## Intervention to Influence Behaviors Linked to Risk of Chronic Diseases

# A Multisite Randomized Controlled Trial With African-American HIV-Serodiscordant Heterosexual Couples

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**Background:** The high morbidity and mortality in African Americans associated with behavior-linked chronic diseases are well documented.

Methods: We tested the efficacy of an intervention to increase multiple health-related behaviors in African Americans. In a multisite cluster-randomized controlled trial, groups of African American human immunodeficiency virus (HIV)-serodiscordant heterosexual couples in Atlanta (Georgia), Los Angeles (California), New York (New York), and Philadelphia (Pennsylvania) were allocated to an individual-focused health promotion that addressed multiple health-related behaviors or to a couple-focused HIV/sexually transmitted disease (STD) risk reduction intervention. Primary outcomes were adherence to fruit and vegetable consumption and physical activity guidelines assessed preintervention, immediately postintervention, and 6 and 12 months postintervention. Secondary outcomes included fatty food consumption, prostate and breast cancer screening, and alcohol use. Generalized estimating equations tested the efficacy of the health promotion intervention over the postintervention assessments.

**Results:** Health promotion intervention participants were more likely to report consuming 5 or more servings of fruits and vegetables daily (rate ratio [RR], 1.38; 95% confidence interval [CI], 1.18 to 1.62) and adhering to physical activity guidelines (1.39; 1.22 to 1.59) compared with HIV/STD intervention participants. In the health promotion intervention compared with the HIV/STD intervention, participants consumed fatty foods less frequently (mean difference, -0.18; 95% CI, -0.30 to -0.07), more men received prostate cancer screening (RR, 1.51; 95% CI, 1.21 to 1.88), and more women received a mammogram (RR, 1.26; 95% CI, 1.06 to 1.50). Alcohol use did not differ between the intervention groups.

**Conclusion:** This trial demonstrates the efficacy of interventions targeting multiple health-related behaviors in African American HIV-seropositive and HIV-seronegative men and women.

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HE ADVENT OF HIGHLY ACtive antiretroviral therapy (HAART) has brought about durable suppression of human immunodeficiency virus (HIV) replication, prevention of AIDS-defining opportunistic infections and malignant neoplasms, and longer life expectancy in people living with

### See also pages 719 and 737

HIV infection.<sup>1,2</sup> In the United States, 66.9% of people living with HIV in 2007 in the 37 states with confidential namebased HIV reporting were 40 years or older, and 28.5% were 50 years or older.<sup>3</sup> Paralleling the aging of people living with HIV is concern about their risk of developing comorbid chronic diseases, including cardiovascular diseases and diabetes mellitus.<sup>4</sup> Indeed, as HIV-infected patients live longer, they will experience increasing mortality from causes not directly attributable to HIV.<sup>5</sup> Moreover, the progression of HIV disease and its treatment with HAART can exacerbate the risk of cardiovascular diseases and diabetes mellitus.<sup>4,6,7</sup> In addition, there is increasing recognition of morbidity associated with obesity in patients with HIV.<sup>8</sup>

The issue of comorbid chronic disease is particularly worrisome for the 48% of people living with HIV in 2007 who were African American.<sup>3</sup> Quite apart from HIV, higher mortality for cancer, cardiovascular diseases, cerebrovascular diseases, and diabetes mellitus in African Americans compared with white individuals is well

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documented.<sup>9,10</sup> Despite a lower breast cancer incidence, African American women have higher breast cancer mortality and lower 5-year survival than do white women.<sup>10</sup> Although the prostate cancer incidence is 60% higher in African American men than in white men, the prostate cancer mortality is 2.4 times higher in African American men.<sup>10</sup>

Regular physical activity is associated with reduced risk of early mortality, cardiovascular diseases, diabetes mellitus, breast cancer, and colon cancer.<sup>11-14</sup> However, the prevalence of physical inactivity is greater in African American women than in white women.<sup>15</sup> Moreover, HIVpositive African American patients undergoing HAART may be especially prone to physical inactivity. A study<sup>16</sup> of African Americans revealed that HIV-positive participants receiving HAART reported less vigorous activity than did those not receiving treatment and less energy expenditure than HIV-positive participants not receiving treatment and HIV-negative participants. Consuming fruits and vegetables is associated with a reduced risk of cardiovascular diseases and certain cancers, but only 35.1% of African American individuals report consuming fruit the recommended 2 or more times per day, and only 23.7% report consuming vegetables the recommended 3 or more times per day.<sup>17</sup>

Screening is important to detect diseases in the early stages, but despite more primary care visits, HIV-infected patients 50 years or older are less likely to be screened for colon cancer than are age- and sexmatched HIV-negative control subjects.<sup>18</sup> Moreover, low rates of cancer screening in African Americans in general are well established. Only 49.9% of African American women 40 years or older report receiving a mammogram in the previous year.<sup>19</sup> Although African American men should discuss prostate cancer with their physician by age 45 years because of their high risk, they are less likely to report having a prostate-specific antigen blood test than are white men.<sup>20</sup>

Although interventions targeting behaviors tied to reduced risk of chronic diseases and early identification of malignant neoplasms in African Americans, particularly those living with HIV, are needed, little research has focused on such interventions for people living with HIV. Physical activity intervention trials with HIV-positive individuals have been limited by small samples, differential attrition, and a lack of attention control groups and follow-up assessments beyond an immediate posttest.<sup>21-23</sup> Accordingly, we drew on social cognitive theory<sup>24,25</sup> integrated with formative research to develop a health promotion intervention to influence behaviors linked to chronic diseases in individuals in African American HIV-serodiscordant heterosexual couples. In a randomized controlled trial designed primarily to test the efficacy of an HIV/sexually transmitted disease (STD) risk reduction intervention,<sup>26</sup> the health promotion intervention served as the attention-matched comparison intervention. Herein, we report the efficacy of the health promotion intervention. We hypothesized that it would increase physical activity, fruit and vegetable consumption, breast cancer screening in women, and prostate cancer screening in men compared with the HIV/STD risk reduction intervention.

The institutional review board at each site approved the trial, and an independent National Institutes of Health–appointed Data Safety and Monitoring Board monitored it. The participants were enrolled in Atlanta, Los Angeles, New York, and Philadelphia using a common recruitment protocol between November 1, 2003, and June 30, 2007, in a trial to test the efficacy of a couple-focused intervention to reduce the risk of STDs, including HIV.<sup>26</sup> Herein, we report the efficacy of the health promotion intervention, which served as the comparison condition in that trial because of the ethical imperative of offering an intervention of benefit to control group participants.

We recruited participants from HIV care clinics, AIDS service organizations, community-based organizations, targeted street outreach, word of mouth, and the media, including radio, magazine, and newspaper advertisements.<sup>26</sup> Heterosexual couples were eligible if they had been together 6 months or more; were aware of each other's HIV serostatus; only 1 partner was HIV seropositive; at least 1 self-identified as African American or black, reported unprotected intercourse with the other in the previous 90 days, and reported that the couple was not planning a pregnancy within 18 months; and each partner was 18 years or older, intended to remain together for at least 12 months, and did not plan to relocate beyond a reasonable distance from the study site. Couples were excluded if either partner did not have a mailing address; evidenced significant psychiatric, physical, or neurologic impairment that would limit effective participation; reported victimization by severe violence perpetrated by the other in the past year; was unwilling or unable to commit to completing the study; or was not fluent in English. Couples who participated in a couple-based HIV/STD risk reduction intervention in the past year were also excluded.

We randomized groups<sup>27</sup> of 3 to 5 couples to 1 of 2 interventions: individual-focused health promotion or couplefocused HIV/STD risk reduction. We used the sex of the HIVpositive partner as a blocking factor to ensure that the number of couples with HIV-positive women was balanced across interventions. The data coordinating center generated, maintained, and sent the randomized intervention assignments in sealed, confidential envelopes directly to the project director at each site, who executed the assignments.

#### **INTERVENTION METHODS**

Both interventions consisted of 8 weekly structured 2-hour sessions delivered by male and female cofacilitators who used manuals containing detailed implementation protocols. We incorporated brainstorming, games, videos, experiential exercises, discussions, and skill-building activities to increase selfefficacy, outcome expectancy, behavioral skills, and risk reduction knowledge.

We developed the health promotion intervention based on social cognitive theory<sup>24,25</sup> integrated with information gathered from focus groups with African American HIV-serodiscordant couples and focus groups and individual interviews with health care providers who served HIV-positive African Americans. It was designed<sup>28</sup> to influence behaviors linked to the risk of cardiovascular diseases, cerebrovascular diseases, diabetes mellitus, and certain cancers, including physical activity, fruit and vegetable consumption, fat consumption, breast cancer screening, prostate cancer screening, and alcohol use.

To build self-efficacy and skills, participants learned about and practiced strength-building, flexibility-increasing, and moderate- and vigorous-intensity cardiovascular physical activity. We encouraged participants to engage in exercise throughout the week, including at least 30 minutes of moderate-intensity physical activity on 5 days or at least 20 minutes of vigorousintensity physical activity on 4 days and strength-building activity on at least 2 days. They used exercise bands for strength training and pedometers to monitor their cardiovascular activity. Participants received these devices along with a videotape to encourage safe exercise at home and brainstormed concrete ways to surmount barriers to exercising, including lack of motivation, interest, time, and physical ability. Activities also addressed participants' positive outcome expectancies regarding exercising.

Activities addressed outcome expectancies regarding adhering to the 5-a-day diet, which meant consuming 5 to 9 servings of fruits and vegetables daily, and barriers to following the 5-a-day diet suggested by focus group members, including cost of fresh produce, taste, and availability. To build self-efficacy and skill, participants generated strategies for overcoming the barriers and prepared fruit smoothies as an example of how to incorporate a healthful snack into their daily diet. Sources of excess fat among African American participants, including mayonnaise, sauces and gravies on meats, and fats added in cooking and frying, were covered.<sup>29</sup> Participants learned about body mass index and discussed the association of obesity with increased risk of heart disease, stroke, hypertension, diabetes, and endometrial cancer. Facilitators emphasized balancing food intake and physical activity to maintain a healthful body weight.

Participants learned the importance of annual breast cancer screening with mammography for women 40 years or older and annual prostate cancer screening with digital rectal examination or a prostate-specific antigen test for African American men 45 years or older. Participants learned about the health risks of excessive alcohol use, particularly for persons infected with hepatitis C virus. Sessions 1 to 7 included takehome assignments, which participants and cofacilitators reviewed in the subsequent session.

The HIV/STD risk reduction intervention<sup>30</sup> focused on preventing HIV/STD transmission and acquisition. It provided a control for the Hawthorne effect, reducing the likelihood that the effects of the health promotion intervention can be attributed to nonspecific features, including group interaction and special attention. Structurally similar to the health promotion intervention, African American male and female cofacilitators also implemented it. Unlike the health promotion intervention, it focused on the participants as members of couples rather than as individuals.

#### ASSESSMENT

Participants independently reported their health behaviors at baseline immediately postintervention and 6 and 12 months postintervention via audio computer-assisted selfinterviewing. Facilitators were not involved in the data collection, and data collectors were blinded to participant intervention. We used the timeline followback method to enhance recall of behaviors.<sup>31</sup>

We used the 7-item food frequency questionnaire developed by the National Cancer Institute for 5-a-day studies to assess fruit and vegetable consumption.<sup>32</sup> Three items concerned fruit consumption and 4 concerned vegetable consumption.<sup>33</sup> The a priori primary outcome was a binary variable indicating whether the participant met the 5-a-day guideline of consuming 5 or more servings of fruits and vegetables daily in the previous 30 days. Other outcomes included number of daily servings of fruits, vegetables, and fruits and vegetables combined. Participants also reported their daily consumption of fatty or fried food in the previous 30 days. This index contained 2 items: 1 concerned fried food and 1 concerned cooking with fat. Physical activity was assessed with 3 items developed by the Centers for Disease Control and Prevention<sup>34</sup> concerning the number of days on which people participate in vigorousintensity aerobic physical activity for at least 20 minutes, moderate-intensity aerobic physical activity for at least 30 minutes, and strength-building activities in the previous 7 days. The a priori primary outcome was a binary variable indicating whether participants met the guideline of engaging in strengthbuilding activity on 2 or more days and engaging in either 20 minutes of vigorous-intensity activity on at least 4 days or 30 minutes of moderate-intensity activity on at least 5 days.<sup>35</sup> Other outcomes included the reported number of days of moderate cardiovascular, intensive cardiovascular, and strengthbuilding activity in the previous 7 days.

At baseline, 6- and 12-month follow-up, men reported whether they were screened for prostate cancer and women reported whether they received breast cancer screening with mammography in the previous 6 months. Immediately postintervention, participants reported whether they were screened in the previous 2 months. At baseline and 6- and 12-month follow-up, all the participants reported their frequency of alcohol consumption in the previous 30 days.

Participants completed measures of sociodemographic characteristics and hepatitis C virus serostatus. The HIV-positive participants reported their CD4 count, viral load, and length of time diagnosed as having HIV. We used the CAGE (Cutting down, Annoyance by criticism, Guilty feeling, and Eyeopeners) questionnaire<sup>36</sup> to assess problem alcohol consumption, denoted by a score of 2 or greater ( $\alpha$ =.73). We used the Texas Christian University Drug Screen<sup>37</sup> to identify a history of heavy drug use and dependence, denoted by a score of 3 or greater ( $\alpha$ =.89).

#### STATISTICAL ANALYSIS

Sample size and power for this trial are described elsewhere.<sup>26</sup> We used Kruskal-Wallis and  $\chi^2$  tests to analyze attendance at the intervention and data collection sessions. To test the efficacy of the health promotion intervention, we implemented generalized estimating equations using the intervention, time (3 categories representing immediate, 6-month, and 12-month postintervention assessment), and time × intervention interaction terms for each outcome, properly controlling for the correlations among repeated measures over time using an exchangeable working correlation matrix. The fitted generalized estimating equation models also accounted for clustering at the couple level. We specified a logit link for binary outcomes and an identity link for continuous outcomes. We report model summaries unadjusted and adjusted for baseline results, estimated rate ratios for binary outcomes, and estimated mean differences for continuous outcomes over the postintervention period as a whole; corresponding 95% confidence intervals; and false discovery rate-adjusted38 significance probabilities. To assess whether sex or HIV serostatus modified intervention effects, we also fit generalized estimating equation models with sex×intervention or HIV serostatus×intervention interaction terms, respectively. Analyses used standard intention-totreat methods in which all available data on all randomized participants were included. All the analyses were completed using a commercially available software program (SAS version 9.22; SAS Institute Inc, Cary, North Carolina).39

#### RESULTS

As shown in the **Figure**, 550 individuals were assigned to the health promotion intervention and 520 to the HIV/

STD intervention. **Table 1** summarizes their baseline characteristics. The mean (SD) participant age was 43.41 (8.08) years. The HIV-positive partner was female in 60.4% of the couples. Attendance at the 8 sessions of both interventions was excellent. Health promotion intervention participants attended a mean (SD) of 6.87 (2.37) sessions (85.9%); HIV/STD risk reduction participants attended 7.35 (1.82) sessions (91.9%) (P < .001). The retention rate at the immediate and 6- and 12-month post-intervention assessments was 90.2% (965 individuals), 86.0% (920 individuals), and 88.1% (943 individuals), respectively, and did not differ between interventions.

**Table 2** presents descriptive statistics for outcomes by intervention and time. **Table 3** presents intervention effects from fitted generalized estimating equation models, unadjusted and adjusted for baseline outcome. In the adjusted analyses, health promotion participants were more likely to meet the recommended 5-a-day servings of fruits and vegetables in the past month and consumed nearly a full serving more of fruits and vegetables daily in the past month compared with HIV/STD intervention participants. Participants in the health promotion intervention reported eating fewer fatty foods than did HIV/STD intervention participants.

Health promotion intervention participants compared with HIV/STD risk reduction participants were also more likely to meet physical activity guidelines in the past 7 days and reported more days on which they engaged in moderate cardiovascular physical activity, intensive cardiovascular physical activity, and strength-building physical activity.

Women randomized to the health promotion were more likely to have had a mammogram in the past 6 months than were women in the HIV/STD intervention, particularly in the analysis restricted to women 40 years or older. Men randomized to the health promotion were more likely to have been screened for prostate cancer in the past 6 months than were men randomized to the HIV/ STD risk reduction, an effect also evident in the subsample 45 years or older. There was no significant intervention effect on alcohol consumption.

In the unadjusted-for-baseline analyses, similar effects were observed with 2 exceptions: the intervention effects on number of servings of vegetables and on mammograms in women irrespective of age were nonsignificant. In the unadjusted model, a significant HIV serostatus × intervention interaction (P=.02) revealed that in men 45 years or older, the health promotion intervention compared with the HIV/STD risk reduction intervention caused a greater increase in prostate cancer screening in HIV-negative men than in HIV-positive men. This interaction was nonsignificant in the adjusted analysis, and no other HIV serostatus × intervention or sex × intervention interactions were significant.

#### COMMENT

The present results demonstrated that a health promotion intervention had significant effects on multiple health behaviors in African American HIV-positive and HIVnegative individuals. Participants in the health promo-



Figure. Eban participant and couple CONSORT diagram. \*Attendance was defined as a full, partial, or make-up session completed by both partners of each couple. †Lost to follow-up: 18 in the risk reduction group (7 deaths, 6 incarcerations, 2 no longer interested, and 3 for other reasons), 17 in the health promotion group (5 deaths, 5 incarcerations, 2 no longer interested, and 5 for other reasons), and the remaining for reasons unknown. IPT indicates immediate postintervention assessment.

tion intervention were more likely to report consuming 5 or more servings of fruits and vegetables daily and adhering to physical activity guidelines compared with HIV/ STD intervention participants. In addition, in the health promotion intervention compared with the HIV/STD intervention, participants reported consuming fatty foods less frequently, more men received prostate cancer screening, and more women received a breast cancer screening mammogram. Moreover, the efficacy of the health promotion intervention did not differ statistically significantly depending on participant sex or HIV serostatus.

The efficacy of the intervention may have been brought about by several factors. We drew on social cognitive theory and integrated it with information from formative research with the population. Thus, the intervention included activities designed to address the specific outcome expectancies and efficacy beliefs of the population, which helped to make the intervention contextually appropriate. The approach of strengthening favorable outcome expectancies, reducing unfavorable outcome expectancies, and buttressing skills and self-efficacy to engage in the specific behaviors may account for the effects of the intervention. It is also possible that targeting couples enhanced efficacy. Research suggests that health promotion strategies that incorporate family members and support networks are more effective than individualfocused strategies<sup>40-42</sup> and may be especially appropriate for African Americans.<sup>41</sup> Although the behavioral goals in the health promotion intervention were geared toward the individual and not the couple, mere participation as a couple may have encouraged the individuals to

#### Table 1. Baseline Sociodemographic Characteristics of Participants by Intervention Condition

|   | Intervention                           |                               |                       |  |  |  |
|---|--|-------------------------------|-----------------------|--|--|--|
| Characteristic  | HIV/STD Risk<br>Reduction<br>(n = 520) | Health Promotion<br>(n = 550) | Overali<br>(N = 1070) |  |  |  |
| Age, mean (SE), y   | 43.25 (8.17)                           | 43.49 (8.16)                  | 43.41 (8.08)          |  |  |  |
| Education, No. (%)  |  |                               |                       |  |  |  |
| <high graduate<="" school="" td=""><td>162 (31.52)</td><td>164 (29.87)</td><td><b>326</b> (30.67)</td></high> | 162 (31.52)                            | 164 (29.87)                   | <b>326</b> (30.67)    |  |  |  |
| High school graduate/GED  | 209 (40.66)                            | 228 (41.53)                   | <b>437</b> (41.11)    |  |  |  |
| Some college  | 143 (27.82)                            | 157 (28.60)                   | 300 (28.22)           |  |  |  |
| Employed, No. (%)   | 144 (28.07)                            | 158 (28.83)                   | <b>302</b> (28.46)    |  |  |  |
| Monthly income, No. (%)   |  |                               |                       |  |  |  |
| <\$400  | 156 (30.41)                            | 151 (27.61)                   | <b>307</b> (28.96)    |  |  |  |
| \$400-\$850   | 202 (39.38)                            | 244 (44.61)                   | <b>446</b> (42.08)    |  |  |  |
| \$851-\$1650  | 106 (20.66)                            | 99 (18.10)                    | <b>205</b> (19.34)    |  |  |  |
| >\$1650   | 49 (9.55)                              | 53 (9.69)                     | <b>102</b> (9.62)     |  |  |  |
| Insured, No. (%)  | 377 (73.35)                            | 423 (77.33)                   | 800 (75.40)           |  |  |  |
| Married, No. (%)  | 203 (39.50)                            | 215 (39.20)                   | <b>418</b> (39.40)    |  |  |  |
| Married to study partner, No. (%)   | 168 (32.68)                            | 177 (32.30)                   | <b>345</b> (32.49)    |  |  |  |
| Relationship duration, mean (SE), y   | 6.72 (7.31)                            | 7.45 (7.40)                   | 6.91 (6.56)           |  |  |  |
| Live with study partner, No. (%)  | 368 (71.88)                            | 438 (79.78)                   | 806 (75.97)           |  |  |  |
| Alcohol dependent (CAGE questionnaire), No. (%)   | 80 (15.59)                             | 91 (16.58)                    | <b>171</b> (16.10)    |  |  |  |
| Drug dependent (TCUDS), No. (%)   | 82 (15.98)                             | 100 (18.35)                   | <b>182</b> (17.20)    |  |  |  |
| HCV positive, No. (%)   | 106 (20.62)                            | 125 (22.77)                   | <b>231</b> (21.73)    |  |  |  |
| HIV-positive participants only  | . ,                                    |                               | . ,                   |  |  |  |
| Female, No. (%)   | 158 (60.77)                            | 165 (60.00)                   | <b>323</b> (60.37)    |  |  |  |
| HIV positive, mean (SE), y  | 9.62 (6.66)                            | 9.83 (7.84)                   | 9.73 (7.29)           |  |  |  |
| CD4 count, mean (SE)  | 543.78 (325.42)                        | 510.74 (344.14)               | 526.75 (335.14)       |  |  |  |
| Do not know, No. (%)  | 76 (29.23)                             | 87 (31.64)                    | <b>163</b> (31.47)    |  |  |  |
| Viral load, No. (%)   |  | . ,                           | . ,                   |  |  |  |
| 0-50 copies/mL  | 61 (25.00)                             | 70 (25.93)                    | <b>131</b> (25.49)    |  |  |  |
| >50 copies/mL   | 76 (31.15)                             | 73 (27.04)                    | 149 (28.99)           |  |  |  |
| Do not know   | 107 (43.85)                            | 127 (47.04)                   | <b>234</b> (45.53)    |  |  |  |

Abbreviations: CAGE, Cutting down, Annoyance by criticism, Guilty feeling, and Eye-openers; GED, general equivalency diploma; HCV, hepatitis C virus; HIV, human immunodeficiency virus; STD, sexually transmitted disease; TCUDS, Texas Christian University Drug Screen.

<sup>a</sup>Due to missing data, the values may not total the total sample size.

support each other even without prompting by the facilitators and may have contributed to the intervention's efficacy.

To our knowledge, this is the first trial to evaluate a health promotion intervention with African American serodiscordant couples. The findings are in accord with those of other studies<sup>33,43-45</sup> of interventions designed to increase fruit and vegetable consumption and physical activity in African Americans who were not selected based on their HIV serostatus. We observed somewhat stronger effects for physical activity than for fruit and vegetable consumption and somewhat larger effects for fruits than for vegetables, which is consistent with the results of a previous trial.<sup>33</sup> The present study addressed more health behaviors than most intervention studies; accordingly, these results underscore the utility of an intervention that targets multiple health behaviors. Compared with single-behavior interventions, adoption of 1 effective multiple-behavior intervention could reduce the burdens on participants and the costs of implementation while achieving the desired behavior changes.

Unlike the positive effects on fruit and vegetable consumption, fat consumption, physical activity, and breast and prostate cancer screening, the health promotion intervention did not reduce alcohol use compared with the HIV/STD intervention, although alcohol use irrespective of intervention condition declined compared with baseline. One possible explanation for the lack of an effect of the health promotion intervention on alcohol use is that the HIV/STD intervention also covered the subject, cautioning that alcohol use could be a trigger for unsafe sexual behavior. The emphasis of the health promotion intervention on the adverse health consequences of excessive alcohol consumption did not cause a greater decrease in alcohol consumption than did the message of the HIV/STD intervention. In this view, then, this trial did not provide a fair test of the efficacy of the health promotion intervention (or the HIV/STD risk reduction intervention) in reducing alcohol use.

This study had several limitations. The outcomes that could be assessed were limited by the fact that the study was funded to test the efficacy of an HIV/STD risk reduction intervention, with the health promotion intervention as the comparison condition. To avoid excessive burden on the participants, priority was given to evaluating the efficacy of the HIV/STD risk reduction intervention, which limited the outcomes relevant to the health promotion intervention. The outcomes were measured using selfreports, which can be influenced by socially desirable responding. However, the use of audio computer-assisted selfinterviewing may have mitigated potential problems with self-report validity. In addition, studies have found that the

|  | Baseline    |             |             | IPT         |             | 6 mo        |             | 12 mo       |  |
|--|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--|
| Health Behavior  | RR          | HP          | RR          | HP          | RR          | HP          | RR          | HP          |  |
| 5-a-day fruits and vegetables in the past month, No. (%)   | 110 (21.15) | 116 (21.09) | 103 (19.81) | 180 (32.73) | 91 (17.50)  | 137 (24.91) | 93 (17.88)  | 111 (20.18) |  |
| Servings of fruit per day in the past month, mean (SE)   | 2.00 (0.11) | 1.90 (0.11) | 2.07 (0.12) | 2.95 (0.14) | 1.76 (0.10) | 2.40 (0.12) | 1.94 (0.11) | 2.13 (0.13) |  |
| Servings of vegetables per day<br>in the past month, mean<br>(SE)  | 1.75 (0.10) | 1.58 (0.07) | 1.85 (0.12) | 2.31 (0.11) | 1.67 (0.09) | 1.89 (0.09) | 1.79 (0.11) | 1.87 (0.10) |  |
| Servings of fruits and<br>vegetables combined per day<br>in the past month, mean<br>(SE)                           | 3.75 (0.18) | 3.47 (0.15) | 3.92 (0.20) | 5.27 (0.22) | 3.43 (0.16) | 4.29 (0.18) | 3.73 (0.20) | 4.00 (0.21) |  |
| Servings of fatty or fried foods<br>in the past month, mean<br>(SE)  | 1.17 (0.06) | 1.14 (0.05) | 1.19 (0.07) | 0.81 (0.05) | 0.99 (0.06) | 0.88 (0.05) | 0.98 (0.07) | 0.92 (0.06) |  |
| Met physical activity guidelines<br>in the past 7 d, No. (%)   | 99 (19.26)  | 103 (18.76) | 121 (25.53) | 223 (45.88) | 107 (23.78) | 151 (32.40) | 114 (25.00) | 155 (31.96) |  |
| Days of moderate<br>cardiovascular physical<br>activity in the past 7 d, mean<br>(SE)                              | 2.34 (0.10) | 2.42 (0.10) | 2.51 (0.10) | 3.37 (0.10) | 2.34 (0.10) | 2.70 (0.11) | 2.29 (0.10) | 2.64 (0.10) |  |
| Days of intense cardiovascular<br>physical activity in the past<br>7 d, mean (SE)                                  | 1.56 (0.09) | 1.61 (0.08) | 1.89 (0.09) | 3.12 (0.10) | 1.72 (0.09) | 2.24 (0.10) | 1.80 (0.09) | 2.13 (0.09) |  |
| Days of strength-building<br>physical activity in the past<br>7 d, mean (SE)                                       | 1.06 (0.07) | 1.05 (0.08) | 1.30 (0.09) | 2.15 (0.10) | 1.23 (0.08) | 1.54 (0.09) | 1.46 (0.09) | 1.52 (0.09) |  |
| Frequency of alcohol<br>consumption in the past<br>month, mean (SE)  | 3.81 (0.29) | 4.35 (0.31) | NA          | NA          | 3.68 (0.30) | 3.66 (0.30) | 3.59 (0.30) | 4.03 (0.30) |  |
| Frequency of alcohol<br>consumption in the past<br>month among patients who<br>are HCV positive only, mean<br>(SF) | 3.56 (0.57) | 4.14 (0.64) | NA          | NA          | 2.84 (0.55) | 3.42 (0.61) | 3.00 (0.66) | 3.46 (0.52) |  |
| Screened for breast cancer with<br>mammogram in the past 6   | 93 (36.05)  | 89 (32.48)  | 46 (19.33)  | 72 (29.39)  | 76 (33.63)  | 103 (43.28) | 86 (37.89)  | 97 (39.59)  |  |
| Screened for breast cancer with<br>mammogram in the past 6<br>mo: women aged $\geq$ 40 y<br>only. No. (%)          | 83 (46.89)  | 72 (39.13)  | 37 (22.42)  | 61 (36.75)  | 63 (38.65)  | 85 (50.60)  | 75 (44.64)  | 82 (47.13)  |  |
| Screened for breast cancer with<br>mammography in the past<br>12 mo. No. (%)                                       | NA          | NA          | NA          | NA          | NA          | NA          | 113 (51.60) | 145 (60.67) |  |
| Screened for breast cancer with<br>mammography in the past<br>12 mo: women aged $\geq$ 40 y<br>only. No. (%)       | NA          | NA          | NA          | NA          | NA          | NA          | 92 (57.86)  | 115 (68.86) |  |
| Screened for prostate cancer in<br>the past 6 mo, No. (%)  | 53 (20.70)  | 65 (23.64)  | 44 (18.57)  | 64 (26.56)  | 54 (24.11)  | 95 (41.85)  | 52 (22.81)  | 88 (36.51)  |  |
| Screened for prostate cancer in<br>the past 6 mo: men aged<br>>45 y only. No. (%)                                  | 39 (27.66)  | 49 (32.89)  | 32 (24.81)  | 45 (35.16)  | 44 (33.08)  | 71 (53.79)  | 41 (30.15)  | 61 (42.07)  |  |
| Screened for prostate cancer in<br>the past 12 mo. No. (%)   | NA          | NA          | NA          | NA          | NA          | NA          | 78 (35.94)  | 127 (55.46) |  |
| Screened for prostate cancer in<br>the past 12 mo: men aged<br>$\geq$ 45 y only, No. (%)                           | NA          | NA          | NA          | NA          | NA          | NA          | 57 (43.18)  | 86 (64.66)  |  |

Abbreviations: HCV, hepatitis C virus; HP, health promotion intervention; IPT, immediate postintervention assessment; NA, not available; RR, HIV/STD risk reduction intervention.

7-item fruit and vegetable consumption index we used was significantly associated with serum carotenoid assessments<sup>46</sup> and with longer food frequency indices,<sup>33</sup> and an intervention trial<sup>43</sup> that used the 7-item measure and 2

other fruit and vegetable consumption indices found that all 3 indices led to identical conclusions. Nevertheless, the study might have been improved if it had included objective measures of fruit and vegetable consumption,

Table 3. GEE Empirical Significance Tests and Effect Size Estimates for the Intervention Effect Averaged Over the Immediate, 6-Month, and 12-Month Follow-up Assessments Unadjusted and Adjusted for Baseline Prevalence

|   | Baseline                                   |                         |  |                         |  |  |  |
|---|--|-------------------------|--|-------------------------|--|--|--|
|   | Unadjusted                                 |                         | Adjusted                                   |                         |  |  |  |
| Outcome   | Estimate (05% CI)                          | P<br>Value <sup>a</sup> | Fetimate (05% CI)                          | P<br>Value <sup>a</sup> |  |  |  |
|   |  | Value                   |  | Value                   |  |  |  |
| 5-a-day fruits and vegetables in the past month <sup>a,b</sup>  | 1.28 (1.09 to 1.49)                        | .005                    | 1.38 (1.18 to 1.62)                        | <.001                   |  |  |  |
| Servings of fruit per day in the past month <sup>b,c</sup>  | 0.24 (0.15 to 0.33)                        | <.001                   | 0.30 (0.21 to 0.39)                        | <.001                   |  |  |  |
| Servings of vegetables per day in the past month <sup>b,c</sup>   | 0.13 (-0.06 to 0.32)                       | .19                     | 0.28 (0.09 to 0.48)                        | .006                    |  |  |  |
| Servings of fruits and vegetables per day in the<br>past month <sup>b,c</sup>   | 0.52 (0.14 to 0.90)                        | .01                     | 0.87 (0.51 to 1.23)                        | <.001                   |  |  |  |
| Servings of fatty or fried food in the past month <sup>b,c</sup>  | -0.15 (-0.27 to -0.03)                     | .02                     | -0.18 (-0.30 to -0.07)                     | .003                    |  |  |  |
| Met physical activity guidelines in the past 7 d <sup>a,b</sup>   | 1.32 (1.14 to 1.53)                        | <.001                   | 1.39 (1.22 to 1.59)                        | <.001                   |  |  |  |
| Days of moderate cardiovascular physical<br>activity in the past 7 d <sup>b,c</sup>   | 0.40 (0.21 to 0.59)                        | <.001                   | 0.48 (0.29 to 0.68)                        | <.001                   |  |  |  |
| Days of intensive cardiovascular physical activity in the past 7 d <sup>b,c</sup>   | 0.53 (0.34 to 0.71)                        | <.001                   | 0.69 (0.51 to 0.87)                        | <.001                   |  |  |  |
| Days of strength-building physical activity in<br>past 7 d <sup>b,c</sup>   | 0.30 (0.13 to 0.47)                        | .001                    | 0.41 (0.25 to 0.58)                        | <.001                   |  |  |  |
| Mean frequency of alcohol consumption in the<br>past month <sup>b,c</sup>   | 0.34 (-0.43 to 1.12)                       | .41                     | -0.02 (-0.64 to 0.59)                      | .98                     |  |  |  |
| Mean frequency of alcohol consumption in the<br>past month in HCV-positive participants<br>only <sup>b,c</sup>  | 0.46 (-0.80 to 1.72)                       | .48                     | 0.01 (-1.32 to 1.35)                       | .98                     |  |  |  |
| Screened for breast cancer with mammography<br>in the past 6 mo <sup>b,d</sup>  | 1.16 (0.97 to 1.38)                        | .13                     | 1.26 (1.06 to 1.50)                        | .009                    |  |  |  |
| Screened for breast cancer with mammography<br>in the past 6 mo in women aged ≥40 y<br>only <sup>b,d</sup>  | 1.17 (0.98 to 1.39)                        | .12                     | 1.33 (1.11 to 1.60)                        | .003                    |  |  |  |
| Screened for prostate cancer in the past 6 mo <sup>b,d</sup><br>Screened for prostate cancer in the past 6 mo in<br>men aged $\ge$ 45 y only <sup>b,d</sup> | 1.46 (1.18 to 1.80)<br>1.42 (1.13 to 1.78) | .001<br>.005            | 1.51 (1.21 to 1.88)<br>1.38 (1.09 to 1.75) | <.001<br>.009           |  |  |  |

Abbreviations: CI, confidence interval; GEE, generalized estimating equation; HCV, hepatitis C virus.

<sup>a</sup>The P values are false discovery rate-adjusted significance probabilities.

<sup>b</sup>Estimate = rate ratio (health promotion intervention vs human immunodeficiency virus/sexually transmitted disease risk reduction intervention) for binary outcome variables.

<sup>c</sup>Estimate = mean difference (health promotion intervention – human immunodeficiency virus/sexually transmitted disease risk reduction intervention) for continuous outcome variables.

<sup>d</sup>A question at the immediate posttreatment assessment asked about behavior in the previous 2 mo.

physical activity, and physiologic variables (blood pressure, body mass index, and waist circumference). In addition, the participants may not be representative of all African Americans in serodiscordant couples.

The study also had important strengths. It used a randomized controlled design, a theory-based contextually appropriate intervention, and a dose- and modalityequivalent comparison intervention, controlling for group interaction and special attention. The retention rate was relatively high and did not differ by intervention arm. Sampling couples in 4 geographical areas of the United States increased generalizability.

In conclusion, African Americans are at high risk for morbidity and mortality from chronic diseases and are less likely to report engaging in behaviors associated with reduced risk of such diseases and to detect them at an early stage. Moreover, the risk of chronic disease is of particular concern for African Americans living with HIV because HIV and its treatment with HAART are associated with increased risk. The present study revealed low rates of fruit and vegetable consumption, physical activity, and cancer screening in African American individuals in HIVserodiscordant couples. Accordingly, this study is important, demonstrating that a theory-based contextually appropriate intervention that teaches skills caused positive changes on multiple behaviors linked to chronic diseases in African American members of HIV-serodiscordant couples. Future studies must explore the generalizability of the findings to objective outcome measures of physical activity and fruit and vegetable consumption. We are optimistic that the present study offers an approach that may help reduce the disproportionately high morbidity and mortality rates from chronic diseases in African Americans.

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