

A CLUSTER-RANDOMISED TRIAL OF WORKSITE CARDIOVASCULAR RISK REDUCTION

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1. INTRODUCTION

This paper illustrates some of the issues raised by David Hand in his opening address to the workshop. In it I will describe a study being undertaken by a PhD student in my department who has a background in psychology. I believe it is important in such circumstances that the student should do the analysis herself, so the issues of comprehensibility and software availability become major considerations, which must be weighed against mathematical sophistication and statistical optimality.

2. DESCRIPTION OF STUDY

This study aims to evaluate four multiple risk factor interventions in a worksite setting. These are health assessments only (HA), health education (HE), behavioural counselling (BC), and incentives (I). The worksites are ambulance stations in the Sydney metropolitan region. There were 28 ambulance stations randomised to the 4 interventions, 8 to each of HA, HE and BC, and 4 to I. All staff within a station received the same intervention. A total of 431 staff participated in the trial.

Participants were assessed at baseline and at 3, 6 and 12 months from baseline. The major study outcome variables were: body mass index ($BMI = \text{weight}/\text{height}^2$), %body fat, systolic and diastolic blood pressure, serum cholesterol, number of cigarettes per day, smoking status (validated by cotinine) and aerobic capacity.

Missing data occurred for two reasons. First, data were missing at baseline because of problems with testing which were discovered too late:

body fat was measured incorrectly for one station randomised to I, and aerobic capacity for a station in group HA. Second, missing data occurred sporadically due to incomplete assessments (colds, broken leg, holidays, dropouts, problems with blood collection procedures). There was no systematic pattern or difference between groups in the latter category of missing data; on average about 88% of subjects completed each assessment.

The investigators were particularly interested in the following contrasts: HA v HE, BC v I, and, if valid, HA+HE v BC+I.

3. ANALYSIS

BMI and serum cholesterol were transformed to Normality by taking logarithms, and square roots of aerobic capacity were used. All other continuous variables were approximately Normally distributed except for number of cigarettes per day, for which transformation to Normality was impossible.

It was essential to choose a method of analysis that was implemented in readily available software and would answer the particular research questions, while taking account of the longitudinal and nested features of the design. SPSSx was chosen because its MANOVA procedure incorporates these features (REPEATED and NESTED), permits adjustment for covariates, allows fitting of polynomial contrasts over time and treatment contrasts as specified above, and the student was already familiar with SPSSx. Note that although the MANOVA procedure was used, the analysis was a univariate analysis of variance for each outcome.

The major disadvantage of this method is that it does not handle missing data, so that it was necessary to estimate missing values from the average of the other measurements for an individual. Another disadvantage, shared by most other methods for analysis of longitudinal data, is the need for distributional assumptions; the smoking data therefore

could not be analysed in this way.

4. DISCUSSION

I invited discussion on the use of a sub-optimal analysis for this study necessitating estimation of missing values. Opinions ranged from those who felt my solution was optimal under the circumstances to those who believed that a technique such as that of Verbyla and Cullis should be used. The most useful suggestion came from David Hand, which was to use the covariates to estimate the baseline values that were missing for a whole station.

5. CONCLUSION

Ideally all studies would be analysed using the most appropriate statistical technique(s) currently available. In practice, of course, the shortage of statisticians and statistical expertise means that applied statisticians must choose between giving reasonable but sub-optimal help to the maximum number of clients or getting deeply involved in only a few projects and rejecting all other calls for assistance. In a multi-disciplinary department such as public health the need for such assistance is great. Had I not become involved at all in this study, the analysis would not even have taken into account the effect of the cluster randomisation, which is likely to be far greater than that of the missing data.

For such situations the main requirements are for a method that is readily available in a user-friendly form, while taking account of the main features of the design and the research objectives. The method needs to be acceptable not only to the researcher but also to the editor and readers of the journal where the results are to be published.

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