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## Composite Cardiovascular Risk Outcomes of a Work-Site Intervention Trial

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### Introduction

Most work-site multiple risk factor intervention trials have used single outcome measures to assess intervention effects. Of six large randomized trials, three have demonstrated significant reductions in at least one risk factor after intervention.<sup>1-5</sup> However, single risk factor outcomes may not reflect the overall effect of intervention, because change in one risk factor may be accompanied by negative or positive changes in other risk factors. Furthermore, small positive changes in individual risk factors may only be detected when the information from each is combined into a summary measure. In fact, this may be the reason why some trials failed to find an effect.

This paper reports a reanalysis of the main results presented in an earlier paper<sup>5</sup>; composite outcomes were used to take into account the extent and direction of change occurring for each risk factor outcome. Two composite outcome measures were used, not for the purpose of comparison but because each had particular advantages for combining the single outcome measures used in this trial.

### Methods

Twenty-eight ambulance stations in metropolitan Sydney, Australia, were ran-

domly assigned to one of four interventions. The methodology and interventions have been described previously in detail.<sup>5</sup> All participants received a risk factor assessment and feedback at baseline, as well as at 3, 6, and 12 months after the initial assessment.

Participants in the health risk assessment condition (n = 130) received the risk factor assessment only. Participants in the risk factor education condition (n = 82) received information on risk factors, an educational resource manual, and videos.

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## ABSTRACT

**Objectives.** Two composite outcome measures were used to assess the efficacy of work-site risk factor interventions: the Framingham multiple logistic function and a standardized composite equation that was an unweighted combination of risk factors.

**Methods.** Twenty-eight work sites in Sydney, Australia, were randomly assigned to health risk assessment, risk factor education, behavioral counseling, or behavioral counseling plus incentives.

**Results.** Over 12 months, scores on the multiple logistic function increased for the behavioral counseling plus incentives condition relative to the other conditions. Standardized scores decreased for behavioral counseling relative to the incentive condition and the average of all other conditions.

**Conclusions.** Behavioral counseling produces larger changes in the life-style behaviors contributing to coronary heart disease risk than other commonly used interventions. (*Am J Public Health*. 1997;87:673-676)

**TABLE 1—Mean Raw Values on Outcome Measures and Percentage of Smokers at Baseline: A Cardiovascular Intervention at 28 Work Sites in Sydney, Australia**

Outcome Measure	Sample
Body mass index, kg/m <sup>2</sup> (n = 430), mean (SD)	25.4 (3.8)
Body fat, % (n = 430), mean (SD)	22.2 (5.6)
Mean cholesterol, mg/100 mL (n = 427), mean (SD)	197.9 (38.8)
Systolic blood pressure, mm Hg (n = 430), mean (SD)	127.1 (12.4)
Diastolic blood pressure, mm Hg (n = 430), mean (SD)	81.7 (10.5)
Aerobic capacity <sup>a</sup> (n = 423), mean (SD)	35.1 (10.2)
No. cigarettes per day for smokers (n = 128), mean (SD)	17.7 (10.2)
Smokers, %	29.7

<sup>a</sup>Milliliters of oxygen per kilogram per minute, in terms of estimated maximal oxygen uptake.

In the behavioral counseling condition (n = 124), participants received risk factor education, up to six behavioral counseling sessions, and a self-instructional manual containing programs for modifying risk factors. Participants in the behavioral counseling plus incentives condition (n = 95) received risk factor education, a goal-setting and review counseling session, and the self-instructional manual. Three incentives were also offered: a \$40 voucher in two lottery draws for those reporting specified healthy lifestyle changes; a \$40 voucher for participants achieving risk factor reduction goals; and a \$1000 prize for the ambulance station that achieved the largest percentage of participants meeting risk factor reduction goals.

The first composite outcome measure used was the Framingham multiple logistic function<sup>6</sup>:  $\alpha + \beta_C \text{CHOL} + \beta_B \text{SBP} + \beta_S \text{SMK} + \beta_W \text{WREL} + \beta_H \text{Hb} + \beta_E \text{ECG} + \beta_A \text{AGE}$ , where  $\alpha$  is the intercept and the  $\beta$ s are the respective coefficients of named risk factors. This score represents the log odds ratio of having a coronary event in 12 years.<sup>7</sup> Values for mean serum cholesterol (CHOL), systolic blood pressure (SBP), and smoking (SMK) were substituted directly. Relative weight (WREL) was calculated according to median weight values for sex–height groupings of the Australian population. Estimated values were used for variables that were not measured. Hemoglobin (Hb) values used were the estimated means for male and female Australians,<sup>8</sup> electrocardiograph readings were assumed to be normal on the basis of screening with the Rose questionnaire,<sup>9</sup> and mean age (AGE) for the women and men in the study population was used because change in age was the same for all subjects.

The second measure was a standardized composite equation or lifestyle score that incorporated body mass index, mean cholesterol (the average of two readings), number of cigarettes smoked per day, mean blood pressure,<sup>10</sup> and aerobic capacity. As a means of improving normality, scores for body mass index and mean cholesterol were logarithmically transformed, and a square root transformation was used for aerobic capacity and number of cigarettes. Each variable  $X$  was standardized by calculating  $z$  scores for participants at each assessment occasion as  $z = (X - \bar{x})/SD$ , where  $\bar{x}$  is the grand mean and SD is the standard deviation from all assessment occasions. For smokers, the  $z$  score was based on the number of cigarettes per day at baseline, with a constant (2.3644) added to give smokers a positive score if still smoking and to give ex-smokers a zero score; nonsmokers at baseline were assigned values of zero for all assessment occasions. The final composite score for each participant at each assessment was calculated as the sum of all of his or her  $z$  scores.

Missing values for each of the variables necessary for the calculation of the composite scores were inputted five times via a method of multiple imputation based on the normal linear regression model, as described by Rubin.<sup>11</sup> At each stage of the imputation, the model incorporated random components to account for uncertainty in estimating the regression variance, each of the regression coefficients, and the prediction of outcome for each subject with missing data. All subjects with complete data at baseline were used for the imputation and in the calculation of composite scores (403 for the multiple logistic function and 392 for the lifestyle score). The five complete data

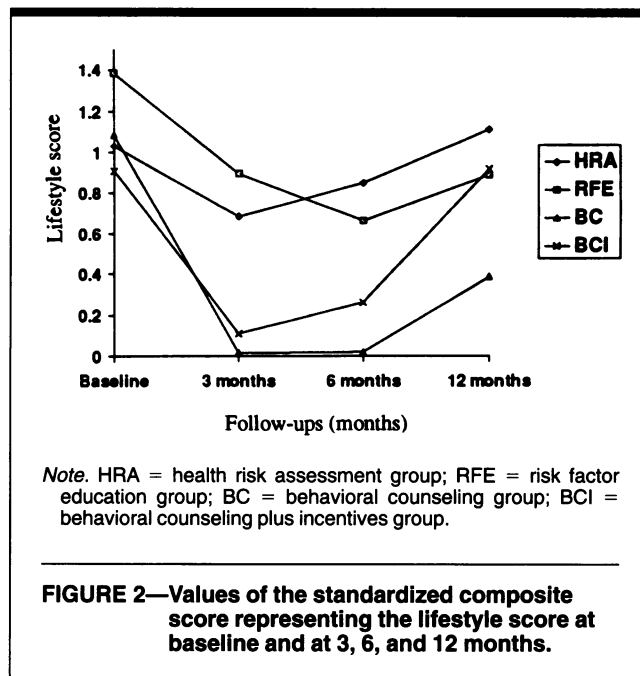
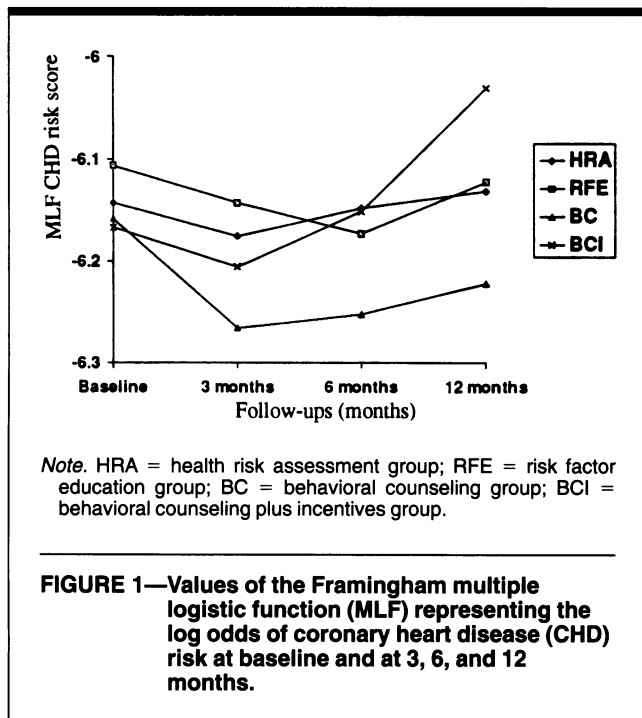
sets formed by the imputation procedure were each analyzed, and the results were combined to estimate the parameters and their variances, the latter appropriately inflated by incorporating the two components (within-imputation plus between-imputation variance).

Univariate repeated measures analysis of variance (SPSS-MANOVA) was used to assess effects of interventions over time on the multiple logistic function and lifestyle scores. Individuals were the unit of analysis, and clustering within stations was taken into account in the analysis of variance. The major comparisons of interest were those involving the interactions between intervention condition and time. Quadratic and linear trends, respectively, were used to examine short-term and longer term changes of the interventions across the 12 months.<sup>5</sup>

## Results

The mean age of participants was 32 years (SD = 8.64); 83% were male, 59% were married, and 54% had completed high school, with an additional 26% having undertaken further education. Seventy-two percent were ambulance officers, 21% were paramedics, and the remainder were management and administration staff. Baseline risk factor characteristics are presented in Table 1. Participation rates, demographic details, and individual risk factor results have been reported previously.<sup>5</sup> Intraclass correlation coefficients for changes in the multiple logistic function and lifestyle scores were .0608 and .0357, respectively.

The group means for the multiple logistic function score are presented in Figure 1. The multiple logistic function score decreased significantly for the behavioral counseling group in comparison with the behavioral counseling plus incentives group across the 12 months ( $t = 4.52$ ,  $df = 72$ ,  $P = .00002$ ). In comparison with the behavioral counseling plus incentives group, the greater initial decrease in the multiple logistic function score for the behavioral counseling group was followed by a smaller increase ( $t = 2.30$ ,  $df = 72$ ,  $P = .024$ ). Because the multiple logistic function score change was significantly different for the behavioral counseling and behavioral counseling plus incentives groups but not for the health risk assessment and risk factor education groups, each was compared with the average of the health risk assessment and risk factor education groups. Over the 12 months, the score increased significantly



for the behavioral counseling plus incentives group in comparison with the average of the health risk assessment and risk factor education groups ( $t = 2.71$ ,  $df = 72$ ,  $P = .008$ ). There were no significant differences between the behavioral counseling group and the average of the health risk assessment and risk factor education groups. However, the multiple logistic function score decreased for the behavioral counseling group in comparison with all other groups ( $t = 1.96$ ,  $df = 72$ ,  $P = .053$ ). This initial decrease was followed by a smaller increase relative to all other groups ( $t = 2.19$ ,  $df = 72$ ,  $P = .032$ ).

Group means for the lifestyle score are presented in Figure 2. Scores decreased significantly for the behavioral counseling group in comparison with the behavioral counseling plus incentives group across the 12 months ( $t = 3.26$ ,  $df = 72$ ,  $P = .0017$ ). Since the 12-month change in lifestyle score was significantly different for the behavioral counseling and behavioral counseling plus incentives groups but not for the health risk assessment and risk factor education groups, each was compared with the average of the health risk assessment and risk factor education groups. There were no significant differences between the behavioral counseling group or behavioral counseling plus incentives group in comparison with the average of the health risk assessment and risk factor education groups. However, the lifestyle score decreased significantly from baseline to 12 months

for the behavioral counseling group relative to all other conditions ( $t = 2.11$ ,  $df = 72$ ,  $P = .04$ ).

## Discussion

Our first major finding was that behavioral counseling was more effective in producing change in the composite of lifestyle behaviors contributing to coronary heart disease risk than the other interventions. This effect was evident despite the combining of risk factors, some of which had not shown significant change previously (cholesterol and aerobic capacity and blood pressure) relative to the other interventions.

Second, both composite outcome measures indicated a negative effect of incentives, an effect that was not as apparent from the results of the single risk factor outcomes reported previously. This finding is consistent with previous research<sup>12,13</sup> and suggests that the use of incentives may detract from lifestyle change through shifting motivation from an intrinsic to an extrinsic source of reward.

Some caution is needed in interpreting the results for the incentive condition and in generalizing the findings of this trial. Recruitment and implementation for the incentive condition occurred during the first recruitment wave of the trial.<sup>5</sup> Also, ambulance officers are a unique population characterized by shift work, unpredictability of work, and stress.

Two composite measures were used in this trial because currently there is no "gold standard" for measuring cardiovascular disease risk factor change. Whereas the multiple logistic function equation may be more appropriate to use when estimates of cardiovascular disease risk are needed, the composite standardized outcome measure may prove more useful for measuring effects in intervention trials, particularly in instances in which the primary focus is on lifestyle change. □

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## ABSTRACT

**Objectives.** This study examined the relation of hysterectomy and oophorectomy to heart disease risk factors.

**Methods.** Data were collected and analyzed for 1150 women aged 50 through 89.

**Results.** Of these women, 21.8% reported hysterectomy with bilateral oophorectomy; 22.1%, hysterectomy with ovarian conservation. Compared with women without hysterectomy, oophorectomized women, especially those 20 or more years post-menopause, had increased lipids, lipoproteins, glucose, and insulin; blood pressures were increased among current estrogen users. Women with hysterectomies with ovarian conservation had similar or more favorable risk factors than nonhysterectomized women.

**Conclusions.** Bilateral oophorectomy, but not hysterectomy, may have long-term negative consequences for heart disease risk factors not totally ameliorated by estrogen use. (*Am J Public Health.* 1997;87:676-680)

## Hysterectomy, Oophorectomy, and Heart Disease Risk Factors in Older Women

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### Introduction

Hysterectomy is the second most common surgical procedure in the United States<sup>1</sup>; approximately one third of all women have a hysterectomy by age 60.<sup>2,3</sup> In women who have completed their families, bilateral oophorectomy is often recommended to prevent ovarian cancer.<sup>4</sup>

Increased risk of heart disease and atherosclerosis after bilateral oophorectomy has been reported in several studies.<sup>5-8</sup> Hysterectomy with conservation of at least one ovary is less consistently associated with heart disease, with recent studies reporting no differences<sup>5,7,9</sup> and older studies reporting increased risk.<sup>10,11</sup> Studies comparing women before and after bilateral oophorectomy reported increases in low density lipoprotein (LDL).<sup>12,13</sup> Some studies reported no differences in high density lipoprotein (HDL) following bilateral oophorectomy<sup>12,14,15</sup>; others reported increases<sup>16</sup> or decreases.<sup>13</sup> Some<sup>12,13</sup> but not all<sup>16,17</sup> studies reported no differences in total cholesterol or triglycerides.

Most previous studies examined small samples close to the time of surgery, did not include hysterectomized women with ovarian conservation, and did not

examine multiple heart disease risk factors. Only one large study<sup>9</sup> of hysterectomized women with and without bilateral oophorectomy examined lipids, glucose, and blood pressures; insulin was not examined.

We examined the association of hysterectomy and oophorectomy to lipids and lipoproteins, blood pressure, glucose, and insulin at a time relatively remote from surgery, in a large, community-based sample of older women.

### Methods

#### Study Population

From 1972 through 1974, 82% of all adult residents in a middle-class southern California community (Rancho Bernardo) were surveyed for heart disease risk factors. Of these women, 1254 (82%) were seen from 1984 through 1987, when

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