Body and Soul

A Dietary Intervention Conducted Through African-American Churches

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Objectives: Body and Soul was a collaborative effort among two research universities, a national

voluntary agency (American Cancer Society), and the National Institutes of Health to disseminate and evaluate under real-world conditions the impact of previously developed

dietary interventions for African Americans.

Methods: Body and Soul was constructed from two successful research-based interventions con-

ducted in African-American churches. Components deemed essential from the prior interventions were combined, and then tested in a cluster randomized-effectiveness trial. The primary outcome was fruit and vegetable intake measured with two types of food

frequency questionnaires at baseline and 6-month follow-up.

Results: At the 6-month follow-up, intervention participants showed significantly greater fruit and

vegetable (F&V) intake relative to controls. Post-test differences were 0.7 and 1.4 servings for the 2-item and 17-item F&V frequency measures, respectively. Statistically significant positive changes in fat intake, motivation to eat F&V, social support, and efficacy to eat F&V

were also observed.

Conclusions: The results suggest that research-based interventions, delivered collaboratively by commu-

nity volunteers and a health-related voluntary agency, can be effectively implemented

under real-world conditions.

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Introduction

ealth promotion interventions are often tested under "efficacy" conditions, whereby investigators exert considerable control over factors such as intervention delivery and subject selection to minimize implementation variability and maximize internal validity. To ensure that interventions are delivered with a high degree of completeness and fidelity, investigators may, when conducting efficacy trials, select highly skilled and experienced staff to deliver interventions and provide them with extensive training and supervision. In the parlance of clinical drug trials, this equates to ensuring that the "drug" is manufactured with high standards of quality control,

correctly prescribed by practitioners, and properly taken by participants.

Establishing efficacy is an important step in determining the potential public health value of an intervention. Efficacy, while necessary, is only one component of the impact on public health. It is also necessary that interventions have the potential for wide-scale dissemination and adoption, that is, that the results be generalizable to other settings and populations. Increasingly, public health researchers have called for more studies that examine the effects of interventions delivered under more real-world circumstances. 1-6 When interventions are brought to scale, fewer resources (both financial and human) may be available relative to what was used during initial efficacy testing. Under realworld conditions, interventions may be delivered by less experienced or even nonprofessional personnel, who may receive less training and supervision, and study participants may come from a broader spectrum of the population. 4-6 Additionally, intervention implementation may be allowed to "play out" more naturally, without the sometimes intense effort of research staff to maximize implementation.

This manuscript reports the results of an effectiveness study conducted by two research universities, a

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national health voluntary agency (the American Cancer Society [ACS]), and the National Institutes of Health. In the parent studies, interventions were implemented in African-American churches by trained professional staff, with somewhat tight control over intervention delivery. A key aim of this study was to test the impact of the intervention when delivered by volunteer members of African-American churches with less training, monitoring, and support, that is, under real-world conditions. An implicit (although not empirically established) assumption of effectiveness trials is that intervention effects may be weaker than those achieved under efficacy conditions. A secondary aim of the study, therefore, was to examine the degree of effect attenuation resulting from the "dilutions" of real-world implementation. This project is one of the first effectiveness trials of a dietary intervention, and also one of the first such studies to be conducted in African-American churches and with volunteer counselors.

Intervention Overview

The intervention tested, a.k.a. Body and Soul, was constructed from two independently developed interventions that were shown to be efficacious in separate randomized studies.^{7–10} Both interventions focused on modifying fruit and vegetable (F&V) intake among African Americans through African-American churches in the Southern United States, but they differed in their approach to behavior change.

The first intervention, Black Churches United for Better Health (BCUBH), was conducted by the University of North Carolina and used an ecologic model, combining environmental changes aimed at increasing availability of F&V at church functions, lay health advisors, church committees, community coalitions and events, educational sessions, pastor involvement, and individually tailored newsletters. The 20-month intervention was tested in a randomized study in 50 rural African-American churches. A total of 2519 adults completed the baseline and 2-year follow-up interviews. At the 2-year follow-up, the intervention group consumed 0.85 servings per day of F&V more than the delayed intervention group (p < 0.0001).

The second intervention, Eat for Life (EFL), was a multicomponent intervention conducted at Emory University, designed to increase F&V intake, and tested using a three-group design. In contrast to the BCUBH project, which had a strong environmental component, the EFL intervention targeted individual-level change. Fourteen churches were randomly assigned to one of three groups: (1) comparison, (2) self-help (SH) intervention, and (3) SH plus three telephone counseling calls. The telephone counseling in Group 3 was based on motivational interviewing (MI) and delivered by dietitians who received extensive training and ongoing clinical supervision. The primary

outcome in EFL, assessed at baseline and at 1-year follow-up, was F&V intake, measured by food frequency questionnaires. Change in F&V intake was significantly greater in the MI group than the comparison and SH groups. The net difference between the MI and comparison group was around 1.2 servings of F&V per day, and the net difference between the MI and SH group was around 1.0 servings per day. Additional details about the two "parent" interventions can be found elsewhere. 7–10

The Body and Soul project was a collaborative effort among the two research groups that designed the "parent" interventions (University of North Carolina and Emory University [The PI subsequently moved to the University of Michigan midway through the project.]), the national office of the ACS, and the National Cancer Institute (NCI). ACS was interested in sponsoring a cancer control program for an underserved population. Another goal for ACS was raising awareness of the Society among African Americans and increasing their involvement as volunteers. A key criterion in choosing the intervention components was that they had been rigorously tested and shown to be efficacious. The resulting composite program (i.e., named Body and Soul) also had to have the potential for large-scale diffusion or "roll-out."

ACS agreed to fund (both through direct expenditure and in-kind contribution) the costs associated with developing and implementing the intervention. This included designing, modifying, and reproducing training manuals, recruiting churches, and covering the costs of the coordinator and MI trainings. The primary costs for the MI trainings related to trainer fees (approximately \$750 per day) and transportation and lodging for the volunteer advisors. The NCI provided funds to conduct outcome and process evaluation of the intervention, including the incentives provided to each church for completion of questionnaires. Members from each organization (University of North Carolina, Emory University, ACS, and the NCI) managed the project as a collaborative team with shared decisionmaking responsibilities. Team interactions occurred primarily through conference calls supplemented with occasional face-to-face meetings.

In creating the aggregate intervention, the project team was guided by two overarching parameters: (1) evidence that the intervention component was "essential," that is, that it at least in part, accounted for the positive intervention effects observed in the parent trials; and (2) the intervention component had the potential to be widely disseminated and adopted. Based on these criteria, the components described below were selected.

Churchwide nutrition activities. In BCUBH, participants in churches that offered F&V more frequently at churchwide events showed a significantly greater in-

crease in F&V intake, and such activities were perceived as highly effective by participants. Churchwide activities were therefore considered an essential program element. As a condition for participating in the Body and Soul project, churches agreed to implement several "core" churchwide activities, which included a "kick-off" event, forming a project coordination committee, conducting at least three churchwide nutrition events plus one additional event involving the pastor, and making at least one policy change.

Churches were provided by ACS staff with an implementation manual describing potential events and activities. Suggested activities included a "Body and Soul Sunday," serving F&V after services or church programs, sponsoring food demonstrations or taste tests, organizing tours of food markets, inviting guest speakers, and having pastor sermons related to health. Potential policy changes included establishing guidelines for the types of foods served at church functions, changing snacks served at youth camps, and creating a food pantry.

In addition, churches were encouraged to promote the project though announcements at gatherings and church bulletin inserts. A volunteer liaison was identified at each church, and this person received training in program implementation from ACS staff. The training typically lasted 1 to 2 hours. Liaisons were given an implementation manual, developed for this project, and ACS staff were available for ongoing technical assistance. ACS staff were provided with a coordinator's manual that was developed for this project to assist them in working with local churches.

Self-help materials. In the EFL trial,¹⁰ as well as a subsequent related study,¹¹ use of self-help materials including the cookbook and video were associated with significantly greater increases in F&V intake, and were considered essential elements of the Body and Soul intervention. All individuals enrolling in the project received the EFL cookbook as well as several ACS educational pamphlets.

The EFL cookbook contains recipes submitted by church members participating in the EFL study. ⁹ Qualifying recipes were required to contain at least a one quarter serving of fruit or vegetable per serving and to be low in fat. The cookbook also contains information about the health benefits of F&V, tips for shopping and storing F&V, and cooking techniques.

In addition, each church received a single copy of "Forgotten Miracles," an 18-minute video developed for the study that targeted F&V intake using both spiritual and secular motivational messages. Whereas in the EFL study each participant received a copy of the video, in Body and Soul, churches were asked to organize public screenings of the video and to make their copy available to members for checkout.

Motivational interviewing. In the EFL trial, individuals receiving the MI calls showed a significantly greater change in F&V intake,¹¹ whereas BCUBH participants who talked with a lay health advisor showed significantly greater increases in F&V intake.⁸ Counseling was therefore considered an essential element of the Body and Soul intervention.

Motivational interviewing is a counseling approach originally developed for addictive behaviors that has more recently been applied to chronic disease behaviors including intake of F&V. 12-14 MI is an interpersonal orientation; an egalitarian, empathetic, and client-centered "way of being" that manifests through specific techniques and strategies such as reflective listening and agenda setting. MI helps individuals to work through their ambivalence about behavior change, solve their own barriers, and explore potential untapped sources of motivation. 12,13 In MI, the client is expected to do much of the psychologic work, although the process is facilitated and subtly guided by the counselor. Counselors establish a safe, nonconfrontational, and supportive climate where clients feel comfortable expressing both the positive and negative aspects of their current behavior as well as the pros and cons for change. To achieve these ends, MI counselors rely heavily on reflective listening and positive affirmations rather than on persuasion or advice giving.

In the EFL trial, the MI was delivered by trained dietitians. This was deemed unfeasible for large-scale dissemination, so instead it was decided that the MI would be delivered by lay church members trained by project staff. Churches were asked to identify individuals, preferably with a college degree or graduate-level education and a background in a "helping profession" (e.g., teacher, psychologist, nurse, counselor, social worker), who were willing to attend a training lasting a day and a half, make two intervention calls with at least five church members, and undergo a tape-recorded evaluation to determine if they met performance criteria. Volunteer advisors without the recommended education were allowed to attend the training and serve as advisors if they met the competency requirements noted below.

A total of 82 (ranging from 5 to 13 across sites) potential volunteer advisors were recruited and invited to attend one of eight trainings held in the three ACS regional areas (California, Southeast, and Northeast). Training was conducted by experienced Emory University staff, generally over a single weekend. The training provided general skills in asking open-ended questions and reflective listening as well as specific strategies to elicit discussion about F&V. A semistructured protocol was developed and role played during the course of the training. At the end of the training, participants were audio-taped conducting a simulated encounter with another trainee, using the semistructured protocol provided by the research team.

| Program element | Parent study | Body and Soul |
|---|--|--|
| | • | , |
| Eat for Life | | |
| Motivational interviewing counseling | 3 telephone calls conducted by dietitians trained 20–30 hours by research staff | 2 telephone calls delivered by lay counselors trained 12–16 hours by research staff |
| Forgotten Miracles video | 1 copy provided to each participant | 1 copy provided to each church |
| Eat for Life cookbook | 1 copy provided to each participant | 1 copy provided to each participant |
| Health fair | Used for recruitment and assessment | Kick-off event included small health fair in some churches; not used for recruitment |
| Black Churches United for Better Health | | , |
| Churchwide activities | Initiated and largely implemented by research staff; received \$2500 to implement activities | Initiated by ACS and implemented by church project coordination committee with assistance from ACS staff or volunteers; no funds provided to implement activities |
| Community coalitions and grocery store promotions | Organized by project director and church health team | Not used |
| Computer-tailored newsletters | Provided to each participant by mail | Not used |
| Lay health advisors | Initiated and implemented (training and support sessions) by research team | See "motivational interviewing" above |
| Nutrition action team | 5-member team chosen by pastor and received training and support from research team to implement churchwide activities | Project coordination team |
| Education sessions and cooking classes | Initiated and implemented by research staff with training materials and resources | Initiated and implemented by churches with technical assistance from ACS staff/volunteer |
| Pastor support | Research team encouraged pastor involvement in training/activities | No specific pastor support provided |
| Printed materials | Monthly packets, church bulletins, recipes, brochures provided to NAT by | ACS brochures provided to each participant |

ACS, American Cancer Society; NAT, nutrition action team.

research team

Tapes were coded by two experienced MI staff. The coding system, based on the method developed by Miller and Mount, ¹⁵ included 17 discrete skills, each scored on a scale of 1 to 7. Participants scoring a mean of 4.5 across the 17 items, from both raters, were considered having adequate competence to proceed as a volunteer advisor. Of the 82 individuals trained, 58 (71%) met competency criteria and were certified as volunteer advisors. The number of certified advisors per church ranged from 2 to 19. Advisors passing certification were asked to make two telephone calls with at least five participants. Participant contact information was provided to callers by the church liaisons.

Intervention Elements from the Parent Interventions Not Included in the Effectiveness Trial

Despite evidence from previous studies as well as process analyses from the BCUBH study^{8,16,17} that the computer-tailored newsletters contributed to the intervention effect, this approach was considered difficult to replicate and disseminate under "real-world" conditions. It was felt that this element would have to be controlled by the research team, which would limit generalizability and local ownership. In addition, the

MI component from EFL, which was considered another type of individual tailoring, represented a better match to existing ACS telephone-intervention programs, such as the breast cancer support program "Tell-A-Friend." Therefore, the tailored newsletters were not included in the Body and Soul program. Other components of BCUBH, such as community coalitions and grocery store promotions, educational sessions, and cooking classes, were not included because process analyses indicated that these components did not appear feasible, effective, or well received by participants. See Table 1 for an overview of elements included, excluded, and modified.

Evaluation Design

The study was a randomized effectiveness trial, with churches recruited through local ACS offices in California, and the Southeast (GA, NC, SC), and Northeast (DE, VA) regions. The intervention operated at two levels. The churchwide events and environmental changes were aimed at the entire congregation, regardless of their consent. On the other hand, the lay counseling was delivered only to individuals who voluntarily enrolled in the study and provided active consent to complete evaluation forms and receive the counseling.

A total of 16 churches (eight intervention and eight comparison) were randomized. One comparison church dropped out, leaving 15 churches completing the baseline and follow-up surveys. One intervention church in California was an aggregate that included five small, affiliated churches, which were treated as a single unit for analytic purposes. All churches had a predominantly African-American membership. Churches were pair matched based on size, socioeconomic status, and urbanicity before being randomized. The primary outcome for the study was F&V intake, assessed by food frequency questionnaires at baseline and at a 6-month follow-up.

Recruitment and Retention

Participants were recruited by liaisons on a first-come, first-serve basis. Liaisons were asked to recruit 60 participants, and their churches were provided with a \$5 incentive per completed baseline interview (up to 100 participants per church). At post-test, churches (rather than participants) were again provided with a \$5 per person incentive, plus \$500 were provided to churches if they obtained follow-up questionnaires from at least 90% of their baseline participants.

Baseline and 6-month follow-up data were obtained from self-report questionnaires distributed to participants by the local church liaisons. Individuals not responding to the 6-month post-test questionnaire were contacted by telephone by trained staff from the University of North Carolina and offered to receive a second questionnaire by mail or to complete the instrument over the phone. Approximately 15% of participants (132 of 854) completed the post-test interview by telephone. Baseline F&V intake did not differ significantly from those completing the instrument by selfreport versus telephone. At post-test, those completing the survey by phone had a similar F&V intake based on the 17-item measure, but for the 2-item measure they had a significantly (p < 0.05) lower intake, 4.2 servings, compared to those completing it by self-report, 4.6 servings. The percentage of participants completing interviews by telephone versus mailed questionnaire did not differ between the intervention (14%) and comparison (16%) churches.

Measures

Main Outcome

Two measures of F&V intake were obtained at baseline and the 6-month follow-up. One was the recently developed NCI 19-item F&V food frequency questionnaire that assessed intake over the past month. The new version includes portion-size estimates for most food items. The two items (one frequency and one portion size) assessing French fry intake were excluded from the computation of F&V, leaving 17 items. The second

measure was composed of two items used to assess usual F&V intake (separate item each for total fruits and total vegetables consumed "each day"). ²⁰ Validity data on the same two measures from a similar trial indicated that the correlation of F&V servings from the 2-item and 17-item measure with three 24-hour telephone recalls was 0.28 and 0.31, respectively. ¹¹ Although small to moderate in magnitude, these correlations are in the range of validity coefficients for other self-report dietary measures. Additional details about the development and validity of these measures can be found elsewhere. ²⁰

Secondary Outcomes

Fat intake was assessed with the NCI's Fat Screener. The instrument assesses intake of 15 foods, and percent kilocalories from fat is estimated by a regression equation weighting foods that are higher in fat positively (e.g., hot dogs and French fries) and foods lower in fat negatively (e.g., skim milk and rice).²¹

Vegetable preparation practices were assessed with an 8-item instrument developed for EFL based on the work of Kristal et al.²² and Glanz et al.²³ The instrument assesses (using the categories "never" through "always") low-fat (e.g., broiling vs grilling, steaming, adding turkey bacon) and high-fat (e.g., adding bacon, deep frying) practices used in preparing vegetables. Higher scores indicate more low-fat practices.

Intrinsic/extrinsic motivation, a key concept from self-determination theory^{24,25} and a proposed mediator of behavior change, was assessed with an adapted version of the TSRQ measure developed by Williams et al. 26,27 The 14-item measure yields two main subscales: (1) autonomous/intrinsic motivation, and (2) controlled/extrinsic motivation. The scale was modified to address F&V intake, and two items were added. Each item begins with the following stem: "The reason I eat fruits and vegetables is..." Sample items from the intrinsic scale included: "Because I personally believe it is a good thing for my health" and "Because I have carefully thought about it and believe it is very important for me." Sample items from the extrinsic scale included: "Because I would feel guilty or ashamed of myself if I didn't" and "Because others would be upset with me if didn't." Alpha for each of the two scales was 0.86.

Social support to eat more F&V was assessed with three items used in the EFL study. One item each assessed perceived support from family, friends/work colleagues, and church members to eat more F&V. Items are answered on a 4-point continuum, ranging from "none" to "a lot," and summed to create a social support index.

Self-efficacy to eat more F&V was assessed with a 10-item scale based on the work of Sallis et al.,²⁸ Baranowski et al.,²⁹ and Sheeska et al.^{29,30} used in previous studies.^{9,14} Sample items included: "How con-

| Table 2. | Body | and | Soul | cohort | description |
|----------|------|-----|------|--------|-------------|
|----------|------|-----|------|--------|-------------|

| Variable | Control | Treatment | Overall |
|---|--------------------|--------------------|------------------|
| Age (mean, range) | 50.9 (18-84) | 50.5 (17–89) | 50.6 (17–89) |
| Gender | | | |
| % female | 72.6 | 75.5 | 74.4 |
| Marital status | | | |
| % married or living with partner | 52.0 | 61.0 | 57.5 |
| Income (%) | | | |
| <\$30,000 | 35.7 | 23.6 | 27.7 |
| \$30,000-\$49,999 | 21.6 | 22.7 | 22.3 |
| ≥\$50,000 | 42.7 | 53.7 | 50.0 |
| Education (%) | | | |
| <high school<="" td=""><td>12.1</td><td>5.5</td><td>8.0</td></high> | 12.1 | 5.5 | 8.0 |
| Completed high school or vocational school | 31.8 | 20.5 | 24.8 |
| Some college | 17.7 | 21.3 | 19.9 |
| Completed college or higher | 38.4 | 52.7 | 47.3 |
| Fruit and vegetable intake (servings/day) | | | |
| 2-item measure | $3.8 \ (\pm 1.94)$ | $4.0 \ (\pm 1.94)$ | $3.9 (\pm 1.94)$ |
| 17-item measure | $4.7\ (\pm 4.38)$ | $5.5\ (\pm 4.83)$ | $5.2(\pm 4.67)$ |

fident are you that you could order fruits and vegetables when eating at a restaurant?" and "How confident are you that you could eat healthy foods like fruits and vegetables, when you are depressed or in a bad mood?" Items are answered on a 4-point scale from "not at all confident" to "very confident." Internal consistency in this study population was 0.92.

Regarding process measure, participants' (intervention group only) self-reported exposure to and satisfaction with each intervention component were assessed with close-ended questions contained in the 6-month follow-up questionnaire. Measures were adapted from previous studies.8 In addition, church liaisons, volunteer advisors, and ACS staff were interviewed by telephone by trained University of North Carolina staff using a semistructured protocol to obtain information about their background as well as feedback about their experiences.

Data Analysis

Churches were the unit of randomization and analyses. Outcomes were therefore analyzed with a mixed-model analysis of variance program, SAS PROC MIXED, that allows for adjustment of subject nonindependence within churches.³¹ The initial multivariate model included fixed-effect terms for experimental condition, baseline values for the outcome of interest, and the covariates; age, gender, household income, and education; and random-effect terms for church nested in treatment condition and individual nested within church.

Results

Sample Description

At baseline, a total of 1022 individuals were recruited across the 15 churches. Of the initial sample, 854

(84%) were assessed at 6-month follow-up. All 15 churches reached the baseline quota of 60 participants, and 7 of the 15 achieved a >90% retention rate. The retention rate was similar in the treatment and comparison groups at 85% and 83%, respectively. Dropouts did not differ from cohort members for any of the variables shown in Table 2, nor did dropouts differ across the two groups (i.e., there was no evidence of differential or selective attrition).

The cohort was predominantly female, with a mean age of 51. Approximately 60% of the sample was married or living with a partner. Half reported household income of >\$50,000 and almost 70% reported at least some college education. At baseline, the two intervention groups did not significantly differ for any of the demographic variables listed in Table 2 or baseline F&V intake.

Interviews were completed with 37 of the 64 volunteer advisors. All were African American (one reported being biracial). The vast majority (34 of 37) were female, 53% were married, 75% were employed fulltime, and 90% had at least some college education. Advisors reported counseling approximately nine participants each.

Process Evaluation

Program exposure. Over 91% of intervention group participants reported receiving the cookbook or other SH-educational materials. Approximately 75% attended the project kick-off event, and 63% attended at least one other program activity. Almost 90% reported experiencing pastor support for the project in the form of a sermon or discussion from the pulpit. With regard to the MI telephone calls, 63% of intervention group participants reported receiving at least one call, with the majority (70%) of those reporting having received two or more calls.

Table 3. Body and Soul: adjusted post-test values with standard errors and post-test effect size for F & V (n = 854)

| | Post-te | Effect | | |
|---|--|--------------------------------------|-------------------------------|--|
| F & V | Intervention | Comparison | size estimate ^b | |
| 2-item measure ^c 17-item measure (NCI) | $4.8 \ (\pm 0.12)$ $6.6 \ (\pm 0.39)$ | $4.1 (\pm 0.12)$ $5.2 (\pm 0.45)$ | 0.39* 0.18* | |
| Fruit | | | | |
| 1-item | $2.4 \ (\pm 0.08)$ | $2.0 \ (\pm 0.09)$ | 0.46* | |
| 4-item (NCI) | $3.3\ (\pm0.26)$ | $2.4\ (\pm0.30)$ | 0.15 | |
| Vegetables | , , | , , | | |
| 1-item measure | $2.4\ (\pm0.07)$ | $2.2 \ (\pm 0.07)$ | 0.18* | |
| 13-item measure (NCI) | $3.2\ (\pm0.17)$ | $2.7\ (\pm0.19)$ | 0.10 | |

^aAdjusted for baseline value, age, gender, marital status, education, and income.

Program satisfaction. More than three fourths (77%) of participants reported being very satisfied with the cookbook and educational materials, and 72% of those receiving at least one call reported being very satisfied with their volunteer advisors. More than three fourths of participants reported that they had a better opinion of the ACS as a result of the project, and 58% reported being more likely to volunteer for the organization.

Primary Outcomes

At post-test, participants in the intervention group reported significantly greater consumption of F&V than those in the comparison group (Table 3). The adjusted post-test difference was 0.7 servings per day based on the 2-item measure and 1.4 servings for the 17-item measure. These differences equate to standardized effect sizes (difference in adjusted post-test scores divided by the standard deviation, pooled from the intervention and comparison groups) of 0.39 and 0.18

standard deviation units for the 2-item and 17-item measures, respectively. The change in F&V was comprised of 0.4 and 0.9 servings from fruit across the 2-item and 17-item measures, respectively, and 0.2 and 0.5 servings from vegetables from the two measures. Based on the 17-item measure, which assessed separately fruit and fruit juice intake, approximately 0.15 servings of the 0.9 net difference in fruit intake was attributable to an increase in fruit juice (data not shown).

Secondary Outcomes

The intervention group showed small, but significantly greater changes (in the desirable direction) for percentage of calories from fat, intrinsic and extrinsic motivation to eat F&V, self-efficacy to eat F&V, and social support to eat more F&V (Table 4).

Discussion

This project demonstrated that a research-based intervention can be adapted and implemented under realworld conditions using volunteer staff and lay counselors and, under these conditions, positive effects on behavior change can be achieved. The effect size for change in F&V intake, although somewhat smaller than that observed in the parent efficacy trials, was nonetheless statistically significant and could be considered of public health value if it could be widely replicated at a reasonable cost. The somewhat attenuated effect size is not surprising given that the volunteer lay health advisors had little professional counseling experience entering the project, and that they received only a 1.5 d training session in the use of MI. Additionally, the churchwide activities were conducted by church volunteers with less professional supervision, technical assistance, and resources than provided in the BCUBH project. These "dilutions" of implementation are consistent with the transition from efficacy to effectiveness. As noted by Flay, a logical next step for this intervention would be to test various methods for disseminating

Table 4. Body and Soul: adjusted post-test values with standard errors and post-test effect size for secondary outcomes (n = 854)

| | Post-te | est (SE) | |
|-----------------------|---------------------|-------------------|-----------------------------------|
| Secondary outcome | Treatment | Comparison | Effect size estimate ^b |
| Percent energy fat | $32.8 \ (\pm 0.27)$ | $33.7 (\pm 0.31)$ | 0.26* |
| Autonomous motivation | $6.3~(\pm 0.08)$ | $6.1\ (\pm0.09)$ | 0.21* |
| Controlled response | $3.0\ (\pm0.09)$ | $2.9 (\pm 0.10)$ | 0.33* |
| Self-efficacy | $3.1~(\pm 0.04)$ | $3.1~(\pm 0.04)$ | 0.22* |
| Social support index | $2.9\ (\pm0.06)$ | $2.6\ (\pm0.07)$ | 0.39* |
| Food preparation | $2.7\ (\pm0.03)$ | $2.6\ (\pm0.03)$ | 0.11 |

^aAdjusted for baseline value, age, gender, marital status, education, and income.

^bEffect size was computed as the difference in adjusted post-test means divided by the pooled standard deviation.

^cDue to rounding error, total F&V for the two-item measure is slightly different than the sum of fruits and vegetables separately.

^{*}Significant (p <0.05) difference in adjusted post-test means between conditions (bolded).

NCI, National Cancer Institute; SE, standard error.

^bEffect size was computed as the difference in adjusted post-test means divided by the pooled standard deviation.

^{*}Indicates significant (p < 0.05) difference in adjusted post-test means between conditions.

What This Study Adds . . .

Researchers are increasingly being asked to develop interventions that can be brought to scale.

A key step in moving interventions through the dissemination process is evaluating their impact under real-world conditions.

This article reports the results of a randomized effectiveness trial, where a church-based dietary intervention, originally implemented by researchers, was delivered by lay volunteers.

The effects achieved by the lay staff, although somewhat smaller than those achieved by professional staff, suggest potential for wider dissemination.

the program, including variations in training counselors and church coordinators.

The intervention effect appeared somewhat larger for fruits than vegetables. This is consistent with the results of the BCUBH project, which found that most of the effects on F&V intake were due to increased fruit (0.66 servings) than vegetable intake (0.19 servings).⁸

Of the 82 volunteer advisors trained, 58 (71%) met criteria for counseling competence. This encouraging certification rate was driven at least, in part, by churches following the recommendation set out by project staff that volunteer advisors should ideally have at least some college education. Around 90% of the trainees met this criterion. As noted previously, 8,32–34 the African-American church as an institution contains a substantial network of individuals with high levels of education, a wide range of professional skills, and a strong commitment to community service that can be mobilized to improve the health of the African-American community.

As with many multicomponent interventions, it is difficult to determine which element(s) of the program accounted for the observed treatment effect. The current study was not designed to tease out the impact of individual intervention elements, as the primary goal was to determine if the aggregate intervention, delivered under real-world constraints, could result in positive behavior change. Future studies are needed to disentangle the independent "active ingredients."

Although volunteer advisors were responsible for delivering the counseling component of the intervention, the training of these counselors was conducted by experienced professionals. This required some initial startup costs to "install" the program. Larger-scale dissemination of this intervention would require a considerable cadre of trainers to implement the MI component, which would involve substantial costs. To bring the intervention to scale, more cost-effective training methods, such as "cascading" (training the trainer) or autodidactic programs, may be needed.

The study had several limitations and threats to validity. It is possible that the reported effects on F&V intake and secondary outcomes in the intervention groups were an artifact of social desirability bias. That the two measures of F&V used in this study have been validated against serum carotenoids among African Americans²⁰ suggests that self-reported behavior in this study may have been at least partially valid. Nonetheless, intervention participants may have over-reported behavior change at post-test, and social desirability bias cannot be dismissed entirely as an alternative explanation for the findings.

Participants were recruited by liaisons in each church using a quota sampling framework (e.g., first come/ first serve). Therefore, it is possible that study participants were not representative of the entire church population. There was not sufficient information from the participating churches to empirically examine the issue of sampling bias, reach, or representativeness, and external validity remains a concern. Program exposure was determined largely by self-report and may therefore be biased. More objective measures would have provided a better assessment of program exposure and intervention use. Another problem with the study is that despite the promising effects of MI as delivered by the lay health advisors, these effects may not have been due to MI per se, but rather generic effects of attention or other elements of counseling not unique to MI. To better determine the independent effects of MI versus attention, it would be useful to test the effects of an MI-based intervention compared to other counseling modalities holding constant the client contact. The study also has several strengths, including the relatively high cohort-retention rate and the inclusion of a sociodemographically diverse sample of African Americans.

The team conducting this project comprised a unique partnership of university researchers, a prominent national nongovernmental health agency, and the National Institutes of Health. This group is currently exploring possible methods for bringing the intervention to scale, which may include partnering with national African-American religious organizations, social service agencies, or corporate sponsors, as well as state and local departments of health. In the case of the ACS, the organization had an internal mission to reach out to the African-American community. Future dissemination partners will also likely require similar "intrinsic" organizational motivation to invest in the program. Whatever channels or organizations eventually may be used to disseminate the program, bringing it to scale will require modification of intervention materials and training methodology. Key challenges ahead include developing a cost-efficient means for training lay health advisors while maintaining quality control, and finding ways to not only install the program, but institutionalize it so that activities continue beyond initial adoption.

AW was employed at the American Cancer Society during the study.

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