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Intraclass correlation coefficients for cluster randomized trials in primary care: The cholesterol education and research trial (CEART)☆

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Abstract

Cluster randomization trials are increasingly being used in primary care research. The main feature of these trials is that patients are nested within large clusters such as physician practices or communities and the intervention is applied to the cluster. This study design necessitates calculation of intraclass correlation coefficients in order to determine the required sample size. The purpose of this study is to determine intraclass correlation coefficients for a number of outcome measures at the primary care practice level. The CEART study is a randomized trial testing the effectiveness of translating ATP III guidelines into clinical practice, with primary care physician practices as the unit of randomization and patients as the unit of data collection. The intraclass correlation coefficient (ICC) was<0.02 and the design effect ranged from 1.0 to 2.3, respectively, for weight, total cholesterol, LDL, non-HDL, glucose, creatinine, and % at non-HDL goal. For smoking status, body mass index, systolic blood pressure, HDL cholesterol triglycerides, total cholesterol/HDL ratio and % at LDL goal, the ICC was 0.02–0.047 and the design effect was 2.6–4.1. The largest ICCs (0.05–0.12) and design effects (4.4–9.4) were found for height and diastolic blood pressure. These findings suggest that cluster randomization may substantially increase the sample size necessary to maintain adequate statistical power for

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selected outcomes such as diastolic blood pressure studies compared with simple randomization for most outcomes evaluated in this study where the design effect is small to moderate. Overall, the ICCs presented will be useful in calculating sample sizes at the primary care level.

Keywords: Intraclass correlation coefficients; Primary care; Cluster randomized trials

1. Introduction

Cluster randomization in primary care practice intervention trials is an increasingly popular design whereby individuals are nested within larger clusters such as practices, hospitals, or communities [1–4]. The practical advantages are that "whole practice populations can be studied; the organization of the trial might be simpler; many primary care providers may find this method of research less intrusive on the daily clinical practice; and the practical problems of offering an intervention to some, but not others, within a practice are overcome" [5] which is particularly important for quality improvement initiatives where most of the interactions will occur at the practice level using a team-based approach. However, to implement this study design, it necessitates special power calculations and data analysis because observations on individuals within the same cluster may be correlated [6]. Within-cluster correlation affects the power of a trial because a greater homogeneity of members in the clusters will increase the standard error of the estimate of the treatment effect resulting in a loss of power to detect a difference between the intervention and control groups [7,8]. Therefore, primary care intervention trials may require calculation of intraclass correlation coefficients in order to determine the required sample size.

There are repeated calls for the publication of intraclass correlation coefficients to aid in the design of future cluster-based intervention studies [1,9–12]. Our objective was to provide intraclass correlation coefficients for a number of outcome measures at the primary care practice level from practices in response to this need.

2. The intraclass correlation coefficient

The intraclass correlation coefficient is the measure of variation between and within clusters of individuals and measures the clustering effect or lack of independence among individuals who make up the cluster [13]. The intraclass correlation coefficient is based on the relationship of the between-cluster to within-cluster variance and is given by $\rho=\sigma_b^2/(\sigma_b^2+\sigma_w^2)$, where σ_b^2 is the between-cluster component of the variance and σ_w^2 is the within-cluster component of the variance [9].

Factors that need to be taken into account in sample size calculations are the distribution of the outcome measures in the population and the presumed effect of the intervention, the size of the individual clusters, and the value of the intraclass correlation. A large intraclass correlation coefficient will reduce statistical power requiring a larger sample size while a smaller intraclass correlation coefficient indicates greater power and will not require significant adjustment to the sample size. However, simply increasing the number of subjects in each cluster will do relatively