

Methods

In this talk we propose an alternate correlation structure in which the within-cluster correlation is allowed to vary depending on the distance between measurements of individuals. In the special case of exponential decay in the within-cluster correlation and an equal number of subjects per period in each cluster, we present results for the variance of treatment effect estimators for varying amounts of decay addressing the following two questions:

- How does the precision in stepped wedge trials compare to parallel-group cluster trials of the same size as the decay varies?
- What are the consequences of this variation for sample size planning?

Results and conclusions

Our results indicate that in certain design configurations a correlation decay can have an impact on the variance of treatment effect estimators, and hence on sample size and power.

O3

Challenges and solutions for the operationalisation of the ENHANCE study: a pilot stepped wedge trial within a general practice setting

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Background

The ENHANCE pilot trial aims to examine the feasibility and acceptability of an integrated approach to Long Term Condition (LTC) management by tackling the under-diagnosis and under-management of osteoarthritis (OA) related pain and anxiety &/or depression in patients aged 45 years and over with other LTCs in primary care, using a stepped wedge trial design. This abstract describes some of the challenges faced in operationalising this trial design within general practice, together with solutions that have been implemented.

Method

The intervention is an 'ENHANCE' LTC review, delivered by Practice Nurses and in accordance with a stepped wedge design, has been rolled out to four general practices (clusters) over time. Operationalisation challenges linked to the methods required for this trial design have included; Scheduling of intervention training visits to fit with randomisation schedules; Initial recruitment enthusiasm waning prior to implementation of the intervention phase; Increase in trial delivery requirements within clusters as the practice moves into the intervention phase.

Results

In order to address these challenges the following solutions have been implemented; a 2 week 'wash out' period to ensure clusters make a smooth transition from control to intervention phase; Dedicated trial management communication, forward planning and organisation of intervention training delivery; Identical study materials across control and intervention phases; Communication and updates around recruitment figures to ensure recruitment and adherence to study design.

Conclusions

The stepped wedge design is an attractive option for delivering an intervention within complex settings, however presents challenges for implementation which need careful planning.

Trial registration
ISRCTN 12154418

O4

Early lessons from the implementation of a stepped wedge trial design investigating the effectiveness of a training intervention in busy health care settings: the Thistle study

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Background

There is increasing methodological literature on design, sample size calculations and analyses of stepped wedge trials (SWT). However, the challenges encountered and potential solutions developed during the implementation of SWTs are described less well. We aim to share the experience of implementing the Thistle study, an on-going SWT evaluating the effectiveness of a multi-professional obstetric training programme across a health service.

Method

Our 36-month study consists of 12 Scottish maternity units randomised in groups of four, to three intervention-steps of 6-months length. Teams from each unit were trained in how to deliver the intervention. The primary outcome (Apgar score) will be modelled using marginal logistic regression following the intention-to-treat principle (ITT).

Results

Departures from the randomisation plan were required to accommodate clinical constraints at four Maternity Units and ensure that they were retained within the study. Heterogeneity in the timing and frequency of local training post implementation was observed; some units started prior to their allocated intervention step, some after, and some completed their implementation over several steps. We will use the wealth of routinely collected clinical and training data to supplement the ITT-analysis with several sensitivity analyses to account for the actual intervention implementation.

Conclusions

Using a SWT design to evaluate the effectiveness of training intervention in busy health care settings is complex. We have highlighted problems regarding adherence to allocated step and the sensitivity analyses we propose to tackle them. These findings will help guide investigators in the designing and analysis of future SWTs.

Trial registration

UKCRN ID: 15400

O5

Sample size calculation for longitudinal cluster randomised trials: a unified framework for closed cohort and repeated cross-section designs

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Background

Recent articles have considered stepped wedge trials as part of a broader class of cluster randomised trials where two or more independent cross-sections are taken from each cluster at fixed times, with all participants in any given cross-section in any given cluster receiving either the experimental or the control treatment. A unified