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Cardiovascular Disease Risk Reduction: The Massachusetts WISEWOMAN Project

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ABSTRACT

***Background*: This report presents the effectiveness of the Massachusetts Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Project (MWWP) in reducing the cardiovascular disease (CVD) risk of uninsured and underinsured women aged ≥50.**

***Methods*: Healthcare sites were randomly assigned to an enhanced intervention (EI) or minimum intervention (MI). Women enrolled at all sites received CVD risk factor screening, onsite counseling, education, referral, and follow-up as needed. Women enrolled at EI sites received additional services and specially designed interventions, including one-on-one nutritional and physical activity counseling and group activities, such as walking groups, nutrition classes, and cultural festivals. We report results for 1443 women who attended the initial screening in 10 study sites. Blood pressure, total cholesterol, number of servings of fruits and vegetables, and level of moderate or vigorous physical activity were assessed at baseline and 12-month follow-up screenings. Baseline data were collected between March and June 1996; follow-up data were collected 12 months later.**

***Results*: The comprehensive screenings significantly lowered the overall prevalence of hypertension, resulting in a 7% reduction in high blood pressure among women at the EI sites ($p = 0.02$) and a 9% reduction at MI sites ($p = 0.009$). A significantly greater percentage of women became physically active at the EI sites (18%) than at the MI sites (6%) ($p = 0.04$).**

***Conclusions*: MWWP is a promising model for providing comprehensive preventive healthcare to uninsured and underinsured women.**

INTRODUCTION

HEART DISEASE, CANCER, AND STROKE are the leading causes of death among women in the United States,[1] and more than half of all cardiovascular disease (CVD) deaths occur in women.[2] Although CVD mortality in the United States declined from 1990 to 1998, declines in age-adjusted death rates were greater among men than they were among women.[3] Among women, race/ethnicity and socioeconomic status predict significant disparities in CVD morbidity and mortality.[3–5] Moreover, women who are uninsured or underinsured are likely to have a poorer

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CVD risk profile and, therefore, are at greater risk of developing CVD.[6] Uninsured adults, both men and women, are less likely to have had their blood pressure or cholesterol checked in the recent past.[7]

As with other chronic diseases, not only is CVD highly prevalent and costly, but also it is largely preventable. Promoting healthy behaviors, such as moderate physical activity and eating fruits and vegetables, and expanding the use of early detection practices, such as blood pressure and cholesterol screening, are key health promotion activities that can reduce the burden of CVD in women.[2,4]

The Massachusetts Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) project (MWWP) began in October 1995 as one of three WISEWOMAN studies funded by the Centers for Disease Control and Prevention (CDC).[8] The MWWP used a randomized controlled design to test a comprehensive chronic disease prevention and health promotion approach to reduce CVD risk factors among uninsured and underinsured women aged ≥50. The combined results for the Massachusetts and North Carolina WISEWOMAN projects have been reported elsewhere.[9] Here, we present the results of the Massachusetts study alone, focusing on the specific outcomes targeted by the MWWP.

MATERIALS AND METHODS

Study setting and population

The MWWP was part of the Massachusetts Breast and Cervical Cancer Initiative (MBCCI). The purpose of the MWWP was to enhance the state's commitment to providing CVD risk-reduction activities, health education, and screening services to women by adding cholesterol, blood pressure, and glucose screening to existing MBCCI programs. Fifteen MBCCI agencies across the commonwealth, including community health centers, hospitals, and visiting nurses associations (VNAs), applied to be project sites. The organizations were eligible to apply if they had provided breast and cervical cancer screening to at least 150 women in the previous 12 months, of whom at least 50% had to be age ≥50. A team of investigators evaluated the applications and chose 12 of the 15 sites to participate. After matching the sites on the type of site (e.g., hospital, health center, VNA) and the demographic characteristics of the target population (e.g., rural or urban), one member of each pair was randomly assigned to the enhanced intervention (EI) and one to the minimum intervention (MI) condition. During the first screening period, it became clear that one EI site could not recruit the required number of participants. This site was dropped from the study, leaving a total of six MI and five EI sites (five intact pairs of sites).

Sites used two strategies to recruit participants to the MWWP. First, each site recruited and enrolled women through an initial screening event, conducted between March and June 1996. Women were eligible to participate if they were age ≥50, were uninsured or underinsured, and also were eligible for MBCCI enrollment. Second, women who had enrolled in MBCCI in the 3 months prior to the initial screening event were invited to participate in MWWP. At baseline, a total of 1586 women were enrolled in MWWP and screened at the 11 study sites. Our analysis is limited to the cohort of women initially screened in the 10 study sites representing the five intact randomization pairs ($n = 1443$).

Screening and intervention

Participants at both EI and MI sites received breast and cervical cancer screening, CVD risk factor screening, on-site multiple risk factor assessment, counseling and education, referrals, and follow-up as needed. A comprehensive health risk appraisal was used to assess blood pressure, cholesterol levels, and health behaviors, including diet, physical activity, and smoking. Referrals to primary care providers were made when clinically appropriate. All MWWP participants received a set of low-literacy fact sheets on cholesterol, blood pressure, blood glucose, nutrition, physical activity, and stress reduction. Each site conducted a follow-up screening 12 months after enrollment.

Women at EI sites received lifestyle interventions focused primarily on nutrition and physical activity to reduce CVD risk. The additional services included one-on-one nutritional and physical activity assessments and counseling, individual and group education, and behavioral intervention activities. Agency staff also promoted opportunities for social support and social interaction by implementing women's groups. The goal of these interventions was to help women learn new information and skills and gain support for integrating healthy behaviors into their lives.

A key aspect of the project at both the EI and MI sites was the inclusion of client input into the design and implementation of the intervention activities. The printed materials were developed and tested in focus groups with women who were demographically similar to the MWWP's target population. At EI sites, program participants collaborated with agency staff and community health advisors in designing activities. As a result of this participatory planning approach, each EI site offered a unique assortment of nutrition and physical activity interventions that reflected the resources available in the community and the creativity and initiative of participants and staff. Activities included walking groups, nutrition classes on modifying or translating recipes, and cultural festivals.

Staff at the EI sites attended a special 2-day training workshop that focused on implementing innovative outreach and education strategies. Topics included adult learning principles, cultural competency, nutrition and physical activity assessments, program development, counseling strategies, and methods to foster peer support.

Instruments

We collected baseline and follow-up data using the computerized HealthChek® Personal Risk Assessment (PRA) (Medical Sciences, Inc. Boston, MA) and a supplemental form developed by the project. We assessed sociodemographic and health characteristics, such as smoking, seat belt use, regular physical activity, and consumption of fruits and vegetables.

A trained health professional measured resting blood pressure using a stethoscope, blood pressure cuff, and mercury sphygmomanometer. At least two measurements (one per arm) were taken, and measurements were averaged to arrive at a blood pressure value. Another health professional obtained blood samples by fingerstick and used the Cholestech L·D·X® Lipid Analyzer (Cholestech Corporation, Hayward, CA), a portable lipid analyzer, to measure nonfasting total cholesterol (TC). Using the PRA software, we produced a report that outlined each woman's personal risk of CVD and other chronic conditions. We used the risk profiles to guide one-on-one counseling and to assess the primary outcome measures.

Measures

Outcomes. We evaluated four primary outcomes, using two physiological measures and two behavioral measures: high blood pressure (systolic blood pressure ≥140 or diastolic blood pressure ≥90),[10] high cholesterol (TC ≥240 mg/dl),[11] low daily fruit and vegetable intake, and low daily physical activity.

Dietary behavior was assessed with a question that asked, "On average, how many servings of fruits and vegetables do you eat in a day (including potatoes and 100% fruit juices)?" Responses were categorized dichotomously as five or more servings per day or fewer than five servings per day. Two questions measured physical activity: (1) "In an average week, how many times do you engage in physical activity (exercise or work that lasts at least 20 minutes without stopping and that is hard enough to make you breathe more heavily and your heart beat fast)?" and (2) "Thinking about your average day, about how many minutes do you think you spend doing activities that really get you moving, like walking briskly, dancing, heavy cleaning, raking, or doing exercise (activities in the moderate and heavy categories)?" Although the questions were not exactly complementary, a woman was categorized as being physically active if she reported engaging in physical activity at least three times a week and reported at least 30 minutes of moderate or vigorous activity on an average day. A woman who reported less activity on either or both questions was categorized as having low physical activity.

Other variables. Sociodemographic characteristics included age in years, body mass index (BMI), highest school grade completed, and race/ethnicity. BMI was calculated as the ratio of weight (kg) to squared height (m^2). Race and ethnicity categories were combined into four categories: Hispanic, non-Hispanic white, non-Hispanic black, and other. Because of small numbers, however, these categories were further collapsed into non-Hispanic white and all other.

Statistical methods

The units of randomization were healthcare sites, and the units of measurement were women. Considering that participants were enrolled by individual healthcare sites (i.e., women were clustered within sites), for all analyses, we computed a repeated measures mixed model logistic regression analysis with healthcare site included as a random effect.[12] This method can incorporate cases with missing data, as long as the data are missing at random.[13] We computed the adjusted percentages using the coefficients from the linear logistic regression model. To carry out the analyses, we used the GLIMMIX macro to the SAS statistical software (SAS Institute, Inc., Cary, NC, 1996). This macro uses iteratively reweighted likelihoods to fit a logistic regression model where the subjects are clustered in the random effect.[14]

We evaluated the effectiveness of the interventions in changing each of the four outcome measures separately. Time (baseline and 12 months) and intervention group (EI or MI) were included as fixed effects, and study site was included as a random effect. To test the null hypothesis of no difference in improvement between the two intervention groups, we assessed the interaction effect of time by group. This is analogous to a *t* test on the difference between the mean change in the EI group compared with the MI group.

To control for factors that may have been unbalanced despite randomization, we added age, BMI, education, and race/ethnicity to the logistic regression analysis. Each covariate was tested alone. All covariates that were statistically significant individually were added to the model, and a final multivariable model was fitted for each outcome.

RESULTS

Sociodemographic characteristics

Table 1 presents the characteristics of the 1443 women who were screened at baseline in the 10 matched-pair sites. On average, participants were 58 years old. Most participants (79%) spoke English, 12% spoke Spanish, 4% spoke Portuguese, and the remaining 5% spoke other languages (data not shown).

High cholesterol and hypertension were very common CVD risk factors among women in our cohort. Few women reported eating at least five servings of fruit and vegetables per day or engaging in physical activity at least 30 minutes per day and three times per week. The average BMI was 28.7. Overall, 70% of participants were either overweight (BMI = 25–29.9) or obese (BMI ≥30).

To evaluate the effectiveness of randomization, we compared characteristics of participants at the EI and MI sites (Table 2). The differences between women in the two intervention groups were not statistically significant.

Loss to follow-up

The percentage of women who returned for the 12-month screening ranged from 57% to 86% by site, with an overall average of 77% ($n = 1105$). More women from the EI sites (80%) returned for follow-up screening than from the MI sites (73%), but the difference was not statistically significant. Although age and education were not associated with follow-up, the association between race/ethnicity and follow-up was significantly different in the two intervention groups, with women from other racial/ethnic groups considerably less likely to return for follow-up at MI sites (Table 3). Women with low consumption of fruits and vegetables and low levels of physical activity tended to have lower follow-up rates in both the EI and MI groups. The differences between the groups were not statistically significant, however.

Evaluation of intervention effectiveness

In Table 4, we present results for the 1105 women in the 10 study sites who attended both baseline and 12-month screenings. Sample sizes differ across outcome measures and time points because of missing values on individual data items.

In both groups, the percentage of women with high blood pressure decreased significantly, but the difference between groups was not statistically significant ($p = 0.51$). The percentage of women with high cholesterol did not change significantly in either intervention group, and the difference in change between the two groups was not statistically significant ($p = 0.21$). In both groups, the percentage of women who reported consuming at least five servings of fruits and vegetables per day increased over time, but the increase was statistically significant only among women in the EI sites ($p = 0.009$). The difference in the increase between the two groups was not statistically significant ($p = 0.18$). Similarly, the percentage of women reporting adequate levels of physical activity increased in both groups, but the increase was statistically significant only for women in the EI group ($p = 0.002$). The difference in increase between the two groups was statistically significant ($p = 0.04$).

We added age, BMI, education, and race/ethnicity to our analysis of intervention effects for each risk factor (data not shown). These variables

TABLE 1. CHARACTERISTICS OF STUDY PARTICIPANTS AT BASELINE (n = 1443)

Characteristic	*Number*[a]	%
Race/ethnic group		
White, non-Hispanic	1146	79.4
Black, non-Hispanic	39	2.7
Hispanic	169	11.7
Other/unknown	89	6.2
Education		
Less than high school	446	31.3
High school graduate	509	35.7
Post high school	471	33.0
Age, years		
50–64	1193	82.9
≥65	246	17.1
Blood pressure[b]		
Taking blood pressure-lowering medication	366	25.4
Normal (SBP <140 and DBP <90)	725	50.3
High (SBP ≥140 or DBP ≥90)	349	24.2
Total cholesterol		
Normal (<240 mg/dl)	868	65.3
High (≥240 mg/dl)	455	34.6
Fruits and vegetables		
Low (<5/day)	983	72.1
Adequate (≥5/day)	381	27.9
Physical activity		
Low (<30 min/day or <3 days/week)	829	59.2
Adequate (≥30 min/day and ≥3 days/week)	571	40.8

[a]Numbers do not total 1443 because of missing values.
[b]SBP, systolic blood pressure; DBP, diastolic blood pressure.

were associated with the risk factors, but controlling for the four covariates had no effect on the changes in risk factors or on the differences between intervention groups.

DISCUSSION

The MWWP screenings were effective in reducing the prevalence of hypertension but not

TABLE 2. EFFECTIVENESS OF RANDOMIZATION AT BASELINE: ADJUSTED PERCENT OF SELECTED CHARACTERISTICS BY INTERVENTION GROUP (n = 1443)

Characteristic	*EI adjusted*[a] %	*MI adjusted*[a] %	p *value*[b]
Racial/ethnic group			
White, non-Hispanic	86.9	80.5	0.67
Education			
Completed high school or more	69.8	75.2	0.74
Age, years			
≥65	17.0	13.6	0.57
Blood pressure[c] (excluding women on medication)			
High (SBP ≥140, DBP ≥90)	33.8	30.8	0.44
Total cholesterol			
High (≥240 mg/dl)	35.6	33.2	0.68
Fruits and vegetables			
Adequate (≥5/day)	23.8	28.8	0.59
Physical activity			
Adequate (≥30 min/day and 3 days/week)	36.7	43.7	0.34

[a]Percent adjusted for the clustering of clients in study sites.
[b]p value for test of difference in adjusted percents.
[c]SBP, systolic blood pressure; DBP, diastolic blood pressure.

TABLE 3. 12-MONTH FOLLOW-UP STATUS BY INTERVENTION AND RESPONDENT CHARACTERISTICS, CONTROLLING FOR SITE

	12-month follow-up		
Risk factor	*EI (%)*	*MI (%)*	p *value*[a]
Racial/ethnic group			0.01
White, non-Hispanic	80.4	78.1	
Other/unknown	80.1	58.1	
Education			0.46
Less than high school	79.6	67.2	
High school graduate	80.0	73.0	
Post high school	81.3	77.9	
Age, years			0.89
50–64	79.8	72.0	
≥65	83.1	75.3	
Blood pressure[b] (excluding women on medication)			0.80
Normal	81.6	73.1	
High (SBP ≥140, DBP ≥90)	82.3	75.4	
Total cholesterol			0.63
Normal	81.4	74.6	
High (≥240 mg/dl)	79.1	69.1	
Fruits and vegetables			0.12
Low (<5/day)	80.5	69.8	
Adequate (≥5/day)	81.6	80.0	
Physical activity			0.06
Low (<30 min/day or <3 days/week)	82.2	70.7	
Adequate (≥30 min/day and 3 days/week)	78.7	76.0	

[a]*p* value for test of interaction of intervention group and characteristic on follow-up rate.
[b]SBP, systolic blood pressure; DBP, diastolic blood pressure.

hypercholesteremia among study participants. In both the MI and EI sites, we found a statistically significant reduction in the percentage of women with high blood pressure. The change in the prevalence of high blood pressure among women who attended the MI screenings indicates that the screenings alone may have been an effective intervention. It is also possible that the observed improvements in blood pressure among MI women were due to general improvements in the population.

Compared with women at MI sites, more women at EI sites showed an increase in reported consumption of fruits and vegetables from baseline to the 12-month screening, most probably as a result of the educational sessions on diet and nutrition included as part of the special intervention activities at EI sites. Of the outcomes we examined, however, a statistically significant intervention effect was achieved for physical activity only. Women at EI sites were significantly more likely to increase physical activity levels than were women at MI sites. This finding can be understood by considering several aspects of the study design. First, behavioral interventions were offered only at EI sites, where women helped select and design intervention activities. Perhaps because the activities were tailored to participants' expressed interests and needs, 96% of EI participants reported being very satisfied with them. Second, three fourths (72%) of intervention activities included a physical activity component, providing participants with repeated opportunities to build physical activity skills. Third, women's involvement in planning the intervention activities and their subsequent participation in those activities provided opportunities for social interaction and support, and social support was associated with increased physical activity. Fifteen percent of participants at EI sites reported engaging in physical activity with other MWWP participants. Designing interventions that are culturally and age appropriate, providing repeated exposure to physical activity opportunities, and increasing social support appear to be promising strategies for effective physical activity programs for midlife and older women. These elements seem worth incorporating into future WISEWOMAN projects and should be tested for their effectiveness in other populations.

Except for blood pressure, we used crude screening instruments to assess our outcome

TABLE 4. FREQUENCY OF RISK FACTORS AT BASELINE AND 12-MONTH SCREENINGS, BY INTERVENTION GROUP (n = 1105)[a]

		EI		MI		
Variable	*Screening*	*Total* n	*Adjusted*[b] %	*Total* n	*Adjusted*[b] %	*EI vs. MI* p *value*[c]
High blood pressure						
(Excluding women on	Baseline	461	33.8	375	31.5	
medication at baseline)	12 months	461	27.0	372	22.9	
Change			−6.8		−8.6	
p value			0.02		0.009	0.51
High cholesterol						
	Baseline	553	36.5	456	32.8	
	12 months	575	33.0	461	35.7	
Change			−3.5		+2.9	
p value			0.31		0.42	0.21
Adequate fruit and vegetable consumption						
	Baseline	580	24.1	472	31.8	
	12 months	600	43.6	462	39.7	
Change			+19.5		+7.9	
p value			0.009		0.23	0.18
Adequate physical activity						
	Baseline	592	36.4	482	45.8	
	12 months	600	54.5	475	52.0	
Change			+18.1		+6.2	
p value			0.002		0.13	0.04

[a]Sample sizes differ by time and outcome measure because of missing values.
[b]Percent adjusted for the clustering of clients in study sites.
[c]*p* value for test of difference in adjusted percents.

measures. We assessed total cholesterol using a nonfasting blood sample obtained by fingerstick. For diet, we used a single question regarding usual intake of fruits and vegetables, and we assessed physical activity by combining responses to two general questions about usual levels of activity. Although these brief and general assessment methods offered the advantage of being easily incorporated into the screening assessment tool, their crudeness may have introduced measurement error into the assessment of outcomes. Such measurement errors would have applied to women in both the EI and MI conditions and, thus, would not have introduced differential misclassification bias. Nevertheless, increased variance due to measurement error could have resulted in our not being able to detect changes in behavior as statistically significant.

We paired EI and MI sites before randomization to achieve comparability in the two intervention conditions.[12] When one EI site dropped out after the project's inception, the remaining site in the pair was quite different from the sites in the other pairs, reducing overall comparability between EI and MI sites. We excluded the odd site from the analysis to retain the study's internal validity. Had we been able to analyze six sites in each condition, we would have had additional statistical power to detect differences between the conditions.

The EI and MI sites were equally effective in providing comprehensive screening services to the MWWP's target population at baseline. Although 77% of enrolled women overall returned for the 12-month follow-up screening, the MI sites were somewhat less effective in following women in the other racial/ethnic category (composed primarily of black and Hispanic women) compared with white women. When we controlled for race/ethnicity in the analysis, however, the results did not change, suggesting that any effect of nonresponse bias was minimal.

Our results can be generalized to hospitals, health centers, and VNAs that serve a substantial population of older (≥50 years) uninsured and underinsured women and have the resources to provide WISEWOMAN's array of screening and intervention services. Although the results may also apply to smaller and more resource-poor sites, the chances of success probably would be increased by providing additional support to the individual healthcare sites that are considering offering such a program. Our experience indicates that successful implementation also depends on obtaining top administrative support and planning the coordinated service components before program delivery begins.

The MWWP comprehensive disease screenings were effective in reducing high blood pressure rates among all participants. The EI was more successful than the MI in increasing participants' physical activity levels. The WISEWOMAN program's broad approach to women's health includes both breast and cervical cancer screening services and CVD screening. The Massachusetts experience suggests that adding CVD screening and lifestyle interventions to existing breast and cervical cancer screening programs holds promise as an effective means of improving CVD risk factors for uninsured and underinsured women.

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