Simultaneous vs Sequential Counseling for Multiple Behavior Change

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Background: Many patients in primary care settings present with multiple behavioral risk factors for cardiovascular disease. Research has provided little information on the most effective ways to approach multiple behavior change counseling in clinical settings.

Methods: We implemented a randomized trial in a publicly funded primary care setting to test whether a sequential presentation of stage of change–based counseling to stop smoking, reduce dietary sodium level to less than 100 mEq/L per day, and increase physical activity by at least 10,000 pedometer steps per week would be more effective than simultaneous counseling. African Americans with hypertension, aged 45 to 64 years, initially nonadherent to the 3 behavioral goals, were randomized to the following conditions: (1) 1 in-clinic counseling session on all 3 behaviors every 6 months, supplemented by motivational interviewing by telephone for 18 months; (2) a similar protocol that addressed a new behavior every 6 months; or (3) 1-time referral to existing group classes (“usual care”). The primary end point was the proportion in each arm that met at least 2 behavioral criteria after 18 months.

Results: A total of 289 individuals (67.3% female) were randomized, and 230 (79.6%) completed the study. At 18 months, only 6.5% in the simultaneous arm, 5.2% in the sequential arm, and 6.5% in the usual-care arm met the primary end point. Results for single behavioral goals consistently favored the simultaneous group. At 6 months, 29.6% in the simultaneous, 16.5% in the sequential, and 13.4% in the usual-care arms had reached the urine sodium goal (P = .01). At 18 months, 20.3% in the simultaneous, 16.9% in the sequential, and 10.1% in the usual-care arms were urine cotinine negative (P = .08).

Conclusions: Long-term multiple behavior change is difficult in primary care. This study provides strong evidence that addressing multiple behaviors sequentially is not superior to, and may be inferior to, a simultaneous approach.

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Much of the US adult population combines multiple risk factors for cardiovascular morbidity and mortality.1 The need to identify effective ways to promote multiple health risk behavior change in primary care settings has been identified as an urgent public health priority.2,3 Research3,4 on risk factor modification (theoretical and applied) has given surprisingly little attention to the process of changing multiple adverse health behaviors. A question that arises immediately is whether it is more effective to intervene in 1 behavior at a time or in all adverse health behaviors simultaneously. Rosal et al5 reported that physicians prefer to approach multiple risk behaviors serially rather than simultaneously, and, thus, it is important to establish whether this is the most effective strategy.

The few studies6-10 that have addressed multiple vs single health risk behavior change experimentally have not provided a clear answer. In intervention studies that were explicitly designed to test a hypothesis regarding the sequencing of multiple behavior change interventions, 1 favored a sequential presentation11 and 2 reported similar results for the sequential and simultaneous approaches.12,13 Only the study performed by Septoe et al8 involved more than 2 target behaviors, and most studies used self-reported behavioral end points only.

In view of the limited information on the results of simultaneous vs sequential delivery of multiple health behavior change interventions in a primary care setting, we designed and implemented a randomized clinical trial to assess the following: (1) whether culturally tailored, theory-based, behavioral interventions for smoking cessation, dietary sodium reduction, and increased physical activity delivered via telephone by a health educator in a primary care setting are effective in improving adherence to lifestyle advice for control of cardiovascular risk factors; and (2) whether a sequential introduction of each behavior is more effective than a simultaneous delivery of the behavior change interventions. These behaviors...
were chosen because they are included in the clinical practice guidelines for treatment of the principal cardiovascular risk factors,14-16 their measurement does not depend exclusively on self-report, and there was evidence that the behaviors were amenable to modification by appropriately designed, home-based, telephone counseling–enhanced, behavioral interventions.17-25

### METHODS

#### SETTING AND STUDY POPULATION

The study was carried out in a public health care system of a large urban county in the southwestern United States. The study population consisted of African American patients, aged 45 to 64 years, who were observed in 2 primary care clinics in the system, had hypertension, and were current smokers. Because less than 25% of the patients in the 2 clinics are of non–African American ethnicity, and of those who are not African American, most were monolingual Spanish speakers, the trial was prospectively planned to recruit only African Americans.

#### RECRUITMENT AND SCREENING

Research assistants identified patients presenting for a clinic visit who met the 3 principal eligibility criteria: aged 45 to 65 years, current smoker, and a history of hypertension. After obtaining consent, the research assistant scheduled the patient for additional eligibility assessment, usually on the same day. Patients were retained and randomized if their screening results confirmed the following inclusion criteria:

1. A 24-hour urine sodium level of greater than 100 mEq/L per day.
2. A 24-hour urine sample that was cotinine positive (>40 ng/ml [>227 nmol/L] by gas chromatography) or a report of smoking at least 5 cigarettes per day.
3. An answer of “no” to the question: “Do you regularly exercise at least 3 times a week, for at least 30 minutes each time, hard enough to work up a sweat?”

Other exclusionary criteria included a systolic blood pressure higher than 180 mm Hg or a diastolic blood pressure higher than 110 mm Hg, insulin-requiring diabetes mellitus, a history of myocardial infarction, and a physical activity limitation that ruled out regular walking at a moderate pace. Persons with diabetes mellitus and those with a positive Rose angina screen result were excluded if an exercise tolerance test result was positive.

#### INTERVENTIONS

Eligible participants were randomized to 1 of 3 experimental conditions: (1) Simultaneous behavioral interventions, in which participants received information and counseling regarding all 3 target behaviors at the same time for 18 months. (2) Sequential behavioral interventions, in which the target behaviors were introduced 1 at a time at 6-month intervals. The order in which the behaviors were introduced to each participant was randomized to avoid confounding of outcomes with patient preferences. (3) Usual care, in which a brief review of educational materials was provided regarding the 3 target behaviors, with no telephone follow-up.

**Theoretical Framework for the Interventions**

The interventions were based on the stages of change or trans-theoretical model, which posits that behavior change is a dynamic process that may involve periods of relapse and recycling through 5 phases: precontemplation, contemplation, preparation, action, and maintenance. This model has served as a theoretical framework for the design of interventions to change a wide range of health behaviors, including physical activity, smoking cessation, diet, and multiple chronic disease risk factors.17-19,26-30

**Format and Content of the Interventions**

The interventions consisted of a brief in-clinic session with a health educator every 6 months to review the benefits of the recommended behavioral change(s); the home-based, self-help, instructional materials developed to facilitate behavior change; and the schedule of telephone counseling sessions planned over the following 6 months. In the simultaneous arm, all 3 behaviors were reviewed at each clinic session. In the sequential arm, only the behavior randomly assigned for that interval was discussed. The home-based instructional materials included a printed manual and a motivational videotape. The physical activity and dietary sodium materials were adapted from existing handbooks and videos that had been used in behavioral interventions for predominantly African American groups.31,32 The project team (D.J.H., V.N.P., W.C.T., and G.K.G.) wrote a manual and produced an accompanying videotape to support the smoking cessation intervention. All materials were reviewed by volunteers recruited from the target population, and their feedback indicated that the materials were easy to use, informative, and helpful as a tool to aid in behavior change.

Each clinic counseling visit was followed by 7 telephone counseling sessions scheduled 2, 4, 6, 8, 12, 16, and 20 weeks later. The health educators used the motivational interviewing approach in their counseling. Motivational interviewing, based on motivational enhancement therapy, attempts to help clients resolve ambivalence about lifestyle change. The tone of motivational interviewing is nonjudgmental, empathetic, and encouraging. Clients are guided to articulate an argument in favor of positive change and to describe a concrete course of action to achieve the goal.33

The counseling sessions began with a staging of the individuals’ readiness to make the behavior change, followed by the elicitation of importance and confidence ratings that are used as a frame of reference for the motivational interviewing session. Participants were referred to the educational manuals as needed for technical information and specific behavioral suggestions. The calls were limited to 15 minutes in the sequential and simultaneous groups to reduce the possibility of bias from different exposure times. The counselors addressed all 3 behaviors in the simultaneous group during each call, although the time devoted to each behavior could vary. Feedback from counselors early in the intervention indicated that the 15-minute time limit was not a barrier to delivering multiple behavior change counseling, and that in any event, a longer counseling session would be unacceptable to participants. Nicotine replacement therapy (either patches or gum), buproprion hydrochloride, or both were provided to patients who requested it. The usual-care group received only reminder calls to attend the 6-month measurement session. A computerized system allowed counselors to document participants’ stage of change and topics covered in the session. If an attempted counseling call could not be completed within a defined time window, it was counted as missed. A postcard was mailed to participants after each 6-month measurement to let them know how their behavioral measures compared with the established behavioral goals.

#### PRIMARY AND SECONDARY END POINTS

The prospectively defined primary study end point was the proportion of patients in each group who were adherent to 2

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or more target behaviors at 18 months based on objective measurements (urine negative for cotinine, 24-hour urine sodium level <100 mEq/L per day, and an increase of 10,000 pedometer steps per week above the participants’ baseline level in the week prior to each 6-month clinic visit). There is no absolute goal for pedometer-measured steps per day, and this exercise increase of approximately 1500 steps per day was consistent with the recommendation that physical activity goals should not be so high as to be unachievable by sedentary individuals.34 Prospectively declared secondary end points were the following: (1) proportion of participants adherent to the individual behaviors 6 months after the introduction of the behavior, (2) proportion adherent to each behavior at the final visit, and (3) changes in self-reported stage of change for each behavior.

MEASURES

Study measurements were obtained at baseline and at 6, 12, and 18 months. Urine collection kits were mailed to participants before each examination. Cotinine measurements were obtained from the 24-hour urine collection. Subjects were trained on the use of pedometers and were asked to wear them continuously during waking hours for 1 week at baseline and before each of the 6-month clinic follow-up visits.35 Plasma glucose, glycosylated hemoglobin, and plasma lipid levels were measured from a fasting blood specimen. Three blood pressure measurements, 2 minutes apart, were obtained with an automated device, and the average of the last 2 was recorded as the participants’ seated blood pressure. Behavioral self-reports of stage and self-efficacy for each behavior change were also collected.36-46

STATISTICAL ANALYSES

Based on published reports of results for individual behavior change interventions, we hypothesized that if the sequential approach was superior to the simultaneous approach, 40.0% of participants in the sequential group would be adherent to more than 1 behavior at 18 months, compared with 20.0% in the simultaneous group and 5.0% in the usual-care group.

An evaluation of the primary outcome required 3 comparisons: (1) the effect of the simultaneous intervention vs the effect of usual care on multiple behaviors, (2) the effect of the sequential intervention vs the effect of usual care on multiple behaviors, and (3) the effect of the simultaneous intervention vs the effect of the sequential intervention on multiple behaviors. To maintain the familywise type I error rate at .05, P values of .02 for statistical significance were assigned to the first 2 comparisons and a P value of .01 was assigned to the third comparison. Using the binomial test for proportions as the underlying distribution, 97 patients per group were required to provide 82% power for comparison 1, 99% power for comparison 2, and 70% power for comparison 3.

The primary end point was evaluated by considering participants who did not provide an 18-month measurement as nonadherent in all behaviors and by limiting the denominator to those who completed the final study visit. The χ² test of proportions was used to compare outcomes in each group. Logistic regression analysis was used to confirm that adjustment for relevant baseline covariates did not alter the conclusions.

The results of the screening and randomization process are reflected in Figure 1. A total of 582 persons were screened, and 289 were determined to be eligible and were randomized. Four asked to be withdrawn from the study during follow-up, and their data were not included in the analysis. Of the remaining 285 individuals, 4 died during follow-up (1 of lung cancer diagnosed after study entry, 1 of heart failure, and 2 of unknown causes). Thus, our analysis was limited to 281 persons.
who were eligible for final end point ascertainment. The overall retention rate, defined as those alive at their scheduled final study visit who completed the visit, was 81.9% (n=230). The first patient was randomized in October 2002, the final patient was randomized in January 2004, and the final participant follow-up occurred in January 2006. The average number of completed calls per participant ranged from 4.3 between the baseline visit and visit 2 to 3.9 between visit 3 and visit 4. Despite persistent reminders, and mailed replacements, participants were less compliant with bringing in pedometers than the 24-hour urine specimens. Overall, 90% of scheduled pedometer readings were provided compared with 100% of 24-hour urine sodium and cotinine measurements.

The Table reflects the characteristics of participants at baseline and at the 6- and 18-month follow-up points. Except for a small, albeit statistically significant, difference in diastolic blood pressure, the randomization process was successful in distributing characteristics evenly among the study arms; therefore, no adjustment for baseline covariate distributions was necessary.

### PRIMARY END POINT

Eighteen months after randomization, less than 10% of participants in each group met the primary end point (Figure 2). This finding was true whether the analysis was performed by intention to treat, whereby persons not providing follow-up measures were counted as failures, or by considering only those participants who remained in follow-up for 18 months.

### SECONDARY END POINTS

Figure 3 presents the short-term impact of each approach to intervention at the 6-month postintroduction time point. Although the differences were small, the patterns of behavioral adoption reflected in Figure 3 favor the simultaneous intervention. The simultaneous approach, but not the sequential approach, resulted in a statistically significant short-term reduction in sodium intake. Simultaneous group participants were also more likely to meet the physical activity goal at 6 months, but this difference did not reach statistical significance. Par-

**Table. Data for Participants at Baseline and at the 6- and 18-Month Measurements**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Simultaneous Group (n = 92)</th>
<th>Sequential Group (n = 96)</th>
<th>Usual-Care Group (n = 93)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex‡</td>
<td>60 (65.2)</td>
<td>61 (63.5)</td>
<td>68 (73.1)</td>
<td>.33</td>
</tr>
<tr>
<td>Age, y</td>
<td>53.9 ± 5.7</td>
<td>53.4 ± 5.7</td>
<td>52.7 ± 6.5</td>
<td>.36</td>
</tr>
<tr>
<td>Those with type 2 diabetes mellitus‡</td>
<td>17 (18.5)</td>
<td>18 (18.8)</td>
<td>17 (18.3)</td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Systolic blood pressure, mm Hg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>137.4 ± 19.1</td>
<td>142.0 ± 18.0</td>
<td>137.2 ± 17.2</td>
<td>.11</td>
</tr>
<tr>
<td>6 mo</td>
<td>131.6 ± 17.8</td>
<td>134.4 ± 21.8</td>
<td>133.9 ± 19.1</td>
<td>.65</td>
</tr>
<tr>
<td>18 mo</td>
<td>130.9 ± 18.3</td>
<td>134.1 ± 20.1</td>
<td>134.3 ± 18.4</td>
<td>.48</td>
</tr>
<tr>
<td>Diastolic blood pressure, mm Hg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>83.7 ± 9.1</td>
<td>87.4 ± 9.5</td>
<td>84.8 ± 8.9</td>
<td>.02</td>
</tr>
<tr>
<td>6 mo</td>
<td>81.4 ± 8.7</td>
<td>83.3 ± 12.5</td>
<td>81.7 ± 9.4</td>
<td>.47</td>
</tr>
<tr>
<td>18 mo</td>
<td>82.1 ± 9.8</td>
<td>83.5 ± 11.2</td>
<td>81.7 ± 9.6</td>
<td>.53</td>
</tr>
<tr>
<td>Body mass index§</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>31.8 ± 7.5</td>
<td>31.9 ± 7.8</td>
<td>33.4 ± 8.2</td>
<td>.29</td>
</tr>
<tr>
<td>6 mo</td>
<td>31.7 ± 6.9</td>
<td>31.9 ± 8.0</td>
<td>33.3 ± 8.1</td>
<td>.39</td>
</tr>
<tr>
<td>18 mo</td>
<td>31.9 ± 7.5</td>
<td>32.2 ± 8.8</td>
<td>32.8 ± 8.0</td>
<td>.80</td>
</tr>
<tr>
<td>Total cholesterol, mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>194.9 ± 36.5</td>
<td>200.4 ± 34.5</td>
<td>192.8 ± 46.7</td>
<td>.41</td>
</tr>
<tr>
<td>6 mo</td>
<td>192.6 ± 43.8</td>
<td>193.1 ± 38.2</td>
<td>194.1 ± 41.9</td>
<td>.97</td>
</tr>
<tr>
<td>18 mo</td>
<td>195.5 ± 40.2</td>
<td>187.0 ± 37.5</td>
<td>188.8 ± 42.4</td>
<td>.39</td>
</tr>
<tr>
<td>Those with a positive urine cotinine screen result‡</td>
<td>89 (96.7)</td>
<td>95 (99.0)</td>
<td>92 (98.9)</td>
<td>.42</td>
</tr>
<tr>
<td>6 mo</td>
<td>65 (87.8)</td>
<td>70 (93.3)</td>
<td>73 (93.6)</td>
<td>.20</td>
</tr>
<tr>
<td>18 mo</td>
<td>59 (79.7)</td>
<td>64 (83.1)</td>
<td>71 (89.9)</td>
<td>.21</td>
</tr>
<tr>
<td>24-h urine sodium level, mEq/L</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>185.8 ± 77.9</td>
<td>200.7 ± 88.2</td>
<td>189.0 ± 71.0</td>
<td>.39</td>
</tr>
<tr>
<td>6 mo</td>
<td>169.2 ± 104.4</td>
<td>200.4 ± 94.8</td>
<td>189.3 ± 92.1</td>
<td>.14</td>
</tr>
<tr>
<td>18 mo</td>
<td>195.3 ± 110.0</td>
<td>208.6 ± 101.2</td>
<td>189.8 ± 90.5</td>
<td>.49</td>
</tr>
<tr>
<td>Pedometer steps per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3624.4 ± 2917.5</td>
<td>3306.0 ± 2785.3</td>
<td>3933.0 ± 3363.6</td>
<td>.41</td>
</tr>
<tr>
<td>6 mo</td>
<td>4149.4 ± 3446.0</td>
<td>3715.0 ± 4025.6</td>
<td>3852.0 ± 3673.6</td>
<td>.76</td>
</tr>
<tr>
<td>18 mo</td>
<td>3751.4 ± 2697.0</td>
<td>3744.9 ± 5515.7</td>
<td>3648.5 ± 4295.0</td>
<td>.99</td>
</tr>
</tbody>
</table>

Si conversion factor: To convert total cholesterol to millimoles per liter, multiply by 0.0259.

*Data are given as mean ± SD unless otherwise indicated.
†Based on 1-way analysis of variance or the y² test. The degrees of freedom vary for comparisons involving 6 and 18 months of each follow-up measure, based on the number of subjects for whom each measure was collected.
‡Data are given as number (percentage) of each group.
§Calculated as weight in kilograms divided by height in meters squared.
participants in the sequential group were most likely to have stopped smoking 6 months after that behavior was introduced, but the differences among the 3 groups were small.

The ability of participants to change and maintain each recommended behavior during the 18 months of follow-up is reflected in Figure 4. Smoking abstinence was highest in the simultaneous group and lowest in the usual-care group (20.3% and 10.1%, respectively; \( P = .08 \) for trend). A pedometer-measured increase in baseline levels of physical activity followed a similar pattern, favoring the simultaneous arm. The prevalence of dietary sodium intake of less than 100 mEq/L per day was highest in the usual-care group and lowest in the simultaneous arm. None of the between-group differences in behavioral adherence at 18 months reached the 20% level for which the study was powered.
To our knowledge, this is one of the few randomized trials designed specifically to test a hypothesis regarding the sequencing of interventions to promote long-term multiple behavior change in a clinical population with high cardiovascular disease risk, using objectively measured end points. The results do not support the initial hypothesis that behavioral changes in the sequential arm would be cumulative and, thus, eventually result in greater adoption of multiple cardiovascular disease risk reduction behaviors than efforts directed at all behaviors simultaneously. Rather, the pattern of results suggests that multiple behavior change is difficult for individuals to achieve and maintain, but that counseling patients to change multiple behaviors at the same time is more effective at achieving a change in at least 1 behavior than addressing the behaviors individually.

When comparing the results of our multiple behavior intervention trial with others in the literature, it is important to recognize the rigorous design features that distinguish our study from others: (1) all participants had the same combination of behavioral risk factors; (2) more than 2 behaviors were targeted; (3) objective, rather than self-reported, end point measures were used as the primary end point; (4) the study population consisted of primary care patients with identified risk factors, rather than a community sample of volunteers; and (5) the primary end point reflected a rather ambitious requirement that participants reach specific behavioral goals rather than demonstrate a change in a desired direction.

Our hypothesized effect size was based on results of successful single-behavior interventions reported in the literature when the study was designed and on the assumption that, in the sequential group, behavior change would be additive. Clearly, the ability to test a simultaneous vs sequential multiple behavior change hypothesis requires that each targeted behavior can be predictably modified. A meta-analysis of methodologically rigorous, stage of change–based, practical, low-intensity, behavioral interventions in primary care, published in 2004, revealed no intervention effects on actual physical activity levels, limited to no effect on smoking cessation rates, and a positive effect on dietary fat intake. The authors did not consider the reliability and validity of behavioral measurements, or the use of objective vs self-reported behavioral measures, as a factor in the meta-analysis.

The stages of change, or trantheoretical, model is 1 of several models that attempt to explain health behavior as a function of an individual’s personal beliefs, attitudes, motivations, and/or cognitive decision-making processes. Although these models have been widely applied in health behavior research, they may have inherent limitations as frameworks for effecting significant behavior change in a relatively brief time span. More recent conceptual models emphasize the need to address broader social, environmental, and policy factors to promote individual behavior change, and Nigg and colleagues have argued that, in view of the many theoretical models that have been proposed to explain health behavior, more research must be devoted to comparisons of results achieved using different theoretical approaches to the same set of behaviors.

Although we used objective measures of participants’ behavior rather than self-report, we must recognize the limitations in these measures. We observed larger interindividual and intraintividual variance in pedometer readings than expected based on published reports when we began the study. In 2 recent reviews of pedometer performance, the authors concluded that the accuracy of standard spring-loaded pedometers was reduced with slower ambulation speed and higher body mass index and waist circumference, both of which were common in our sample. Concerns about the reliability of a 24-hour urine sodium measurement to represent usual dietary intake have been noted by others, but the measurement still has significant advantages over self-report. Cotinine determinations, in either urine or saliva, have a high accuracy as a biological marker of smoking abstinence but are less reliable to document changes in number of cigarettes smoked.

The primary care population represented in our study was perhaps more challenging than others. It has been previously documented that almost two thirds of ever smokers with hypertension in this same population had already quit smoking. Thus, the prevalent smokers eligible for this study could have represented a subpopulation for whom behavioral change was particularly difficult. However, the willingness of participants to enroll and remain in the study should encourage continued efforts to support their behavior change intentions.

In summary, this trial provided evidence that a sequential counseling intervention in a clinical setting regarding multiple behavior changes is less effective than simultaneous counseling but that treatment success with the simultaneous approach is likely to be limited to a single behavior. Further research is needed to identify the specific target behaviors, demographic groups, and design features (eg, investigator-assigned vs participant-chosen order of interventions) in which simultaneous interventions are more effective than sequential interventions.

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REFERENCES