Square Pegs, Round Holes: Issues and considerations from running a cluster Randomised Control Trial in people who smoke and experience homelessness

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Background

Cluster Randomised Controlled Trials (cRCT)

- cRCTs are a type of RCT where individuals are randomised at group 'cluster' level.
- cRCTs are appropriate where there is risk of contamination or if individuals receiving different interventions may influence each other.
- cRCTs are more complex and expensive than standard RCTs due to additional demands and considerations including: i) design and planning (statistical issues, defining the clusters), ii) conduct (randomisation, selection bias), and iii) analysis and reporting of outcomes (suitable statistical approaches to account for violations of the assumption of independence within clusters).

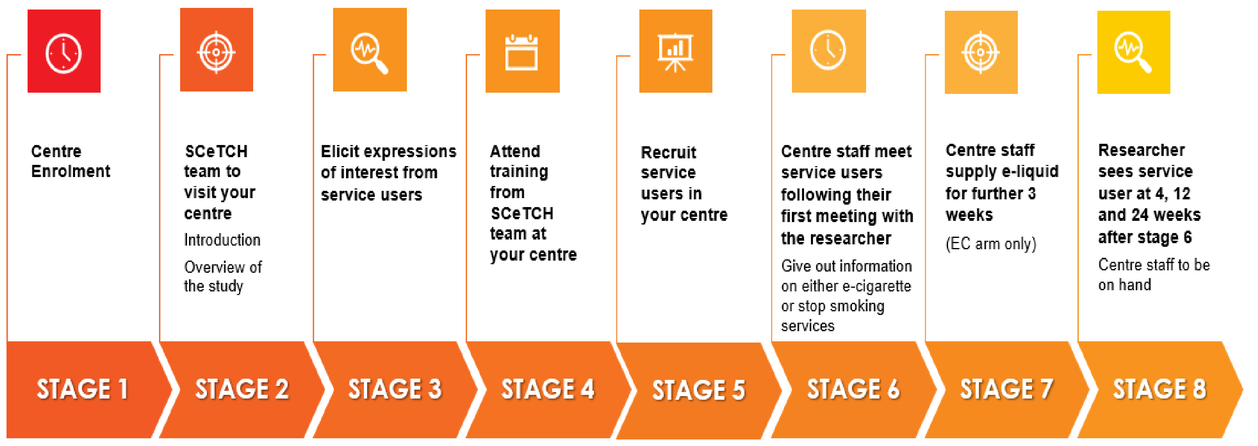
cRCT and SCeTCH

- cRCTs have been recommended for research in the homeless sector[1].
- However, insufficient trials have been conducted in this sector to establish feasibility, and what, if any, additional considerations, specific to working with this population, are warranted.
- In the context of our Smoking Cessation Trial in Centres for the Homeless (SCeTCH), we discuss some additional considerations and challenges involved in running a cRCT in homeless settings.

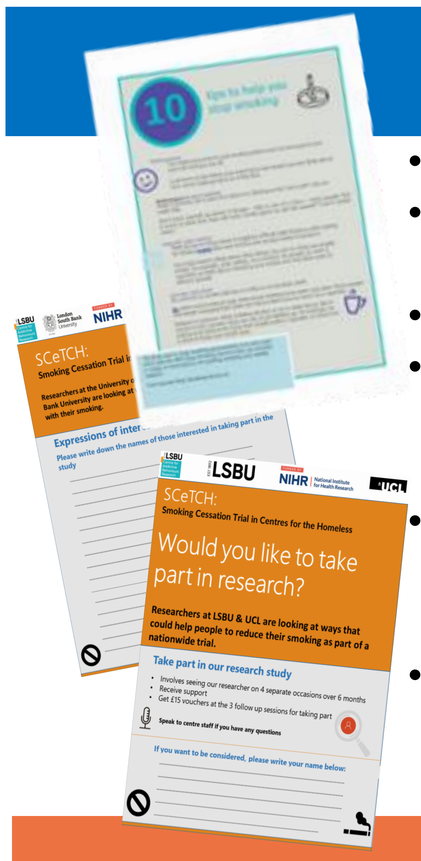
SCeTCH (Smoking Cessation Trial in Centres for the Homeless)[6]

Trial Context: Up to 82% of people who access homeless services smoke but there is a high desire to quit[2]. To reduce health inequalities, there is an urgent need to explore the efficacy of targeted smoking cessation approaches. Pooled trial and observational data shows that e-cigarettes (EC) are more helpful than other nicotine replacement therapies (NRT) in helping people to quit[4] but people accessing homeless services cannot always afford an e-cigarette starter kit hence **supplying free EC starter kits at centres accessed by people experiencing homelessness may help them make a quit attempt.**

- SCeTCH is the first cRCT to determine the efficacy and cost-effectiveness of providing free EC starter kits to people accessing homeless centres compared with UC (Very Brief Advice; VBA+ and signposting to SSS)
- **Primary objective**: to determine the 6-month sustained, biochemically validated abstinence rates in people offered EC compared to people offered UC[5].



Key Considerations & challenges



- A cluster design was used to: 1) avoid disharmony of being given an EC versus a referral, and 2) avoid contamination.
- cRCTs require a larger sample than conventional RCTs to detect intervention effects. Recruiting the required number (n=480) within these settings is time consuming.
- Eligibility needs to be defined for participants as well as clusters (homeless centres).
- Intervention blinding at baseline is recommended but was hard to achieve in our trial given:
  a) staff training in centres needed to be tailored to the intervention allocated to that cluster and,
  b) participants could clearly tell whether ECs were provided.
- To reduce selection bias, recruitment of participants was elicited via expressions of interest (EOI) before allocated arm was announced. Yet with sporadic attendance, distrust and uncertainty of engaging with research, EOI were not always possible.
- Ethical considerations: Trial intervention is determined by cluster so individual choice of intervention is not available. However regardless of arm, the offer, was more than what people would have received had they not participated, given none of the clusters were implementing UC - the national advice for health care workers in delivering VBA+.

Conclusions

- More trials are needed, especially in Europe, to explore smoking cessation and reduction approaches for people experiencing homelessness.
- Our experience highlights that running a cRCT in this population is achievable with some considerations.
- An embedded process evaluation is recommended to help account for variations in clusters.
- Applying a flexible and pragmatic approach to cRCT best practice guidelines is challenging but not insurmountable.

References

1. Ojo-Fati O et al. (2017) Trials 18(1): 305.
2. Soar K et al. (2020) J Smok Cessat 15(2): 94–108.
3. Dawkins L et al. (2019) Addict Behav. 2019 Aug;95: 35-40.
4. ASH (2019) Use of e-cigarettes (vaporisers) among adults in Great Britain. https://ash.org.uk/wp-content/uploads/2019/09/Use-of-e-cigarettes-among-adults-2019.pdf
5. Hartmann-Boyce J et al. (2020) Cochrane Database Syst Rev. 29(4):4
6. Cox S et al. (2021) Addiction 117(7): 2096-2107.

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