

POSTER PRESENTATION

Open Access

Mixed effects approach to the analysis of the stepped wedge cluster randomised trial - accounting for the confounding effect of time

Alecia Nickless*, Merryn Voysey, Ly-Mee Yu

From 3rd International Clinical Trials Methodology Conference
Glasgow, UK. 16-17 November 2015

The stepped wedge cluster randomised trial is becoming more popular, as it is both logistically more viable for large-scale intervention roll-outs than the conventional parallel cluster randomised trial, and can be more ethically responsible when it is perceived that the intervention will do more good than harm. Stepped wedge designs have an inherent time component due to the staggered nature of the design. Although it is possible to analyse the data by ignoring time, for example through the use of a paired analysis, these approaches may result in inaccurate conclusions if there is a time trend in the data. This can occur, for example, when there is a general initiative to improve service, resulting in improvement across both the control and intervention periods over time. If time is not accounted for, there may appear to be a treatment effect where none exists. We compare different mixed effect model formulations, as well as a simple paired analysis, to describe the options available when formulating the mixed effects model, to account for time trends and obtain results which appropriately depict the stepped wedge cluster randomised trial design. These different approaches are illustrated using data from the OXTEXT-7 evaluation of “Feeling Well with True Colours” initiative implemented by adult community mental health teams in the Oxford Health NHS Foundation Trust.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P142

Cite this article as: Nickless *et al.*: Mixed effects approach to the analysis of the stepped wedge cluster randomised trial - accounting for the confounding effect of time. *Trials* 2015 **16**(Suppl 2):P142.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



Nuffield Department of Primary Care Health Sciences, University of Oxford,
Oxford, UK



© 2015 Nickless et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated.