Inequality in Smoking Cessation Clinical Trials – Exclusion of Smokers with Mental Health Disorders (MHDs)

Saki Talukder[1], Julia Lappin, Veronica Boland, Hayden McRobbie, Ryan Courtney

The Difference is Research

Background

People with MHDs have

- higher intensity of smoking and nicotine dependence
- a willingness to quit the same as other smokers and can quit without adverse effects on their existing mental health condition

They are far more likely to die from smoking-related complications than as a result of psychiatric condition

HOWEVER,

- smoking cessation treatments are not readily available for them in the community nor in psychiatric settings
- there is a lack of studies to help health practitioners to make informed decisions about treatment
- They are often underrepresented in clinical research
- **WHY?** Some possible explanation include: To increase internal validity, statistical power, and reduce adverse events

Disparity in smoking rates among persons with MHDs relative to the general population will worsen over time if their needs remain unaddressed

Aim

This review aims to examine the inclusion/exclusion of smokers with MHDs in RCTs involving pharmacotherapy interventions for smoking cessation

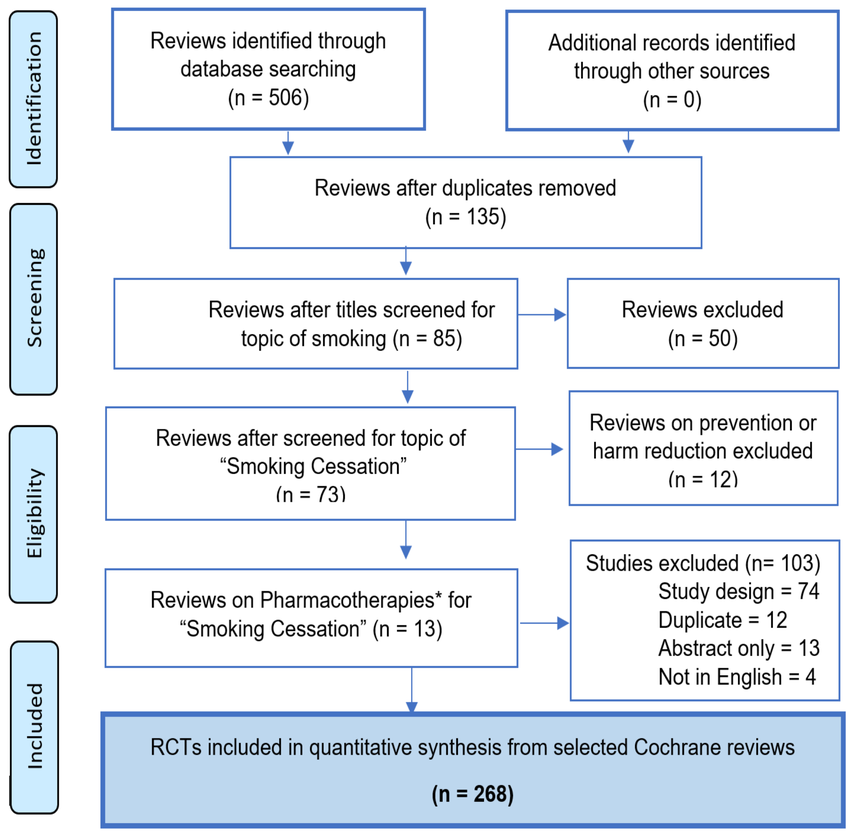
Methods

Search strategy, selection of studies and coding

- Cochrane Database of Systematic Reviews in *The Cochrane Library* for any reviews (origin -2019)
- Studies included if: written in English, randomised control trial (RCT), testing pharmacotherapy for smoking cessation
- MHDs defined as; depression, anxiety, personality disorder, anorexia bulimia or eating disorder and psychotic disorders (all MHDs included)
- SMIs defined as a subset of MHDs; psychosis spectrum disorders (including schizophrenia) and the major affective disorders including bipolar disorder and severe depression
- Pharmacotherapies: Antidepressants, Anxiolytics, Clonidine, Electronic Cigarettes, Lobeline, Mecamylamine, Nicobrevin, Nicotine Receptor Partial Agonists, Nicotine Vaccine, Nicotine Replacement Therapy, Opioid Antagonists, Rimonabant, Silver Acetate

Methods contd.

Figure 1:Flowchart of search strategy and selection criteria of RCTs using PRISMA guideline

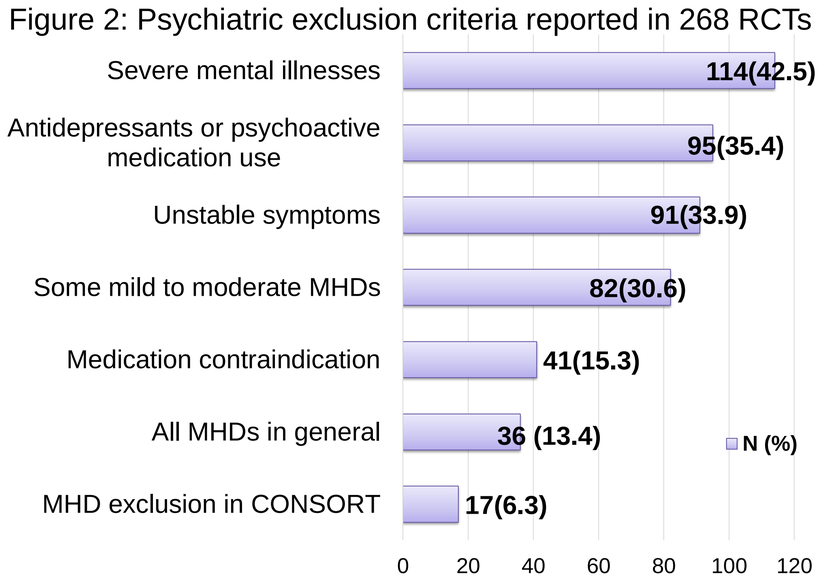


Results

Table 1: Exclusion of smokers with MHDs in 268 included RCTs

Characteristics	N (%) of trials
Class of Pharmacotherapy intervention	
NRT	**121(45.1)**
Antidepressants	**80 (29.9)**
Nicotine receptor agonists	**38 (14.2)**
Opioid antagonists	**7 (2.60)**
Other	**22 (8.20)**
Mention MHD population in selection criteria	**190 (70.9)**
Exclusion of smokers with MHDs	
Explicitly exclude	**38 (14.2)**
Conditionally exclude/include	**107 (39.9)**
Unspecified	**123 (45.9)**
Exclusion presented in CONSORT diagram	**19 (7.10)**
Used at least one MHD exclusion criteria	**162(60.4)**

Figure 2: Psychiatric exclusion criteria reported in 268 RCTs



*categories non-mutually exclusive

Results contd.

Table 2: Exclusion of smokers with MHDs by class of pharmacotherapy intervention for smoking cessation

Class of pharmacotherapy	Explicitly Exclude N= 38	Conditionally Exclude N= 107	P-value
Antidepressants	**9**	**47**	
Nicotine receptors	**7**	**25**	
NRTs	**15**	**27**	**0.054**
Opioid antagonist	**3**	**4**	
Others	**4**	**4**	

* fisher's exact test

Implications

- ❑ RCTs do not always provide enough information about including or excluding participants with MHDs
- ❑ The majority of smoking cessation RCTs testing pharmacotherapy interventions exclude smokers with MHDs
- ❑ Severe mental illness is the most common reason for exclusion, although persons with SMIs have the highest prevalence of smoking
- ❑ Greater access to clinical trial participation needs to be facilitated for this group to reduce the social gradients in smoking rate and subsequent inequalities in health outcomes

Conclusion

These findings highlight a need for careful consideration and transparent reporting (in method & CONSORT) and justification for exclusion in smoking cessation RCTs

We recommend that every reasonable effort be made to include smokers with MHDs in trials testing pharmacotherapy interventions for smoking cessation

References

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Acknowledgements and Declaration of interests NDARC at UNSW is supported by funding from the Australian Government. ST is supported by a NDARC PhD scholarship. **For more information please contact:** Ms Saki Talukder– E-mail: s.talukder@unsw.edu.au

[1]National Drug and Alcohol Research Centre, UNSW Sydney, National Drug and Alcohol Research Centre, UNSW Sydney, National Drug and Alcohol Research Centre, UNSW Sydney, National Drug and Alcohol Research Centre, UNSW Sydney