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Improving the feasibility of stepped-wedge cluster randomised trials: findings of a qualitative interview study

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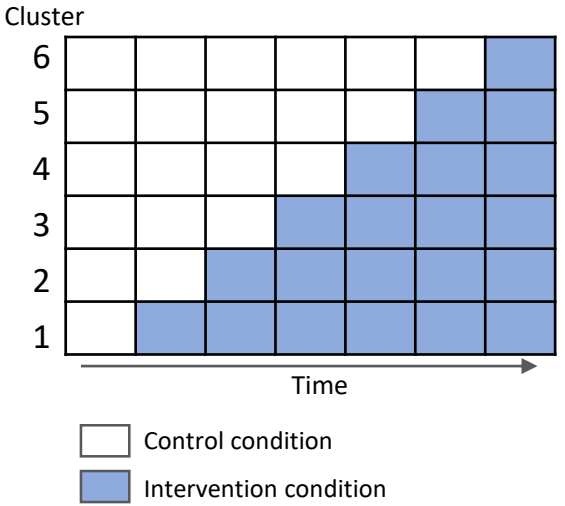
Introduction

- When using a new or complex trial design, such as the SW-CRT, it can be beneficial to have an understanding of the issues that previous SW-CRTs have encountered.
- However, few feasibility studies for SW-CRTs have been published [1] and reports of SW-CRTs often don't discuss any issues encountered.



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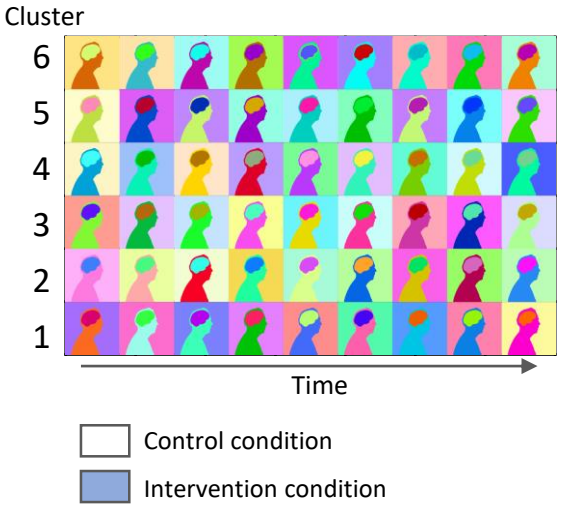
[1] Kristunas, CA, et al. "The current use of feasibility studies in the assessment of feasibility for stepped-wedge cluster randomised trials: a systematic review." BMC medical research methodology 19.1 (2019): 12.

Introduction

- An online questionnaire study identified common issues that were a concern for trialists, advisors, clinicians and funding panel members involved in SW-CRTs.
- Participants selected from example issues, but could also add additional concerns that hadn't been listed.
- Differences were observed in the concerns of the participants, which need to be explored.
- The reasons for these issues being a concern for participants also need to be explored.



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Objectives

- Identify concerns relating to the design and conduct of SW-CRTs
- Understand the reasons for these concerns
- Understand why there are differences in the concerns held by different individuals.

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Recruitment

- Participants identified from questionnaire respondents who provided their contact details.
- A purposive sample, with differing roles and concerns about SW-CRTs, was taken and invited to participate in a short telephone interview.
- Additional funding panel members were recruited through the funder.

If you are happy to be contacted for the purpose of being invited to participate in a short interview, then please complete your contact details in the form below. Otherwise, please proceed to the next question.

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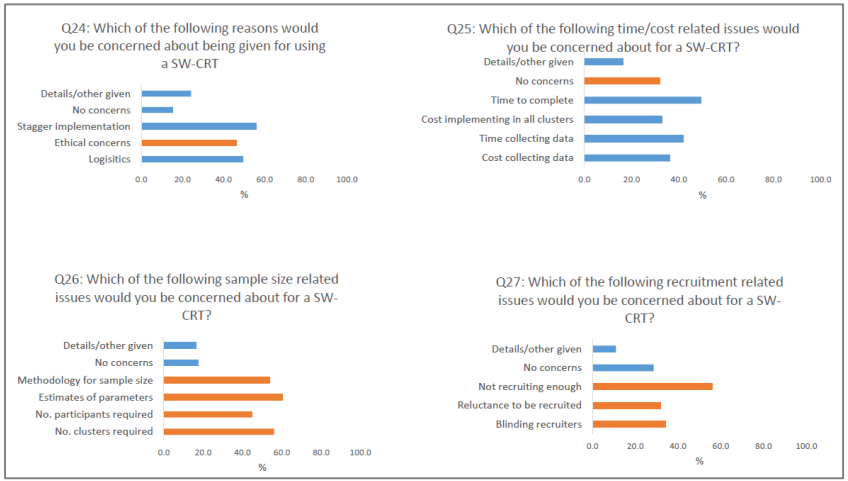
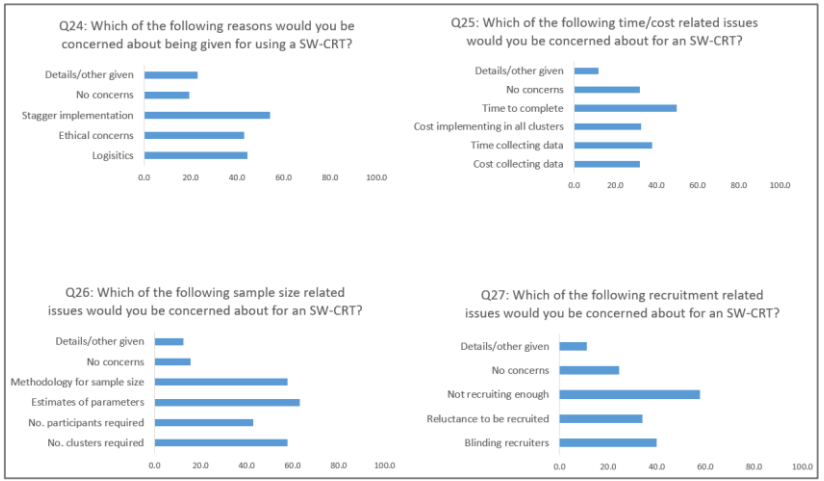
Interviews

- Participants were provided with a copy of their questionnaire responses and a summary of how other participants had answered the questionnaire and asked to elaborate their answers and discuss their thoughts on how other respondents had answered.





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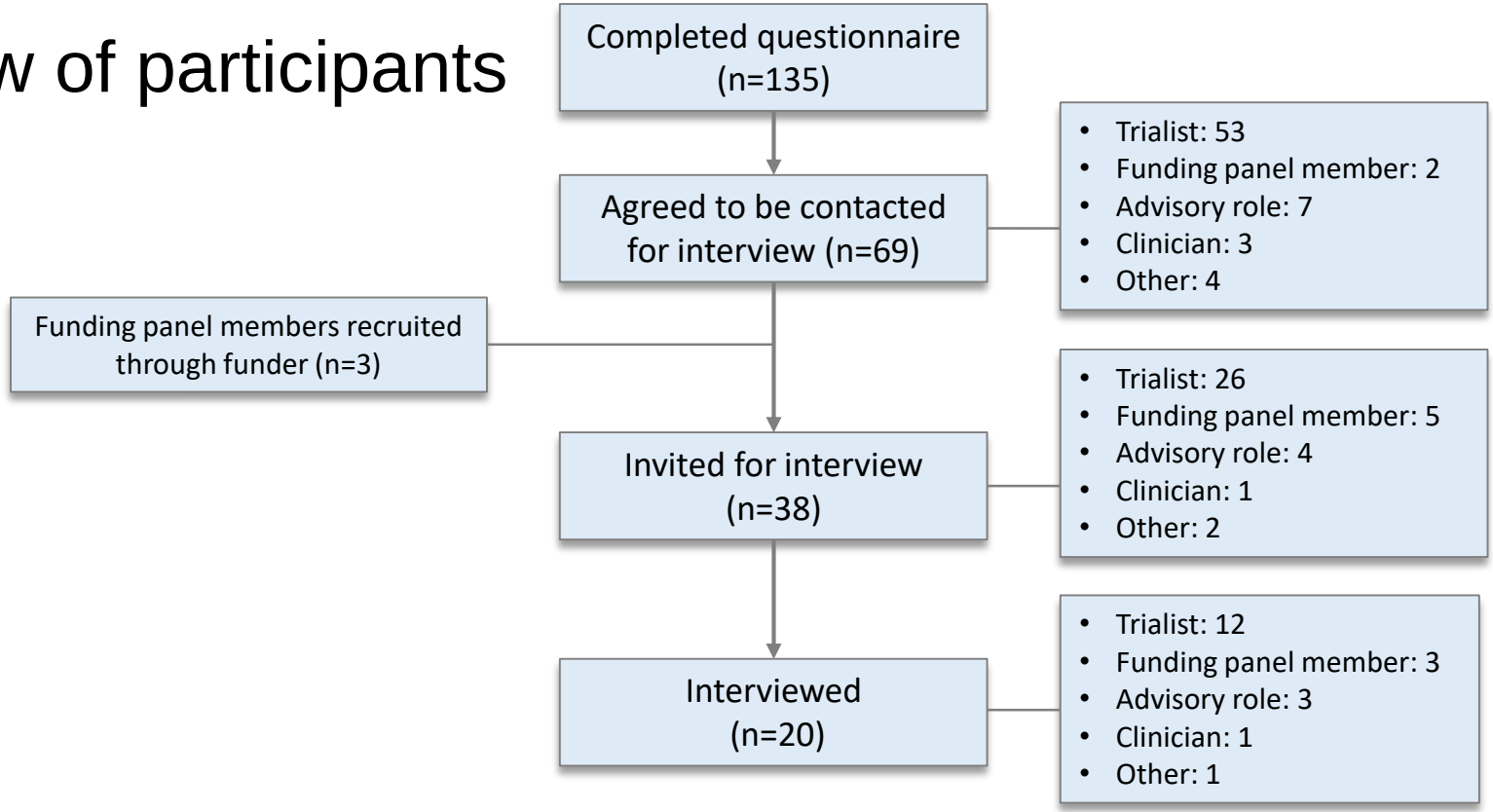
Flow of participants



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Main themes

Ethical issues and perceived equity/fairness

- Relating to the reasons for conducting an SW-CRT

"…it **wasn't really fair** for half of the clusters not to receive the intervention…" [Clinician]

"…it **removes the ethical concern** that one group ends up in the control group throughout…we felt there was no reason to withhold it, it wasn't going to do any harm, so everyone should get it eventually…" [Advisor]

"…in a parallel trial you can easily just, you could have a shorter trial… then you could provide the intervention to the control group after the trial is finished…" [Trialist]

"…where you have early evidence that your intervention could be beneficial, and **depriving** part of the units from this, will have **led to an unethical situation**" [Trialist]

"…I guess the **ethical concern** would be if the trial was going to take a lot longer, and the results might come out later… **delaying** that information becoming public knowledge…" [Trialist]

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Main themes

Treatment preference and equipoise

Relating to the reasons for conducting an SW-CRT, recruitment and adherence

"…if you're coming from a **position of equipoise**, you don't really know if the treatment's better or not. So it's hard to say that [withholding the intervention from some clusters is] an ethical concern really." [Trialist]

"…there are a lot of times where people are reluctant to be, to recruit if they're not going to get that intervention, because they see it as being the **beneficial one**." [Funding Panel Member]

"… they were trying to say that the sites won't take part unless they get the intervention…" [Funding Panel Member]

"…certainly some, some resistance, just because I think everyone **wanted the intervention sooner**…" [Trialist]

"… some communities would **not be happy** if we told them well we're going to do a parallel design, and there's a possibility you could be randomised to control… because they might never get the intervention…" [Funding Panel Member]

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Main themes

Practicalities and logistics

Relating to adherence to the implementation schedule, data collection

"… it was quite hard to maintain motivation for them to be **collecting data** without receiving the intervention." [Clinician]

"…once you've randomised where those sites are going to start the intervention… we can **plan** for when we're going to do the training and so on…more acceptable to them, that they had some idea of when they were going to be trained…" [Trialist]

"… when you randomise the centres to when they start, they almost never start when they're randomised to start… I don't think any of the centres actually started on the date they were randomised to start… it was just **too complex to organise**" [Trialist]

"…if we had not had the registry data, I'm not sure whether this sort of study would have been able to go ahead because of the **burden** on the units to collect data…" [Trialist]

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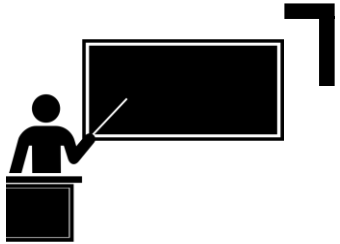
Main themes



Awareness and knowledge

Relating to design, conduct and analysis

"...if it was a maybe more standard kind of RCT, maybe people would be **more familiar** with it... saying kind of well they're control now, but they're going to get it anyway, might just be kind of a **newer concept**." [Trialist]

"...how we would estimate the parameters...how it would be analysed, which two-way comparisons and things like that... seemed more **complicated** when we were trying to nail that down... don't see many of them, so that's the difficulty... finding **good examples** of successful published ones is quite tricky." [Advisor]

"Not necessarily more complicated, but you just need **different information**, and perhaps it's a bit **harder to get** that, to get good estimates of that information." [Trialist]

"...the **expectations** around participation need to be made clear and explicit up front, and if you do that well then these aspects shouldn't matter, because they **understand** exactly what's going to happen.. And that they're expected to start when they're randomised to start." [Trialist]

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Conclusions

- Keeping to the implementation schedule can be logistically more challenging than might be expected.
- There is a need for increased awareness of the SW-CRT design: what, when and how.

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