

The Stepped Wedge study design

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T o d a y ' s p r e s e

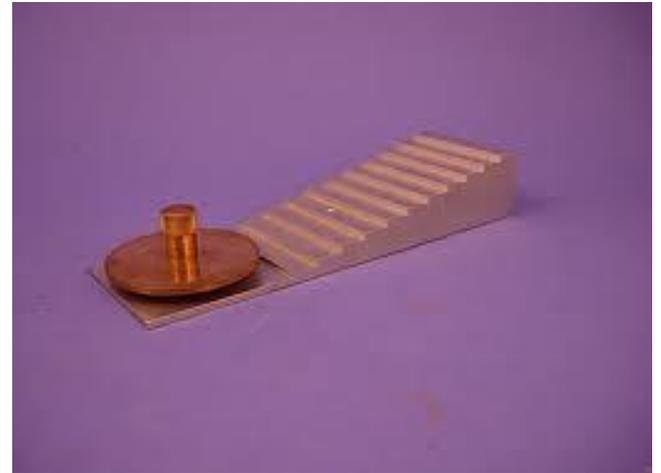
- Stepped Wedge (SW) designs
 - What is a SW design?
 - What are the advantages and disadvantages of using a SW design?
- Systematic review of the use of cluster SW
 - Aims of systematic review
 - Results of systematic review
 - Conclusions

I n a S W d e s i g

- All individuals or clusters will have received the intervention by the end of the study
- T h e o r d e r o f ' s t e p p i n g ' randomised
- I n d i v i d u a l s o r c l u s t e r s
- One or more individuals or clusters can be randomised per step
- Outcome data are collected in each cluster at each time period/step

A S W d e s i g n i

- A step wedge (used to calibrate X-Ray machines)
- A cross-over trial
- A multiple baseline study (repeated baseline measurements obtained until stable)



Advantages

- Solves ethical dilemma of withholding the intervention when not in equipoise
- Offers robust evaluation methodology for interventions where decisions have already been made
- Provides evaluation methodology if there are logistical and financial problems associated with simultaneous implementation
- Can detect trends over time
- Increases statistical power (within and between comparisons)
- Can study the effect of context/process as intervention is implemented in multiple settings
- Can incorporate an economic evaluation



Disadvantages

- Can require a lengthy trial – so best if short time between intervention and outcome
- Multiple data collection points required – so best if using routinely collected data
- Data analysis is fairly complicated if time effects (see paper by Hussey and Hughes, 2007)



Available online at www.sciencedirect.com



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Contemporary
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Design and analysis of stepped wedge cluster randomized trials

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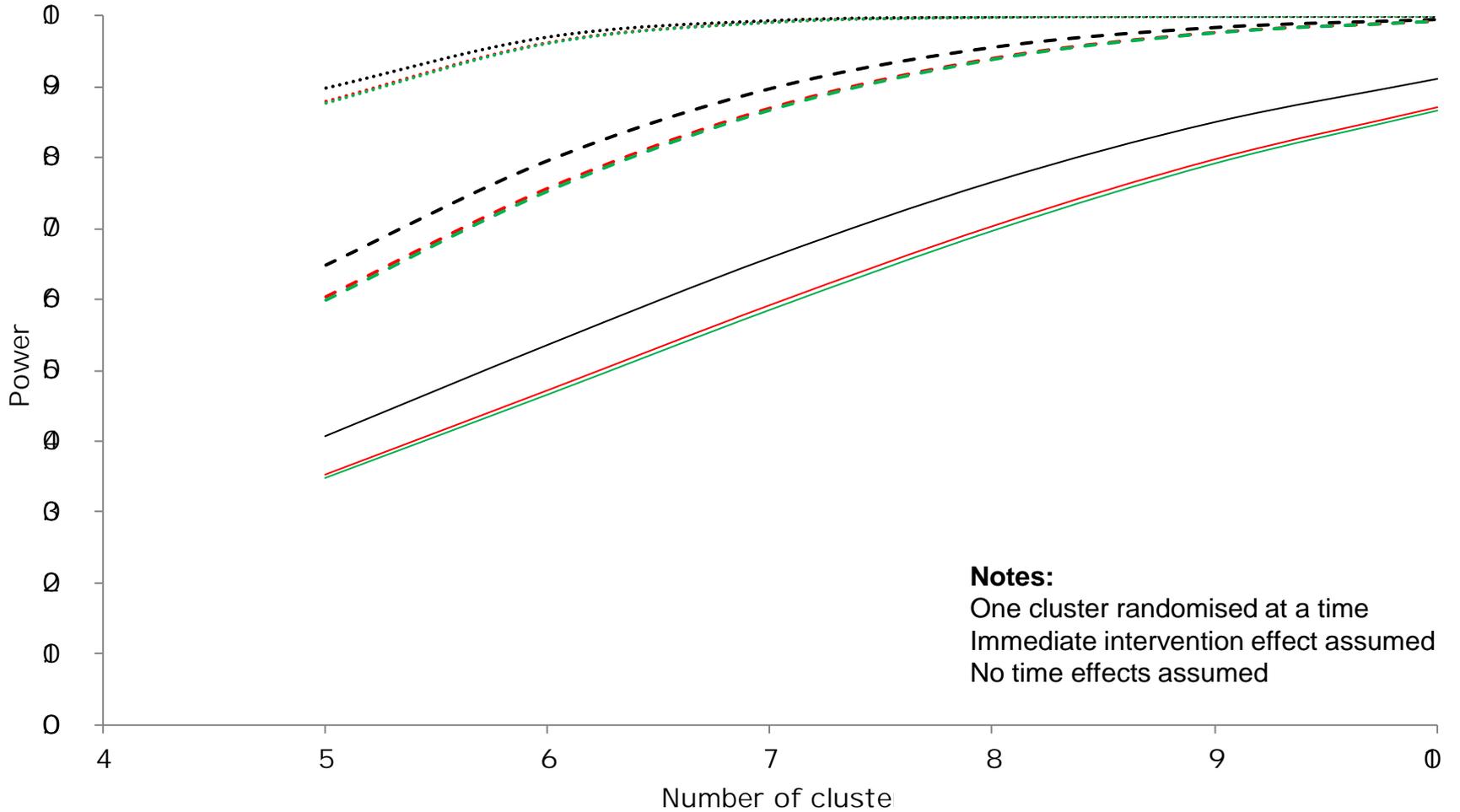
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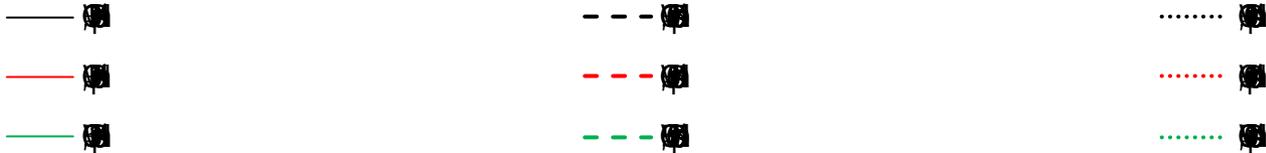
Sample Size for SW designs

- SW factors affecting required sample size (Hussey and Hughes, 2007):
 - Coefficient of variation (power relatively insensitive to CV due to use of within and between cluster information)
 - Number of clusters randomised at each step (loss in power if >1)
 - Delayed treatment effects (reduce power, which is difficult to recover by adding extra measurement periods at the end)

Power for SW design to detect a MID of 10% (60% to 70% compliance), for
(using formula from Hussey and Hughes, 2007)



Notes:
 One cluster randomised at a time
 Immediate intervention effect assumed
 No time effects assumed



Example SW study

Comparison of standard therapy with home-based therapy with therapeutic food' (RUTF) to treat maln al., 2005).

SW design used as 'full' randomisation and cultural beliefs; SW allows control for bias introduced by seasons

7 centres included, 1 every 3 weeks 's

Primary outcome: recovery defined as WHO weight for height z-score > -2 after 8 weeks

Results: recovery rate in RUTF group 79% vs. control group 46%, $p < 0.001$ (N=992 RUTF, 186 control)

Why successful?

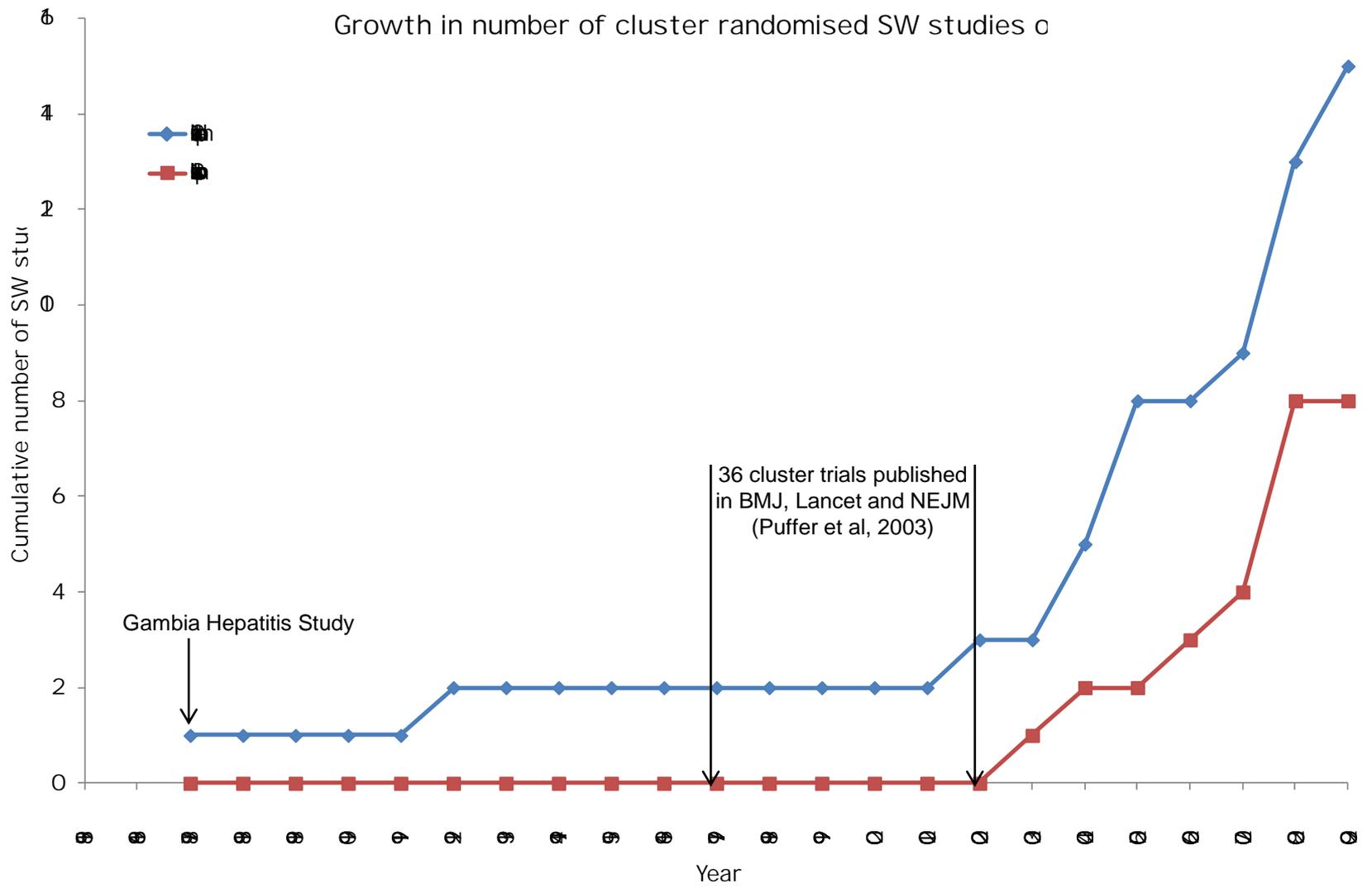
1. Inpatient care as part of standard therapy increases risk of infection
2. Standard therapy food provided on discharge needs preparation 7 times/day over an open fire



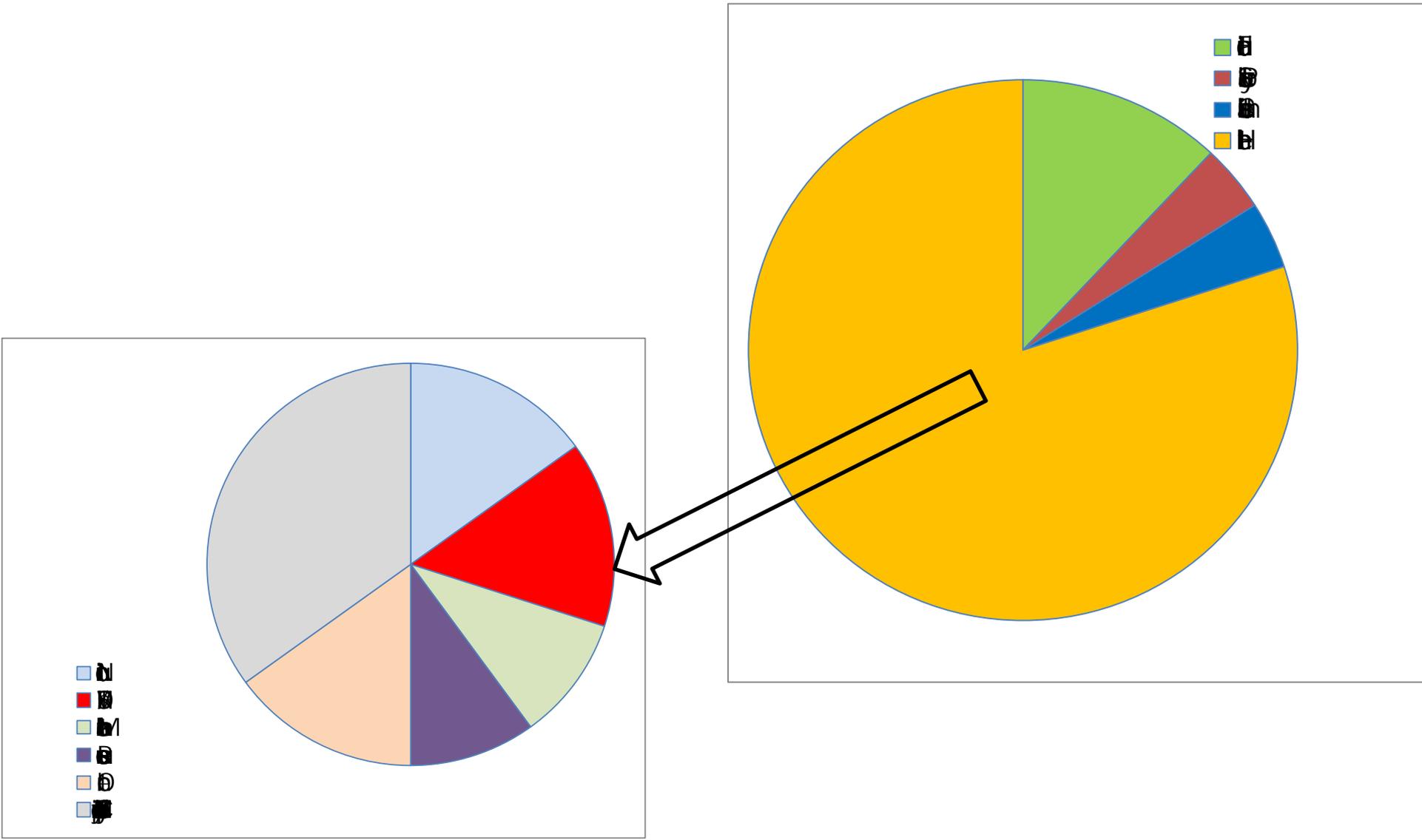
Systematic review

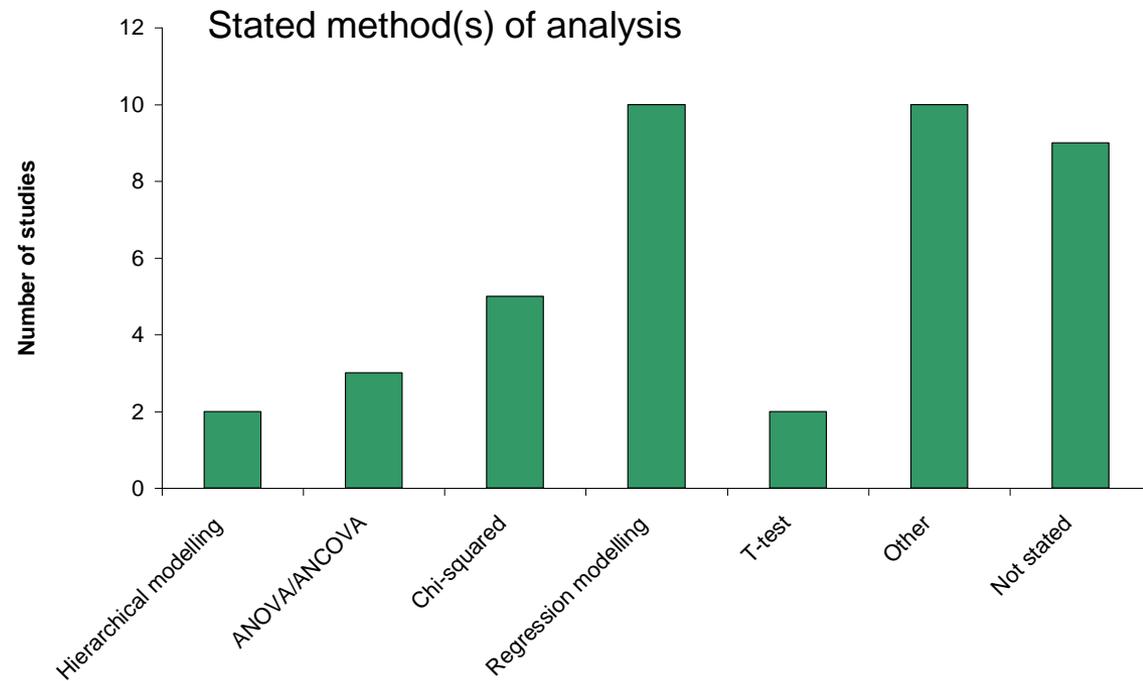
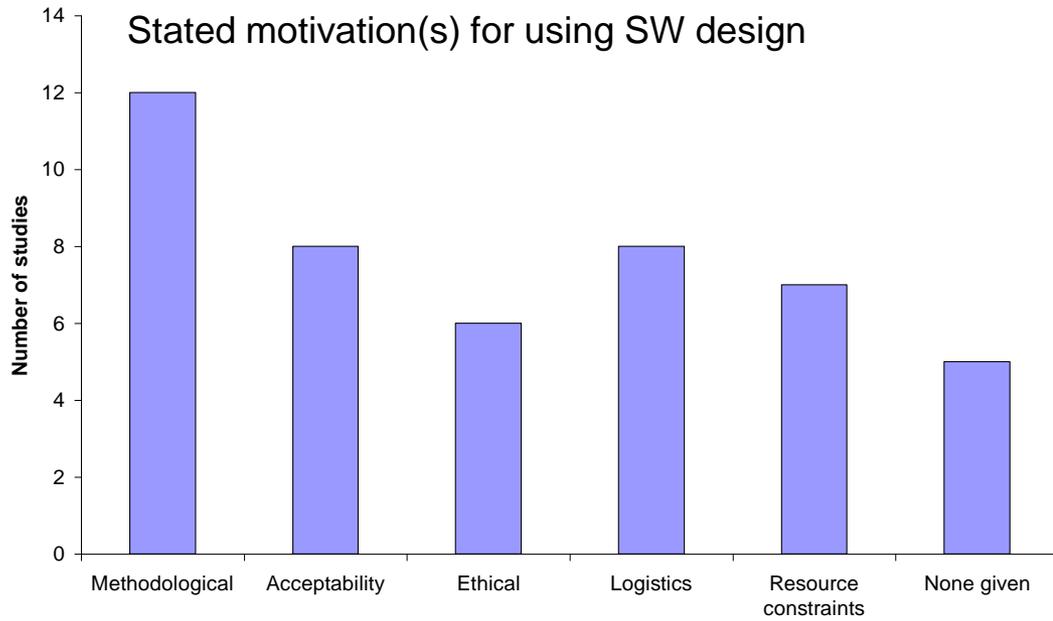
- Aim - to describe the application of the cluster randomised stepped wedge design in terms of:
 - Increase in use over time
 - Research areas where design used
 - Motivations for using design
 - Methods of data analysis
 - Quality of reporting
- 25 Studies included up to January 2010
- 15 completed studies and 10 protocols

Growth in number of cluster randomised SW studies

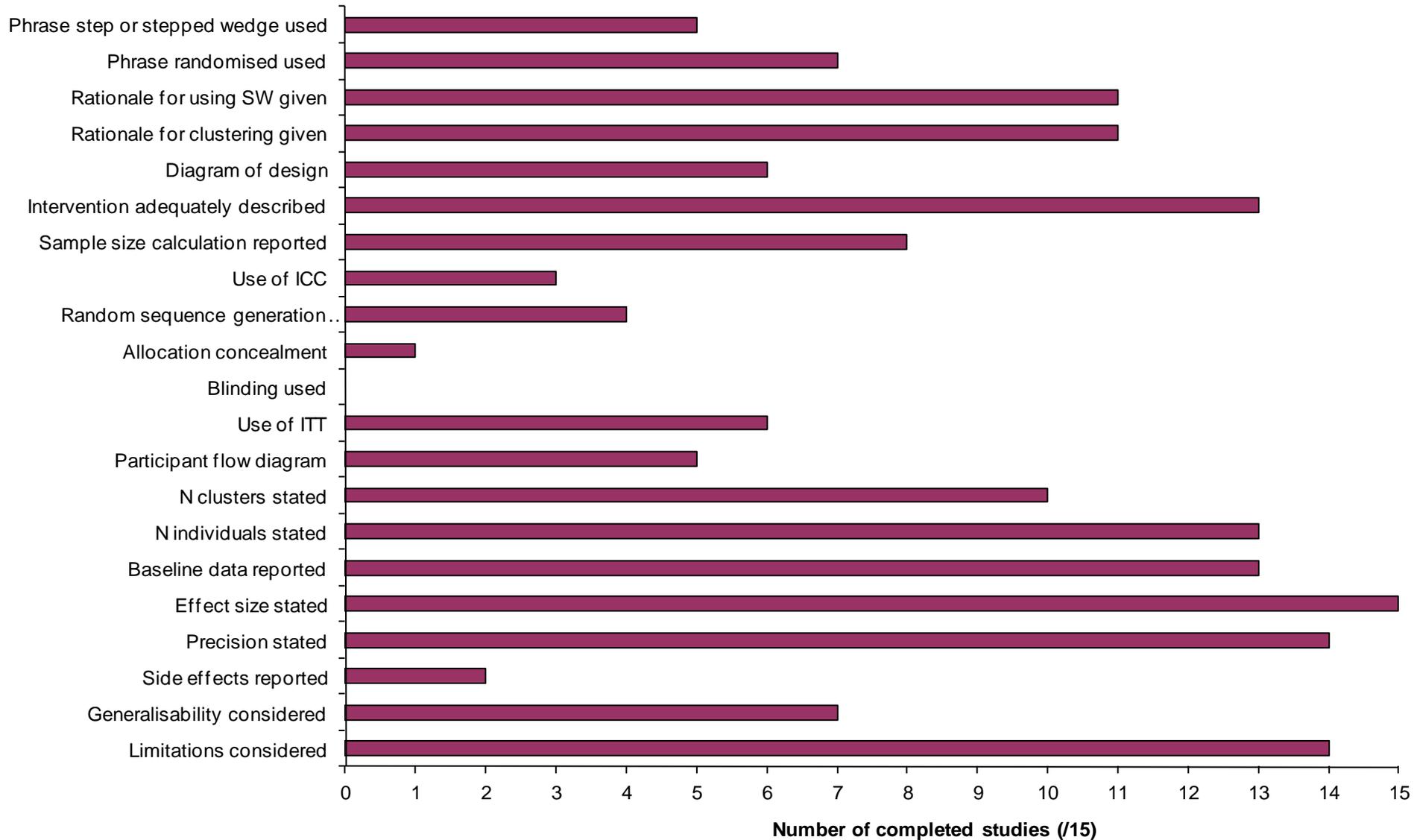


Research areas where SW design used (total N=25)





Quality of Reporting



Conclusions

- Increasing use of design over time
 - Can be a powerful design
 - But requires extensive data collection
- Design used for a variety of reasons
- Most studies in health
 - A high proportion of RCTs of any type are in health
 - Design can overcome ethical constraints often cited in other areas (e.g. education)
- Lack of consistency in describing the design as a “stepped wedge” (so we m
- Other problems with the quality of reporting
 - Adaptation of CONSORT statement required?

Thank you

- And thank you to my co-authors
- Questions?
- Comments?