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## Enhancing Diabetes Self-care Among Rural African Americans With Diabetes:

### Results of a Two-year Culturally Tailored Intervention

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### Abstract

**Purpose**—The purpose of this study is to test the feasibility of conducting a community-based randomized controlled trial evaluating a culturally tailored community-based group diabetes self-management education (DSME) program among rural African Americans.

**Methods**—Thirty-two African American rural adults with type 2 diabetes were recruited and 25 adults were retained and participated in an interventional study designed to test the effectiveness of the “Taking Care of Sugar” DSME program for the 2-year follow-up. Participants were selected from rural central Virginia. Primary outcomes variables included average blood sugar levels, cardiovascular risk factors, and general physical and mental health. These outcomes were assessed at baseline, 3 months, 6 months, and 12 months post baseline.

**Results**—From baseline to 3-month follow-up assessment, participants exhibited significant improvement on several physiological and behavioral measures. Given the small sample size, hypothesis testing was limited. Results show change from baseline over time, illustrating that the primary outcome of A1C decreased, although not significant. Additionally, participants reported more knowledge about diabetes self-management and personal care skills (ie, exercise and foot care) that persisted over time. The feasibility of the culturally tailored DSME was established, and participation with the program was high.

**Conclusions**—A community-based group DSME program using storytelling is feasible. This research will help to inform clinicians and health policymakers as to the types of interventions that are feasible in a larger rural population. If such a program is carried out, we can improve knowledge, reduce complications, and improve quality of life among rural African Americans.

Diabetes mellitus (DM) is a serious and growing public health problem that affects 25.8 million Americans—8.3% of the general population and 26.7% of those over 65. Another 79 million adults (50% of people over 65) with prediabetes (impaired glucose tolerance) are at high risk of developing the disease over the next decade<sup>1</sup>; this includes 1 in 3 American children born in 2000 who are likely to develop the disease during their lifetimes.<sup>1</sup> Diabetes

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also contributes to other serious health problems, including dementia, pneumonia, and several types of cancer.<sup>2</sup> Adults with diabetes, who frequently have multiple chronic illnesses, often have complex medical regimens. Not surprisingly, rates of depression are doubled among patients with diabetes, compromising health care.<sup>2</sup> In addition to human costs, the estimated total monetary cost of diabetes in the US in 2007 was \$174 billion, which includes medical care, disability, and premature death<sup>2</sup>; an estimated \$1 out of every \$3 in Medicare dollars is spent on people with diabetes.<sup>3</sup>

The toll of DM is particularly serious among African Americans (AAs), both in higher prevalence and poorer rates of disease management. Most recent estimates are that rates of DM among AAs are 18.7% and 35% with prediabetes.<sup>4</sup> Rates of complications from diabetes are also high among AAs. In a recent study among AAs, diabetes prevalence rate was nearly double that of white city neighborhoods, with 5 times the rate of leg amputations.<sup>5</sup> Among AAs in rural areas, rates and complications of diabetes are equally serious; the prevalence of diabetes in these areas is higher than in urban areas likely due to advanced age, lower socioeconomic status, and higher proportions of racial/ethnic groups, particularly in the South and Southeast.<sup>6</sup> Barriers for rural-dwelling AAs to experience adequate DM care and self-management include travel distance, limited access to diabetes specialists, and mistrust/cultural barriers.<sup>6</sup> Rural AAs remain an understudied group, making it difficult to determine what approaches could enhance DM care. A recent meta-analysis of 28 lifestyle interventions for diabetes management reported most intervention studies were conducted in urban areas among non-Hispanic whites.<sup>7</sup> Given that health disparities in diabetes care and the cost of care continue to plague rural AAs, research is needed to test more effective interventions.

Although many challenges are faced by all individuals with DM, rural African Americans typically face additional problems of multiple illnesses, distance from health care, communication problems (language of subculture and/or lack of phone and/or email), limited financial resources, historic racial barriers, cultural preferences that may prevent seeking or accepting help, and a lack of available providers who offer culturally competent help with managing complex medical regimens.<sup>8–10</sup> For patients to manage diabetes effectively, they must maneuver within the health care system, which may have markedly different values and norms than the culture of their family, religion, ethnic group, and/or society as a whole.<sup>11</sup> For this reason, the US Department of Health and Human Services Office of Minority Health recommends activities to promote cultural competence or responsiveness in health care.

Given racial and ethnic disparities in diabetes prevalence and complication rates, researchers need to continue building the evidence base for culturally competent care prevention, education, and management.<sup>12–14</sup> The seriousness of health disparities in the US has led to development of special educational materials and programs designed for African Americans.<sup>15,16</sup> However, culturally appropriate materials alone are not sufficient to create a culturally tailored program for African Americans. Instead, the entire program should be congruent with the values and experiences of African Americans—be Afro-centric. Williams et al<sup>16</sup> recently summarized the literature about Afro-centric culture, noting it usually reflects the following norms: (1) substantive input from the local community, (2)

emphasizing group over individual needs, (3) multimodal methods of learning, (4) positive (avoid negative) approaches to problems, and (5) programs located in the community. When AAs have been intentionally recruited in other studies, it often means using pictures of AAs in recruitment materials and recruiting announcements being placed in AA churches. However, there is an absence in the literature of study protocols designed in an Afro-centric culturally sensitive manner. The purpose of the current study was to test the feasibility of conducting a community-based randomized controlled trial evaluating a culturally tailored community-based group diabetes self-management education (DSME) program among rural African Americans delivered at a rural intergenerational community center.

## Methods

### Study Design

A quasi-experimental design was used in which African Americans adults with type 2 diabetes living in a rural community were invited to participate. Volunteers were screened by telephone and at the community center and then enrolled by signing an informed consent. Inclusion criteria were that participants be age 18 or older, be African American or multiracial, be willing to attend 8 educational sessions, and have type 2 diabetes. A sample of 32 was recruited from a rural community using flyers and newspaper and radio ads. Over the course of the 2-year study, only 25 participants completed the study. The study was approved by the University Institutional Review Board.

### Description of the Culturally Tailored Intervention

The intervention is culturally tailored based on literature about Afro-centric culture<sup>16</sup> and adapted to the local region based on results of our pilot studies. Engaging participants in the learning process will be enhanced by showing videotaped stories of typical problems faced by this population and inviting participants to identify their own specific areas of need. Other strategies include providing key information with simple/culturally appropriate materials and learning activities, helping each participant set an individual goal, supporting participants as they make changes, involving a key family/friend as a supporter for achieving the goal, and problem solving to overcome barriers to goal achievement. In this group-delivered DSME, some of the sessions will involve the participation of the supportive family or friend to encourage shared learning and to enhance the ability of the support person to know how to be helpful, an approach affirmed as important to successful behavior change among urban African Americans in a similar program.<sup>17</sup>

### Theoretical Framework

A key element for diabetes self-management is developing a set of skills that promote problem solving for daily decisions to enhance glycemic control, prevent complications, and maintain balance between managing the disease and a good quality of life. One of the most frequently used conceptual frameworks for studying health behaviors is social cognitive theory (SCT), developed by Bandura<sup>18</sup> and adapted to diabetes care.<sup>19</sup> The key components of the theory are the person, his or her behavior, and the health outcome—each impacted by efficacy expectations for behavior and outcomes, and in turn impacted by information from many sources. Many studies have been conducted measuring diabetes self-efficacy as an

indicator that the person is gaining in confidence and expectations about taking actions required to manage diabetes. Extensive behavioral research about approaches to teaching diabetes self-management has shown that adults tend to benefit from an approach that empowers them with knowledge, problem-solving skills, and confidence for success in diabetes self-management.<sup>20–22</sup> Researchers also report that such an approach has been well received and is associated with improved clinical and behavioral outcomes among urban African Americans.<sup>23,24</sup> There is reason to believe using this framework would also be effective to conduct research among rural African Americans.

## Measures

Demographic variables assessed include age, gender, education, insurance coverage, race/ethnicity, zip code and description of region of residence, and receipt of diabetes education. Health status and management questions included length of time since diagnosis, history of complications and other current medical problems, current source of care, and prescribed treatment regimen.

Other measures included assessing a participant's knowledge about diabetes self-management by using the Spoken Knowledge in Low Literacy patients with Diabetes (SKILLD) questionnaire, a 10-item instrument.<sup>25</sup> Internal reliability is adequate at 0.72 (Kuder-Richardson value). Another measure used to assess self-efficacy among the participants was the Diabetes Empowerment Scale-Short Form (DES-SF),<sup>26</sup> derived from the extensively tested Diabetes Empowerment Scale (28 items), with an alpha reliability of 0.84 and content validity supported by a recent study and comparisons to the original 28-item instrument. Testing included samples of African Americans ([www.med.umich.edu/mdrtc/survey/request.htm](http://www.med.umich.edu/mdrtc/survey/request.htm)).

Problem-solving skills was measured using a measure of Diabetes Problem-Solving Skills (DPSS)<sup>20</sup>—observation, judgment, trial behavior, conclusions. The following elements of problem solving were scored based on the individual's self-reported specific goal for self-management of diabetes: able to identify personal barriers and facilitators to selected goal, able to problem solve barriers, able to negotiate realistic goal, able to brainstorm creative, concrete, and realistic strategies to achieve goal.<sup>27–29</sup> The DPSS is made up of 6 subscales that are scored 0 to 30, with higher scores indicating better problem solving. The subscales consist of (1) effective problem solving, (2) impulsive problem solving, (3) avoidant problem solving, (4) positive transfer of past experience/learning, (5) positive motivational factors, and (6) motivational factors. A total score is derived from a formula combining subscales to sum subscale averages and reverse score the negative sub-scales. The DPSS scale was validated, and an internal consistency reliability coefficient of .77 was established and ranged from .72 to .78 for subscales.<sup>20</sup>

## Glycemic Control/Hemoglobin A1C Blood Test

The gold standard for testing the adequacy of blood glucose management by the person with DM is the A1C, a measure of the amount of glucose bonded to the red blood cell (RBC), which reveals the average of the blood glucose over a period of 3 months (the 120-day life span of the RBC).<sup>30</sup> Achieving an A1C level of 7% (or below) is associated with a

significant reduction in the microvascular complications of DM, thus A1C is closely followed by clinicians.<sup>14</sup>

### **Cardiovascular Risk Factors: Serum Lipid Profile**

Blood was drawn by a nurse or laboratory technician every 6 months to determine if blood lipids were improving after the DSME intervention; blood pressure was measured by a nurse following the American Heart Association protocol to track trends in blood pressure, an important risk factor for developing microvascular complications of DM; body weight and height were measured and body mass index (BMI) calculated using ADA guidelines and trained personnel.

### **General Physical and Mental Health**

General physical and mental health was collected by using the Medical Outcome Study SF-12, which is an extensively used instrument developed by John Ware and associates at the Medical Outcomes Trust.<sup>31</sup> For purposes of this study, the overall score was used as the outcome variable. Stanford Diabetes Health Care Utilization Form<sup>32</sup> was used to assess the self-reported number of visits for health care for routine, urgent, and emergent care. The form consists of a 5-item questionnaire developed by the Stanford Patient Education Center. These are single items that are scored individually as a total sum number for each type of visit. In the current sample, the observed range for number of physician visits was 1 to 15, emergency department visits was 0 to 7, and nights hospitalized was 0 to 8.

### **Data Collection Procedures**

The intervention was culturally tailored based on results of an extensive literature review and from focus group research previously completed by this team.<sup>33-35</sup> Participants in this intervention study attended a series of 8 weekly sessions of 2 hours each, in groups of approximately 6 to 8 members, facilitated by a certified diabetes educator (CDE) and nurse practitioner/case manager. Sessions were loosely organized around the topics of the AADE 7 Self-Care Behaviors. Interactive learning activities were based on the topic for each session and involved active participation by all present. During each session, participants viewed a videotaped story (vignette) depicting an African American adult confronting a typical problem related to diabetes self-management. The 6 videotaped stories were selected from a series published by the University of Michigan Diabetes Research and Education Center.<sup>36</sup> The CDE and nurse case manager facilitated a discussion about the problem situation depicted and encouraged members of the group to problem solve for the characters in the vignette and then to apply the situation to their own lives and identify solutions. Data were collected on measures at baseline, 3 months after the intervention, and 12 months following the intervention. For these data collection time points, participants received appointment times by mail and a packet of surveys to return at their appointment. At the appointment, blood samples were drawn and survey questionnaires were completed if necessary and reviewed with study personnel.

## Data Analysis

To address the study's purpose of examining intervention changes over time in primary health outcomes, multilevel modeling was used to assess changes in mean levels of diabetes management behaviors and general physical and mental health and well-being variables. Statistical analysis involved testing differences between groups on key outcomes such as glycemic control (reducing A1C levels), improved cardiovascular risk factors, and improvements in general physical and mental health after the intervention (score on SF-12). In addition, mediating outcome variables such as knowledge about diabetes self-management, self-efficacy, changing self-management behaviors, use of problem-solving skills, achieving self-management goals, and appropriate use of the health care system was examined. Analyses were conducted using SPSS Software and pairwise analyses. *P* values less than .05 are reported as significant and *P* values less than .10 are reported as trends. Feasibility and satisfaction of the intervention were examined via descriptive statistics on retention rates and self-report items regarding the participants' perceptions of the intervention experience.

## Results

### Demographics

Demographic characteristics of the 25 enrolled participants at baseline who completed all assessments are described in Table 1. Participants' average age was 62 years (range, 37–81 years), and 80% were female. Close to 80% of participants had completed high school and about 40% had received any type of diabetes education. More than 70% had health insurance, although this finding is likely because of the age of the sample, as 36% were over the age of 65 and thus qualified for Medicare. Almost half of all participants were prescribed oral diabetes medications. In terms of meeting the American Diabetes Association recommendations for standards of care, the sample was high risk, with the majority of participants classified as overweight or obese and fewer than half meeting the guidelines for A1C levels, systolic and diastolic blood pressure, and high-density lipoprotein (HDL).

### Baseline Results and Postintervention Results at 3 Months and 1 Year Follow-up

Table 2 presents results of paired *t* tests and repeated measures ANOVA assessing the mean differences in the primary and intermediate outcome variables across the study assessments at 3 months post intervention. Our primary outcome measures include A1C levels, cardiovascular risk factors, and general physical and mental health. The mediating or intermediate variables included (1) knowledge about diabetes, (2) daily self-management actions, (3) diabetes-related self-efficacy, (4) diabetes self-care problem-solving ability, (5) success in attaining self-management goals, and (6) appropriate use of health care system. Results revealed that levels of A1C decreased, although not significantly, from post-intervention and 3-month follow-up: 8.0% to 7.6%,  $t(23) = 1.23$ ,  $P = .22$ , and decreased further at 12 months (7.4%). Additionally, systolic blood pressure and waist circumference decreased consistently over the 12-month period but not significantly (see Table 2).

However, BMI levels did significantly decrease for our participants over the first 3 months from 38.5 at baseline to 38.0 ( $P = .03$ ). It decreased further to 37.4 at month 12, but this was



not significant. In terms of daily self-management actions, level of exercise increased significantly post intervention to 3-month follow-up: 2.12 to 3.10 ( $P = .007$ ). Although there was a drop between 3 and 12 months, the final value was still consistently higher than at baseline. There were also significant increases in one's knowledge about diabetes at 3 months, 0.6 to 0.7 ( $P = .001$ ) and another increase 12 month post intervention, 0.8 ( $P = .001$ ). A similar improvement was seen in participants' attention to foot care: 4.2 to 4.9 ( $P = .013$ ) at 3 months post intervention and 5.7 ( $P = .001$ ) at 12-month follow-up.

With regards to self-efficacy, it appears that the greatest impact was soon after the intervention (3.99 to 4.25,  $P = .11$ ); however, there does appear to be an enduring effect as the level at 1 year is still higher than the baseline (4.18 vs 3.99). Among health and well-being variables, mental health well-being showed a significant change from post-intervention to 3-month follow-up, 39 to 43 ( $P = .05$ ), and it continued to show an increase over baseline at 42, although not significant ( $P = .09$ ). Physical health, slightly improved at 3 months post intervention, though not significant ( $P = .43$ ) although, at 12-month follow-up, participants' physical health had significantly declined ( $P = .06$ ) from baseline 43.3 compared to 39.6 at 12 months.

### Retention and Acceptability of the Intervention

The retention rate from baseline to the 1-year follow-up assessment was 78%. Of the 32 participants recruited, 25 have remained to complete the active intervention phase, which involves attending 8 weekly 2-hour sessions. Before the intervention and education classes began, 2 people dropped from the study because of work and school obligations during the timeframe the diabetes classes were being offered. The 5 remaining participants were lost to follow-up; these participants did not participate in any of the educational session. Due to several severe winter weather delays during the time period of recruitment for the current study, the overall retention rate was positive. The key member of the research team charged with retention was the nurse case manager, who continued to make monthly phone calls to promote diabetes self-management and encouraged participants to return for data collection.

During focus group interviews at the conclusion of the study, participants reported being satisfied with the culturally tailored diabetes education program (100%). All participants stated that they would do the program again if it was offered in the same community. Participants were all from the rural community, which typically does not provide group diabetes educational programs specifically geared toward African Americans.

### Discussion

In general, given the severity of the illness among this sample population, the outcomes across the time period of this study is encouraging. Findings demonstrate the conditions faced by participants in our study, who typically have had diabetes for many years (mean = 11, range, 1–38 years), yet only one-third have ever had diabetes classes, and about one-half have ever seen a dietician. All 32 participants also have hypertension, with only one-third under good control. Based on measures of body weight, BMI, and waist circumference, all participants are either overweight (10%) or obese (90%). Of particular concern is that A1C measures at baseline average 8.1% (range, 5.9%–14%). As a result, participants in the

current study were at high risk for developing complications of diabetes and have not previously received effective diabetes self-management education to reduce risks, prevent complications, and achieve a good quality of life by effective management of diabetes and hypertension.

Consistent with previous studies, the community-based culturally tailored education intervention was feasible and effective in that participants did show improved cardiovascular levels and self-care behaviors. Our results, similar to previous research, showed the importance of cultural factors and health beliefs, noting that providers need to elicit expectations and tailor interventions to health beliefs.<sup>37</sup> The results continue to highlight the importance of cultural factors and that being culturally sensitive in the design of the educational program is effective in reducing A1C levels over time. Similarly, a randomized controlled trial of 201 African Americans reported low rates of long-term maintenance for improved body weight and glycemic control after a community-based diabetes education program—a frequently noted problem reported in the literature<sup>38</sup> that current researchers confirmed as well. A more positive outcome was reported in the current study and confirmed by other researchers in a study of 488 patients from a federally qualified clinic, showing that underserved populations, even non-English-speaking people with high rates of depression, could be successful at setting and attaining goals for diabetes self-management with skillful coaching.<sup>39</sup> The current study also supports the finding that successful diabetes management requires effective education that is also acceptable to the population under study to ensure patients ultimately finish the intervention with the knowledge and the tools needed to engage in better day-to-day self-management activities.

The retention rate observed in this study was 78% for this hard to reach population, rural African Americans. Although a good retention rate, it is important to note that the 8-week educational session was conducted during the weekdays and not offered on the weekends, which may have prevented some participants from committing for the entire 8 weeks. However, once participants started the educational sessions, there was great attendance. It was only during the data collection time periods where participants did not show.

Despite the positive results shown in the current study, there are also a few limitations to note. First, the study did not include a control group. Due to the severe winter weather and delays in recruiting a sufficient number of participants to compose a group, some who were randomly assigned to the “immediate intervention” group had to wait for several weeks until there were enough people for the next group to begin. Thus the definition of “immediate intervention” versus “wait list control group” was abandoned. Statistical analyses revealed that although some participants waited longer than others, there were no significant differences between the groups. As a result, all participants were grouped together for analyses. Second, some of the key outcome variables did not show evidence of significant change across the assessments, although the change was in the right direction, except for physical health. This finding may be due to the small sample size and the timing of when the intervention was conducted. There were 2 holiday events during the assessment period, which have been known to influence eating habits and potentially limit physical health capabilities. Future studies should consider these limitations and examine a similar intervention with a larger sample and depending on the cultural group of interest, conduct



the intervention during spring and summer, when there are less weather-related events and fewer holidays that are associated with large meals. Future research should also consider the generalizability of their sample, given the current study is limited to rural African Americans in a culturally tailored diabetes self-management group intervention.

## Implications

It has clearly been shown that providing culturally sensitive DSME programs is an effective strategy to improve education and support for persons with type 2 diabetes.<sup>35,40–43</sup> Further development and understanding of how nurses and case managers can be used to address the needs of rural and remote residents, as well as for older persons (older than 60), which may increase the positive impact of the DSME on blood sugar levels over time. Results of this research will also help to inform clinicians and health policymakers as to the kinds of interventions effective in promoting better diabetes management to reduce complications and improve quality of life among African Americans who experience a high burden of disease. Findings from the study presented here suggest that in particular, rural African Americans are likely to benefit in terms of reduced cardiovascular risk, knowledge about diabetes, and their mental well-being, whereas further development of these programs is needed to extend this benefit to other groups.

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**Table 1**

Participant Demographics and Key Variables at Baseline for Completers (N = 25)

Continuous Variable	Mean (SD)
Age	61.92 (10.85)
Duration of diabetes	11 (range, 1–38)
Physician visits <sup>a</sup>	2.68 (1.89)
Glucose tests per week	4.94 (2.68)
Categorical Variables	Percentage
Male	20
Education	
Less than high school completion	24
High school graduate	52
College education	24
Received diabetes education	40
Health insured	76
Diabetes medication	
No medication	8
Oral medication	48
Insulin	20
Insulin + oral medication	24
American Diabetes Association Standard of Care Guidelines <sup>b</sup>	Percentage Meeting Criteria
Hemoglobin A1C < 7%	36
Systolic blood pressure < 130 mmHg	32
Diastolic blood pressure < 80 mmHg	36
Total cholesterol < 200 mg/dL	80
Low-density lipoprotein < 100 mg/dL	60
High-density lipoprotein, mg/dL (> 40 men, > 50 women)	28
Triglycerides < 150 mg/dL	72
Body mass index < 23 kg/m <sup>2</sup>	0
Waist circumference (= 90 cm men, = 80 cm women)	0

<sup>a</sup>In the past 6 months, how many times did you visit a physician?

<sup>b</sup>Adapted from the American Diabetes Association, Clinical Practice Guidelines.

**Table 2**  
 Mean Values (SDs) and Significance Tests for Outcome Measures at 3-month and 12-month Follow-up<sup>a</sup>

Variable	Baseline	3-month	P	12-month	P
<b>Primary outcomes</b>					
Hemoglobin A1C	7.96 (1.87)	7.59 (1.79)	.22	7.40 (1.32)	.26
Systolic blood pressure	139.64 (20.54)	134.46 (14.58)	.34	126.09 (13.14)**	.008
Diastolic blood pressure	81.88 (9.51)	80.79 (11.29)	.82	77.22 (11.05)	.109
Total cholesterol	166.52 (37.30)			168.61 (34.47)	.41
High-density lipoprotein	44.72 (11.47)			43.65 (12.14)	.88
Low-density lipoprotein	99.24 (28.91)			103.48 (29.08)	.17
Triglyceride	132.52 (68.95)			128.26 (50.79)	.54
Body mass index (BMI)	38.44 (7.94)	38.01 (8.24)*	.03	37.39 (8.29)	.30
Waist circumference (inches)	46.09 (6.40)	45.53 (6.40)	.11	45.38 (6.39)	.45
<b>Mediating outcomes</b>					
Diet: general	4.00 (1.94)	4.54 (1.47)	.11	4.46 (1.53)	.42
Diet: specific	3.90 (2.09)	4.25 (1.62)	.58	4.40 (1.47)	.24
Exercise	2.20 (1.84)	3.10 (2.19)**	.007	2.91 (2.47) <sup>+</sup>	.094
Glucose checks	4.94 (2.68)	5.08 (2.29)	.85	4.71 (2.81)	.69
Foot care	4.15 (1.94)	4.89 (1.77)*	.013	5.76 (1.76)**	.001
Medication adherence	6.72 (1.40)	6.83 (0.82)	.72	6.13 (2.36)	.33
Diabetes knowledge	.61 (.15)	.70 (0.10)**	.001	.76 (0.14)**	.001
Diabetes self-efficacy	3.99 (0.52)	4.25 (0.56)	.11	4.18 (0.65)	.22
Diabetes problem solving	19.34 (3.62)	20.42 (3.58)	.28	20.24 (4.08)	.23
<b>Health and well-being</b>					
SF-12 physical health	43.36 (11.01)	44.54 (8.90)	.43	39.59 (12.24) <sup>+</sup>	.06
SF-12 mental health	38.61 (10.30)	43.76 (7.02)*	.05	41.20 (7.47) <sup>+</sup>	.09

<sup>a</sup> N varies slightly across variables.

<sup>+</sup>  $P < .10$ .

\*  $P < .05$ .

$P < .10$   
\*\*

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