Coherence and Ethicality

Participants described an **intervention that aligned with their moral identities**, and that they **broadly understood**. The intervention was something that participants generally though was **a positive thing before attempting** the treatment, however this sometimes manifested as **mis-aligned expectations**

"I really pinned all my hopes on this...if it gives me just a little bit of support...maybe I can do the rest"

"I knew that willpower alone wasn't gonna work... I thought that this trial could have been the thing to help"

"I did do some...research before...about the trial in the US"

Burden and Opportunity Cost

The intervention was appealing to participants as it was **considered low burden**, however some thought there **was still too much time investment required**. Despite this, people participating still had to **give up things** to access the treatment, including **missing work, social connection and the pleasure associated with substance use**

Perceived Efficacy and Self-efficacy

Those who completed the intervention described a treatment option **that gave them personal benefit**, with participants expressing **optimism about the future**. Participants ability to complete the intervention was **largely unhindered**, with taking the tablets not causing issues, however this was **impacted by the requirement to attend regular appointments**

"I do believe that [naltrexone/bupropion] affected my MA use. My crystal use did decrease significantly - not just the frequency, but also the quantity were both reducing"

"[Taking the medication was] not a problem for me at all"

"Like I mean, if there was a way like to come like less times — especially, for people who live not too close"

Conclusions

Intervention was broadly acceptable to participants, **supporting the case to move on to RCTs**

Any future investigation should:

- Ensure the range of side effects better understood
- Understand the opportunities people are giving up to participate
- Reduce time investment as possible

Participant feasibility studies **can and should be implemented** in future clinical trials in the pilot phase and beyond

How we have implemented these data into designing the RCT:

1) Implementation of electronic blister-pack adherence measures to reduce reliance on smart-phone apps
2) Reduction in visit frequency to reduce burden and opportunity costs
3) Co-design of participant information forms to ensure better communication of trial related information

Thank You

Acknowledgements

Study Coordinators

- Teodora Zanesheva-Karamanlieva
- Lucy Flood
- Arabella McMahon

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