

POSTER PRESENTATION

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Calculating the design effect for a cluster stepped-wedge trial with varying cluster size; a case study from a trial in type 2 diabetes

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

Background

Type 2 diabetes (T2DM) is a serious chronic disease which can be improved with education. Only 6.0% of people with T2DM are offered education and only 1.6% attend.

Methods

We have designed a cluster trial with a stepped-wedge design (SWD) to test an intervention to increase the uptake to education. This study will include general practices of varying size. There is no published guidance on powering a cluster SWD with varying cluster size. We present the method used to estimate the design effect (DE) which combines the method for calculating the sample size required for a cluster SWD by Woertman et al. with a method for taking into account varying cluster size in a standard cluster trial by Eldridge et al.

Results

We assume a median practice size of 347, IQR 201-678, which gives a Coefficient of Variation (CV) of $119.25/348=0.34$. Using the method of Woertman gives a DE of 1.41; this doesn't take into account variation in cluster size. Using the method in Eldridge with a CV of zero (no variation in cluster size) gave DE of 18.35; replacing CV with 0.34 gave DE of 20.36. Hence variation in cluster size inflates DE by 2.01 (20.36-18.35). The total DE therefore when taking into account the SWD and variation in cluster size was 3.42 (1.41+2.01).

Conclusion

We present a pragmatic way of calculating the DE for cluster SWD with variation in cluster size. Future work should focus on the impact of cluster size variation.

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Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P124

Cite this article as: Ashra et al.: Calculating the design effect for a cluster stepped-wedge trial with varying cluster size; a case study from a trial in type 2 diabetes. *Trials* 2015 **16**(Suppl 2):P124.

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