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Reporting quality of feasibility studies for stepped-wedge cluster randomised trials: a systematic review.

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Outline

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- Motivation
- Objectives
- Methods
- Results
- Conclusion
- Future work

Background: feasibility studies for SW-CRTs

- Feasibility studies can be used to inform the design of complex trials such as those with a stepped-wedge design
- They can help inform the number of steps, duration of time needed to imbed the intervention etc.
- Often SW-CRTs will be large and costly, so getting the design right is important
- Information on common feasibility issues, identified from other SW-CRTs and feasibility studies for these trials can be useful in identify potential issues for future trials

Motivation

- The quality of reporting of SW-CRTs has been shown to be poor
- Previous systematic reviews of SW-CRTs are unlikely to have captured many feasibility studies
- The reporting quality of feasibility studies for SW-CRTs is therefore unknown

Objectives

- The overarching aims of this review were to:

1. Assess the reporting quality of feasibility studies conducted in preparation for a SW-CRT
2. Highlight areas of reporting in need of improvement.

Methods: identification of papers

- We recently conducted a review of feasibility studies for SW-CRT
- The review aimed to identify published feasibility studies for SW-CRTs, to see how feasibility studies are being used to inform this type of trial
- Eligible studies were full reports or protocols of feasibility studies conducted in preparation for a SW-CRT
- Feasibility study: a study with clearly defined aims and objectives, which intended to ascertain the feasibility of a planned SW-CRT, through the assessment of issues other than solely the effectiveness of the intervention.

Methods: data extraction and analysis

- The CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract* was used
- For non-randomised studies and protocols the checklist was adapted, removing items which were not applicable.
- Items 8a, 8b and 9 were not applicable for non-randomised studies
- Any reference to randomisation was removed from items 1a, 2a, 3a, 10, 13a, 13b,16 and 17 for non-randomised studies
- Items 13a-19a, 21-22a and 24 were removed for protocols
- Each item was recorded as “fully reported”, “reported partially”, “not reported” or “not applicable”

*Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

CONSORT checklist for pilot or feasibility randomized trials

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility ~~randomised~~ trial in the title	
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for ~~randomised~~ pilot trial	
	2b	Specific objectives or research questions for pilot trial	
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) ~~including allocation ratio~~	
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
	4c	How participants were identified and consented	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	
Sample size	7a	Rationale for numbers in the pilot trial	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	~~8a~~	~~Method used to generate the random allocation sequence~~	
	~~8b~~	~~Type of randomisation(s); details of any restriction (such as blocking and block size)~~	
Allocation concealment mechanism	~~9~~	~~Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned~~	

Non-randomised studies

Protocols

*Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

CONSORT checklist for pilot or feasibility randomized trials

Implementation	10	Who ~~generated the random allocation sequence, who~~ enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, ~~randomly assigned,~~ received intended treatment, and were assessed for each objective	
	13b	For each group, losses and exclusions ~~after randomisation,~~ together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the pilot trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by ~~randomised~~ group	
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by ~~randomised~~ group	
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
	19a	If relevant, other important unintended consequences	
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	
Protocol	~~24~~	~~Where the pilot trial protocol can be accessed, if available~~	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	
	26	Ethical approval or approval by research review committee, confirmed with reference number	

Non-randomised studies

Protocols

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Results

- 11 feasibility studies conducted in preparation for a SW-CRT were identified up to February 2017
- 8 reports: 1 randomised, 7 non-randomised
- 3 protocols: 2 randomised, 1 non-randomised

Reporting quality: the good…

Checklist item	% Reported fully
Methods	
3a: Description of pilot trial design including allocation ratio	100%
4a: Eligibility criteria for participants	91%
4b: Settings & locations where the data were collected	91%
5: Interventions for each group with sufficient details to allow replication, including how & when they were actually administered	90%
8a: Method used to generate the random allocation sequence	100%
8b: Type of randomisation(s); details of any restriction	100%
9: Mechanism used to implement the random allocation sequence; any steps taken to conceal the sequence until interventions were assigned	100%
Results	
16: For each objective (& by randomised group), no. of participants included in each analysis.	88%
17: For each objective (& by randomised group), results including expressions of uncertainty for any estimates.	100%
Discussion	
22a: Implications for progression from pilot to future definitive trial, including any proposed amendments	88%

Reporting quality: … and the bad

Checklist item	% Reported fully
Title and abstract	
1a: Identification as a pilot or feasibility (randomised) trial in the title	45%
1b: Structured summary of pilot trial design, methods, results, and conclusions	36%
Methods	
6c: If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	18%
7a: Rationale for numbers in the pilot trial	27%
10: (Who generated the random allocation sequence), who enrolled participants, and who assigned participants to interventions	18%
12: Methods used to address each pilot trial objective whether qualitative or quantitative	64%
Results	
13b: For each group, losses and exclusions after (randomisation), together with reasons	29%
19: All important harms or unintended effects in each group	0%
Other information	
23: Registration number for pilot trial and name of trial registry	18%
24: Where the pilot trial protocol can be accessed, if available	0%

Areas for improvement

- Identification as a pilot or feasibility study in the title
- Identification as a pilot or feasibility study **to inform a SW-CRT** in the title (or at least the abstract)
- Generally, clearer and better structured abstracts
- Improve clarity of reporting of how the feasibility study will inform the definitive trial and the criteria for determining feasibility
- Rationale for number included, how participants where recruited and the flow of participants through the study
- Increased registration and publication of protocols

Conclusions

- We are the first to assess the reporting quality of feasibility studies conducted in preparation for a SW-CRT
- The identified studies were generally poorly reported
- It would be difficult to identify the majority of these studies from searches of online databases
- It is therefore likely that not all feasibility studies for SW-CRTs were identified by our search
- Improved reporting of feasibility studies for SW-CRTs would increase the potential for other researchers to learn from previous studies and use their findings to inform future trials

Future work

- Identification of unpublished feasibility studies and feasibility studies for published full SW-CRTs
- Questionnaire and interview study of feasibility issues encountered by SW-CRTs

References: included studies

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