

# PREDICTORS OF RETENTION AMONG AFRICAN AMERICANS IN A RANDOMIZED CONTROLLED TRIAL TO TEST THE HEALTHY EATING AND ACTIVE LIVING IN THE SPIRIT (HEALS) INTERVENTION

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**Introduction:** Retention of racial/ethnic minority groups into research trials is necessary to fully understand and address health disparities. This study was conducted to identify participants' characteristics associated with retention of African Americans (AAs) in a randomized controlled trial (RCT) of a behavioral intervention.

**Methods:** Using data from an RCT conducted from 2009 to 2012 among AAs, participant-level factors were examined for associations with retention between three measurement points (ie, baseline, 3-month, and 12-month). Chi-square tests and logistic regression analyses were conducted to compare retained participants to those who were not retained in order to identify important predictors of retention.

**Results:** About 57% of participants (n=238) were retained at 12 months. Baseline characteristics that showed a statistically significant association with retention status were age, marital status, body mass index (BMI), intervention group, enrollment of a partner in the study, and perceived stress score (PSS). Multivariable logistic regression that adjusted for age, BMI, and PSS showed the odds of being retained among participants who enrolled with a partner was 2.95 (95% CI: 1.87-4.65) compared with participants who had no study partner enrolled. The odds of being retained among participants who were obese and morbidly obese were .32 and .27 (95% CI: .14-.74 and .11-.69), respectively, compared with participants who had normal weight.

**Conclusion:** Having a partner enrolled in behavioral interventions may improve retention of study participants. Researchers also need to be cognizant of participants'

## INTRODUCTION

Retaining racial, ethnic, and other underserved minorities into conventional clinic-based and other trials is known to be challenging.<sup>1-5</sup> Low rates of recruitment and retention compromise the ability of researchers to assess and address health disparities in the United States, especially among disadvantaged groups such as African Americans (AA).<sup>6</sup> Besides generally dismal recruitment rates, widely varying levels of attrition have been reported from intervention trials. This attrition rate ranges from 10% to 80%

depending on the study population, study period, and the intervention.<sup>7-10</sup>

Factors that have been identified by previous research studies as contributing to retention of AAs in randomized controlled trials (RCT) should be incorporated into study design and approaches. Previous studies showed that community-based participatory research (CBPR) approaches lead to increased recruitment and retention rates.<sup>11-15</sup> In fact, use of CBPR approaches to promote health is recognized as a critical strategy in addressing health inequities among socially disadvantaged and

obesity status and potentially target retention efforts toward these individuals. *Ethn Dis.* 2017;27(3):265-272; doi:10.18865/ed.27.3.265.

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marginalized communities.<sup>11,13,14</sup> CBPR-based recruitment strategies involve community engagement in the development and implementation of culturally appropriate interventions as well as the involvement of members of the target population in all aspects of the research (ie, study design, recruitment, implementation, evaluation, and reporting of findings).<sup>11</sup> Decentralized forms of CBPR involve recruitment of participants into the study and implementation of the intervention by the

retention rates as high as 77%, although there were still many “missed” assessment sessions.<sup>11</sup> This finding led to the hypothesis that individual-level factors might affect retention in RCTs among participants, particularly AAs. The main objective of this study was to identify individual characteristics associated with study retention among AA study participants.

## METHODS

Data for this study were gathered from an RCT to test the Healthy Eating and Active Living in the Spirit (HEALS) intervention conducted among AA churchgoers in and around Columbia, SC from 2009-2012.<sup>13</sup> Block randomization of 21 churches was performed by using social class and education to create two groups: the intervention group and control group. For ethical reasons and at the request of the community, participants in the control group could opt to receive the intervention at the end of the one-year period of the study; however, data were not collected during this time period.

After randomization of churches, recruitment of individuals took place. Details of the recruitment of participants, using a CBPR approach have been reported previously.<sup>11,13,21</sup> Individuals eligible to enroll in the study were AAs aged  $\geq 30$  years with no previous cancer diagnosis, or other unstable comorbidities. Participants in churches assigned to the intervention group engaged in 12 weekly then 9 monthly classes lasting about 1.5 hours per class. These sessions were aimed at improving diet and physical activity

behaviors while also reducing stress.<sup>13</sup>

Data collection occurred at three time points, and was usually conducted at the participating churches. The first data collection took place at the beginning of the study; the second took place three months following the start of the study (after the 12 weekly sessions); and the third took place one year after the start of the study (after the nine monthly sessions).

At each of the three time points, participants completed questionnaires, provided a blood sample and wore Body Media's SenseWear® physical activity monitors for 7 days. Blood was drawn and analyzed for inflammatory markers.<sup>13</sup> Selected variables included in this analysis came from questionnaires that included: a food frequency questionnaire (FFQ), Center for Epidemiologic Studies Depression (CESD), Perceived Stress Scale (PSS), demographics, health history, Multiethnic Identity Measure (MEIM), Pittsburgh Sleep Quality Index (PSQI) as well as questionnaires on social approval, desirability and support.

Participants randomized to the control group were slightly older than participants in the intervention group (mean age  $57.5 \pm 9.6$  vs  $54.2 \pm 10.8$  years). Although participants were generally well-educated (39% of intervention group and 44% of controls had completed college), intervention group participants were more likely than the control group to have less than a high school education (31% vs 14%). Overall, the majority of participants were women (80%), who were much less likely to be married compared with men (56% vs 91%). Individuals were, on average, obese (mean

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*The main objective of this study was to identify individual characteristics associated with study retention among AA study participants.*

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partnering site and not study staff.<sup>11</sup>

Factors that have been identified as influencing retention in weight-loss trials include age, sex, race, distance to intervention site, cognitive impairment, occupational status, education, socioeconomic status, smoking, physical activity level and depression.<sup>9,16-19</sup> A review of 50 studies of AAs in clinical trials identified barriers to retention including lack of a study partner, lower educational level, and lack of compensation.<sup>20</sup>

An earlier study conducted by our team found that a decentralized CBPR approach led to intervention

BMI of intervention group=33.6  $\pm$  7.6, control group=32.6  $\pm$  6.3). Details about participants' recruitment and sociodemographic findings have been previously reported.<sup>13</sup>

### Exposure and Outcome Variables

For the purpose of this study, the main outcome variable was retention status defined as participation in all three data collection time points (baseline, three months and twelve months). Retention status was dichotomized into retained (attended all three data collections) and not retained (attended only one or two of the three data collections). Baseline characteristics examined with respect to retention status were age (years), sex (male, female), educational status (high school graduate or less, some college, completed college, and more than college education), marital status (single, divorced/separated, widowed, married), and employment status (unemployed, full-time, part-time, retired).

Body mass index (BMI) based on measured height and weight (kg/m<sup>2</sup>) was also examined and categorized using the following groupings: normal weight (18.5 to <25 kg/m<sup>2</sup>; overweight (25 to <30kg/m<sup>2</sup>; obese (30 to <40 kg/m<sup>2</sup>; and morbidly obese (>40 kg/m<sup>2</sup>). Body fat and lean body mass were obtained through bioelectrical impedance assessment (BIA).<sup>13,22</sup> Other baseline characteristics examined were: intervention group (whether the participant was in the intervention or control group), road network distance from home address to data collection sites' address (miles) utilizing Arc-

GIS Version 10.1 (ESRI, Redlands, CA), and enrollment of a partner in the study. Enrollment of a partner was examined and categorized as "yes" when the participant's partner was enrolled and "no" when no partner was enrolled (partnering was a design element to facilitate support; however, not all participants were able to enroll a partner). Perceived stress measured as Perceived Stress Score (PSS) and presence of depressive symptoms were also examined. A PSS of  $\leq 20$  was considered low stress while a PSS of  $>20$  was considered high stress.<sup>23</sup> Depressive symptomology was dichotomized into "yes" when the CESD-10 score was  $>10$  and "no" when  $\leq 10$ .<sup>24</sup>

### Sample Size

Of the 412 participants, 238 reported for data collection at time points 1,2 and 3 and were classified as retained. The remaining participants (n=174) were classified as not retained and included participants who attended time point 1 only, time point 2 only, time point 3 only, time points 1 and 2 only and time points 1 and 3 only.

### Analysis

SAS<sup>®</sup> Version 9.4 (Cary, NC) was utilized to compute chi-square tests and to fit logistic regressions in order to compare retained to not-retained participants with the goal of identifying important predictors of retention. Bivariate analyses of baseline characteristics stratified by retention status were examined to identify associations with retention, and are presented as crude odds ratios (OR) with 95% confidence intervals (95%

CI). In the bivariate analyses, participants' characteristics that were significantly associated with retention were age, distance, marital status, body mass index, having partner enrolled in the study and stress.

A model-building procedure was used to fit the best model. Variable selection began as a series of bivariate analyses (ie, exposure + potential covariate) where covariates with a  $P \leq .20$  were added to a "full" model.<sup>25-27</sup> The covariates that were entered into the first model (full model) were age, BMI, intervention group, distance to data collection site, partner status, depression symptoms, and employment status. Backward elimination procedures were used to develop "final" models that included all covariates that were statistically significant ( $P < .05$ ) The Likelihood Ratio Test (LRT) was also performed to assess the difference between models as variables were removed. The first variable that was taken out was depression ( $P = .84$ ) followed by employment status ( $P = .50$ ), and finally distance to data collection site ( $P = .30$ ). The final model was based on  $P$  significant at an alpha  $< .05$  level. The final model included age, BMI, PSS, Intervention group and enrollment status of partner in the study.

Two-way interactions were assessed between the four variables in the final best-fitting model (BMI\*Intervention group, BMI\*Partner, BMI\*Stress, Intervention group\*Partner, Intervention group\*Stress, Partner\*Stress). There was statistically significant interaction between BMI and stress ( $P = .04$ ); however, further stratification by BMI and stress yielded unstable esti-

mates because of the small sample size in some cells. Complete analysis of all observations was carried out because there were very few missing observations in most of the predictor variables and the final, ie, the best fitting model utilized 374 out of a total of 412 respondents (91% of all observations).

## RESULTS

More than half (57%, n=238) of participants were retained for all three data collection time points. Table 1 shows the frequency distribution of baseline characteristics of participants by their retention status. Baseline

characteristics significantly associated with retention status in bivariate analyses include age, employment, BMI, intervention group, partner enrolled in the study, and PSS score.

Simple logistic regression analyses showed that participants who had a partner enrolled in the study

**Table 1. Descriptive baseline characteristics of participants and the odds of being retained in the HEALS study, Columbia SC, 2009-2012**

	Characteristic	Retained, n=238 <sup>a</sup>	Not retained, n=174	Crude OR (95% CI)
Age, mean ± SD		57.27 ± 11.08	51.58 ± 11.90	1.04 (1.03-1.06)
Age	<41 years	20 (37.04)	34 (62.96)	reference
	41-50 years	45 (45.00)	55 (55.00)	1.39 (.71-2.74)
	51-60 years	81 (66.39)	41 (33.61)	3.36 (1.72-6.55)
	>60 years	92 (67.15)	45 (32.85)	3.48 (1.80-6.71)
Distance, mean ± SD		8.52 ± 9.23	10.41 ± 10.26	.98 (.96-1.00)
Distance	≥5 miles	116 (52.73)	104 (47.27)	reference
	<5 miles	114 (63.69)	65 (36.31)	1.57 (1.05-2.35)
Sex	Female	193 (58.84)	135 (41.16)	reference
	Male	45 (52.94)	40 (47.06)	.79 (.49-1.27)
Educational status	≤High school	43 (59.72)	29 (40.28)	reference
	Some college	76 (53.90)	65 (46.10)	.79 (.44-1.40)
	Completed college	60 (61.86)	37 (38.14)	1.09 (.59-2.04)
	>College	57 (64.77)	31 (35.23)	1.24 (.65-2.36)
Marital status	Single	26 (49.06)	27 (50.94)	reference
	Divorced/Separated	40 (62.50)	24 (37.50)	1.73 (.83-3.62)
	Widowed	31 (73.81)	11 (26.19)	2.93 (1.22-7.01)
	Married	140 (58.33)	100 (41.67)	1.45 (.80-2.64)
Employment	Unemployed	20 (51.28)	19 (48.72)	reference
	Employed full time	111 (53.62)	96 (46.38)	1.10 (.55-2.18)
	Employed part time	22 (66.67)	11 (33.33)	1.90 (.73-4.95)
	Retired	83 (68.60)	38 (31.40)	2.08 (.99-4.33)
Body mass index, kg/m <sup>2</sup>	Normal (18.5 to <25kg/m <sup>2</sup> )	35 (23.91)	11 (23.91)	reference
	Overweight (25 to <30 kg/m <sup>2</sup> )	57 (64.77)	31 (35.23)	.58 (.26-1.29)
	Obese (30 to <40 kg/m <sup>2</sup> )	109 (55.33)	88 (44.67)	.39 (.19-.81)
	Morbidly obese (>40 kg/m <sup>2</sup> )	35 (50.72)	34 (49.28)	.32 (.14-.74)
Intervention group	Intervention	111 (49.78)	112 (50.22)	reference
	Control	127 (66.84)	63 (33.16)	2.03 (1.36-3.04)
Partner enrolled in study	No	68 (40.96)	98 (59.04)	reference
	Yes	170 (68.83)	77 (31.17)	3.18 (2.11-4.79)
Perceived Stress Score <sup>b</sup>	High stress (> 20)	27 (43.55)	35 (56.45)	reference
	Low stress (≤ 20)	199 (62.78)	118 (37.22)	2.19 (1.26-3.79)
Depressive symptoms <sup>c</sup>	Depressive symptoms	39 (48.75)	41 (51.25)	reference
	No depressive symptoms	183 (61.00)	117 (39.00)	1.64 (1.00-2.70)

Data are n (%) unless indicated otherwise.

a. The main outcome variable (retained) was defined as those participants who attended all three time points while participants who missed either one or two of the time points were classified as not retained.

b. Perceived Stress Scale used was measured by the Perceived Stress Scale 10 by MacArthur Research Network. A stress score of ≤20 was considered as low stress while a stress score of >20 was considered as high stress.

c. Depression was assessed using the Center for Epidemiological Studies Depression (CESD-10) scale. Depression symptom was dichotomized into depressive symptoms when the score was >10 and no depressive symptoms when ≤10.

were more likely to be retained. The mean age among participants who were retained at all time points was higher than the mean age of participants who were not retained. Participants with higher educational attainment had a higher likelihood of being retained. Participants with higher BMI were less likely to be retained, with morbidly obese participants being the least likely of the BMI groups to be retained (Table 2).

Multivariable logistic regression (Table 2) showed that the odds of being retained among participants who had a partner enrolled in the study was three times higher (OR = 2.99, 95% CI: 1.89-4.72) than among participants who had no partner after adjusting for age, BMI, intervention group, and PSS score. The odds of being retained among participants who were obese and morbidly obese were .36 and .29 (95% CI: .16-.82 and .12-.73), respectively, compared with participants classified as normal weight. The odds of being retained among participants who were aged 51-60 years and aged >60 years were 2.84 and 2.40 (95% CI: 1.33-6.06 and 1.14-5.03, respectively, compared with participants aged <41 years in the multivariable model (Table 2). PSS score did not have a statistically significant association with retention status in this analysis.

## DISCUSSION

We found that overall retention in this study, defined as attending all three data collection time points, was 57%. This is on the low end of the range of retention rates reported by

**Table 2. Multivariable logistic regression<sup>a</sup> of participants' characteristics associated with retention of participants**

	Multivariable logistic regression <sup>a</sup> Adjusted OR (95% CI)
Age	
<41 years	reference
41-50 years	1.36 (.63-2.89)
51-60 years	2.84 (1.33-6.06)
>60 year	2.40 (1.14-5.03)
Body mass index(kg/m <sup>2</sup> )	
Normal (18.5-24.99kg/m <sup>2</sup> )	reference
Overweight (25-29.99 kg/m <sup>2</sup> )	.47 (.19-1.15)
Obese (30-39.99 kg/m <sup>2</sup> )	.36 (.16-.82)
Morbidly obese (>40.00 kg/m <sup>2</sup> )	.29 (.12-.73)
Perceived Stress Score <sup>b</sup>	
High stress(>20)	reference
Low stress(≤20)	1.70 (.90-3.10)
Intervention group	
Intervention	reference
Control	1.44 (.91-2.27)
Partner enrolled in study	
No	reference
Yes	2.99 (1.89-4.72)

a. Adjusted for body mass index, age, perceived stress score and partner enrolled in the study.

b. Perceived Stress Scale used was measured by the Perceived Stress Scale 10 by MacArthur Research Network. A stress score of ≤20 was considered as low stress while a stress score of >20 was considered as high stress.

other minority population studies in the United States, where rates range from 56% - 90%.<sup>4,28-31</sup> Warner et al found that 56.2% of participants in a weight-loss trial completed all four data collection time points evenly spaced at six months interval.<sup>31</sup> We found that control group allocation, normal BMI, having a partner enrolled in study, and low levels of stress (at least in crude analyses) were associated with increased retention.

The finding that participants who had a partner enrolled in the study were about three times more likely than participants without a partner to be retained has important implications for behavioral trials in which recruitment of partners into the study can be incorporated into the study design. Having a partner enrolled in

the study is a crude measure of social support. However, future studies are needed to examine nuances of social support such as type of support provided (eg, emotional or instrumental) and whether all support coming from the partner is positive.

Participants with higher baseline BMI were less likely to be retained. This is similar to previous studies in which higher baseline BMI was a predictor of attrition.<sup>17,32</sup> One reason why obese participants may be less likely to be retained is because of the stigma associated with being overweight and obese, especially within trials that include diet and physical activity behavior change.<sup>33</sup> One study also suggested that weight loss within the first two weeks of studies predicted retention.<sup>19</sup> While weight loss was

not a goal of this particular study, the addition of tracking weight or other observable changes may help participants who are obese be retained in lifestyle behavior change studies.

The odds of being retained among participants with low stress (PSS score of <20) was about two times as likely when compared with those with high stress level though the effect size decreased and became non-significant in the multivariable logistic analysis. Future studies with larger sample sizes and longer-term endpoints

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*We found that control group allocation, normal BMI, having a partner enrolled in study, and low levels of stress (at least in crude analyses) were associated with increased retention.*

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should test whether incorporation of stress reduction strategies encourages retention among AAs. A previous study showed that three one-on-one educational sessions were successful in reduction of stress among AA women.<sup>34</sup> Our current study found that participants in the intervention group were less likely to be retained compared with those in the control group. This is similar to a finding among minorities whereby intervention participants were less likely to

complete the 24-month visit than those in the usual/control group.<sup>31</sup>

One strength of this study is the availability of a wide range of covariates that were utilized in the analysis. To our knowledge, this is the first study that was able to identify the role of enrolling a partner and the ability it may have in determining retention of AAs in RCTs. Also, in assessing the role of obesity, we have identified obesity as a predictor of low retention. Limitations of this study include that it was conducted over a relatively short one-year period; and because of a relatively small sample size, we could not conduct sub-group analyses to assess the interactions between stress and BMI. Additionally, due to the slow development of both increasing BMI and increasing stress, examination of interactions between these two variables may require studies with longer follow-up time. As noted above, our assessment of partner status is a crude measure of social support, but the nuances of social support that could increase retention should be examined in future studies.

## CONCLUSION

In conclusion, having a partner involved in behavioral trials may be a good strategy to improve retention. Ironically, persons who are categorized as obese and morbidly obese, who potentially could have benefited the most from the HEALS intervention, were less likely to stay in the program. It would be important to understand the reason for the lack of retention among obese and morbidly obese individuals. Future stud-

ies are needed to elucidate whether this lack of retention could be due to infirmity, embarrassment or low self-efficacy, or discouragement based on perceived success factors (eg, lack of weight loss during trial). Examination of these variables as well as the interaction between BMI and stress and the more nuanced role of social support should be examined in studies with longer follow-up to add to our understanding of retention, especially the retention of AAs.

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## COMPLIANCE WITH ETHICAL STANDARDS

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**Research involving human participants:** Our research was approved by the University of South Carolina's institutional review board and all procedures followed were in accordance with the ethical standards of the IRB and the Helsinki Declaration of 1975, as revised in 2000.

**Informed Consent:** Informed consent was obtained from all participants included in this study.

CONFLICT OF INTEREST

No conflicts of interest to report.

AUTHOR CONTRIBUTIONS

Research concept and design: Babatunde, Adams, Eberth, Davis, Hurley, Brandt, Hebert; Acquisition of data: Babatunde, Adams, Wirth, Davis, Drayton, Hurley, Brandt, Hebert; Data analysis and interpretation: Babatunde, Adams, Wirth, Eberth, Sofge, Choi, Harmon, Drayton, Hurley, Armstead, Hebert; Manuscript draft: Babatunde, Adams, Wirth, Eberth, Sofge, Choi, Harmon, Hurley, Brandt, Armstead, Hebert; Statistical expertise: Babatunde, Adams, Wirth, Eberth, Sofge, Hurley, Hebert; Acquisition of funding: Adams, Brandt, Hebert; Administrative: Babatunde, Adams, Eberth, Sofge, Choi, Harmon, Davis, Drayton, Brandt, Armstead, Hebert; Supervision: Adams, Drayton, Hurley, Hebert

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