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Outcomes from the Body & Soul Clinical Trials Project: A university-church partnership to improve African American enrollment in a clinical trial registry

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Abstract

Objectives—Historically, African Americans have been underrepresented in clinical trials (CTs) compared to whites. A growing number of research institutions have created CT registries to match volunteers with appropriate studies. In a sample of 745 African Americans from 16 churches, we tested the impact of a culturally tailored intervention aimed at increasing enrollment in a university-based CT registry.

Methods—Half of the churches received a culturally tailored CT education program (intervention) and half of the churches received a program about healthy eating (comparison). The main outcomes were the odds of posttest self-reported enrollment and verified enrollment. Using linear regression, posttest willingness to participate in a CT was also assessed.

Results—Odds of verified enrollment were higher in the intervention than comparison group (OR= 2.95, 95% CI: 1.33–6.5, $p=0.01$). Posttest self-reported enrollment in the registry was also higher among the intervention group than comparison group members (OR=1.94, 95% CI: 1.08–3.47, $p=0.03$). Willingness to participate in a future CT was higher in the intervention group ($\beta=0.74$, $p=0.02$).

Conclusions—A culturally tailored education program about CTs can increase enrollment of African Americans in a university-based clinical trials registry.

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Informed Consent and Patient Details

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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Practice implications—Community engagement and health education workshops may improve minority CT enrollment over time.

Keywords

African Americans; clinical trials; registry; enrollment; minority; research

1. Introduction

Clinical trials (CTs) are the primary mechanism by which new methods of screening, prevention, diagnosis, or treatment of disease are developed and tested. In addition to benefitting society at large, CTs may benefit individual volunteers by providing access to new treatments before they become available to the general public. Since 1993, the NIH has required that all sponsored research include adequate representation of women and minority groups [1]; however, participation of African Americans (AAs) in CTs remains low [2, 3]. Without adequate representation of AAs and other minorities in CTs, it is impossible to know if therapies will work equally well across populations and how, if at all, progression of disease may differ by racial/ethnic subgroup.

Over the last 10 years, the use of registries as a method to recruit study participants has grown. RegistryMatch.org was the first national registry to promote clinical trials across NIH-funded Clinical and Translational Science Award (CTSA) programs [4]. A small number of research institutions have created local registries to match potential volunteers with relevant clinical trials [5]. These newer “opt-in” registries allow healthy volunteers and patients with health conditions to proactively enroll in the registry. Once a profile is created, members of the registry begin receiving “personalized study recommendations,”[6] thus eliminating the need for health care providers to serve as gatekeepers.

Commonly reported reasons for lower CT participation among AAs include distrust of health care institutions, fear of experimentation, lack of awareness of CTs and how to find them, and limited representation of minority investigators [7–10]. Logistical factors such as transportation, protocol design, and lack of social support may also impact participation [11]. There is a growing body of evidence showing that minorities are just as willing to participate in health research as their white counterparts when provided with a culturally appropriate opportunity or invitation [12, 13]. Although the predictors of CT registry participation have not been adequately examined, many of the same factors associated with CT participation are likely to be associated with registry use among AAs.

Previous efforts to improve the CT knowledge of AAs have largely focused on building trust or addressing the history of medical abuse in the AA community [14, 15]; however, relatively little has been done to investigate the best strategies for improving awareness of local CT registries. More specifically, the role of faith-based interventions as a means to enhance minority participation in CTs has not been adequately explored. Faith based interventions have been conducted around a variety of health issues such as healthy eating and physical activity [16–21]. However, a faith-based setting has not been used as a vehicle to enroll AAs in a CT registry. To assess the efficacy of a CTs education program in a faith

based setting, we collaborated with black churches in Southeast Michigan to implement the Body & Soul Clinical Trials Project.

The primary aim of this study was to examine the effect of a culturally tailored CTs education program on church members' enrollment in the University of Michigan Clinical Studies Registry.

2. Methods

Formative Research

Prior to recruiting churches, a pastors' advisory board (PAB) was created to provide feedback about what would be feasible and appropriate in their churches. The PAB was comprised of clergy serving as head pastors or support staff. The group included five men and two women, three with Master of Divinity degrees, and one with a PhD. All clergy were from local predominantly AA Christian churches and represented the Baptist, Apostolic, African Methodist Episcopal, and Free Methodist denominations. The PAB met quarterly in the first year of the project, then twice a year after that. The PAB provided feedback on several aspects including content for recruitment materials, content for our CTs video and educational workshops, pre-test and post-test survey items, and strategies for successful recruitment and retention. At each PAB meeting, breakfast was served and a \$50 Visa gift card was given in return for the pastors' time and feedback.

Additionally, a focus group comprised of 10 church members (three men and seven women) from churches in the Detroit Metro area was conducted in August of 2011. The group provided feedback on the survey tool, recruitment materials, and specific points that should be covered in the educational materials for healthy eating and CT education (e.g., the top 10 causes of death for AAs, healthier ways to cook soul food, and protections for research participants).

2.1 Church Recruitment

Church recruitment began in July of 2011 with the mailing of an introductory letter and a brochure to approximately 200 African American churches in Southeast Michigan, all of which are in 60 mile radius of the registry housed at the University of Michigan in Ann Arbor. This mailing was followed by telephone calls and e-mails with interested pastors or health ministry members, and when possible, an in-person meeting. After personal contact was made with the pastor, both the pastor and designated church coordinator signed a commitment agreement that outlined roles and responsibilities for the church and the study team.

Power calculations assumed an enrollment rate in comparison churches of 5%–10% and 10%–20% among intervention churches. Due to the cluster randomized design we needed to account for the effect of sampling individuals from clusters (churches) rather than randomly sampling individuals from the population [22]. This required computing a Variance Inflation Factor based on the Intraclass Correlation (ICC). The precise ICC of enrollment was not known; however, based on our prior studies of other health behaviors in churches [17, 23–25] we estimated an ICC of around 0.02. With these parameters and 40 individuals per

church, power of 0.80 and alpha of 0.05, we required 6 churches per condition. To account for possible church attrition we oversampled churches by 2 per arm, leaving 8 churches per arm. We randomly assigned churches to the comparison group or intervention group. We classified churches into three size categories for purposes of pair matching; small (<200 members), medium (200–400 members), and large (>400 members) churches.

2.2 Participant Recruitment

Church coordinators were given a goal of recruiting 40 to 60 members from their church. The recruitment strategy was left to the discretion of the coordinators; however, we provided promotional flyers for display around the church and talking points about the study. Coordinators were encouraged to recruit individuals by making church announcements, posting information on bulletin boards, and by making appeals to groups within the church that met regularly (e.g., choir, bible study, and women's ministry).

2.3 Comparison Group Protocol

The comparison churches received an adapted version of the national Body & Soul program, which promotes fruit and vegetable intake and is tailored for AA church members. The original Body and Soul program used four program pillars: pastoral support, church activities, church environment, and peer counseling. At the suggestion of our Pastors' Advisory Board, we added information on heart disease, cancer, type 2 diabetes, stress management, how to read nutrition labels, and healthy eating recommendations since many of their church members suffer from chronic diseases. A website was created for the comparison group with general information about CTs and medical research. The information presented on the comparison group website was taken directly from the University of Michigan Clinical Studies web page and was not tailored for AAs.

2.4 Intervention Group Protocol

The intervention churches received a CTs education module that was developed from materials from the National Medical Association's Project IMPACT campaign, feedback from our Pastors Advisory Board, and input from colleagues at the University of Michigan Clinical Studies Registry (UMClinicalStudies.org). The goals of the tailored CTs module were to: 1) Raise awareness about CTs, 2) Describe the research process, and 3) Describe the role of race and culture in medical research. Given the sensitive nature of medical research for some AAs, in addition to addressing issues related to racism and medical exploitation we also provided messages about the potential positive reasons why AAs may want to participate in research and how diversity in CTs may help improve the health of AAs. Other topics in the module included epigenetics (the concept that the human genome dynamically responds to social and environmental factors such as toxins and stress), common terminology (e.g., informed consent, randomization), the process for developing new therapies (e.g., phase 1–4), and study participant rights and protections.

Participants in the intervention group watched a short, locally produced video about CTs that highlighted the need for more AAs in medical research. This video was shown at the first data collection session *after* the baseline surveys were completed. The video featured three local African-American clergy members in Southeast Michigan, three African-

American physicians, and one African-American CT participant from the University of Michigan Health System. A website was created for the intervention group churches with CT and medical research information adapted from the National Medical Association's Project IMPACT (<http://impact.nmanet.org/>). Lastly, intervention church members received two e-mail invitations to join the registry. Those without e-mail addresses received a hard copy letter with the same information.

2.5 Educational Workshops for Comparison and Intervention Churches

Each church received one workshop, which focused on healthy eating for comparison churches and CTs for intervention churches. All workshops were conducted at the churches and lasted approximately one hour. Members of the research team facilitated the workshops. Group-tailored, culturally sensitive messages were implemented in both groups. For example, we used statistics specific to AAs, appeals to spiritual motivations, and images of AAs in the educational materials.

2.6 Baseline and Post-Test Data Collections

All study participants completed a self-administered baseline survey and a post-test survey approximately 1-year from baseline. The baseline survey was 13 pages long, contained 66 questions, and took participants approximately 15–25 minutes to complete. The post-test survey was 17 pages long, contained 88 questions, and took participants approximately 20–30 minutes to complete. Baseline and post-test data collections were conducted in a group setting in the churches' fellowship hall. Graduate level research assistants were present at all data collection sessions to distribute and collect surveys and to answer questions. Most participants completed the surveys on Sunday afternoons, immediately following the church service. However in some cases, at the request of the study coordinator, participants completed surveys in a group setting on a different day of the week, or completed the survey at home if they could not attend the pre-scheduled group session. In these cases, the survey was returned to the church coordinator in a sealed envelope and later picked up by one of the research assistants.

All participants completed the pen and paper survey independently unless they requested assistance from the study team or church coordinator. For example, a few participants (less than 10) had limited reading skills and/or mobility issues with their hands. In these cases, research assistants read the survey questions to the participant and/or filled out the form on their behalf. Refreshments were provided during each data collection event, and participants were given \$10 in cash for completing the baseline and the post-test survey (for a total of \$20).

2.7 Survey

The survey assessed past participation in CTs and future willingness to participate in a CT, as well as knowledge, attitudes, and beliefs about medical research and clinical trials.

2.8 Dependent Variables

The primary outcomes were verified enrollment and self-reported enrollment (evaluated separately) in the University of Michigan Clinical Studies Registry and willingness to

participate in a CT in the future. Self-reported enrollment and willingness to participate in a CT were obtained from the posttest questionnaire.

2.9 Verified Enrollment

The registry keeper verified enrollment by tracking phone, mailed, or website registrations from January 1, 2012 – June 30, 2013. Mailed enrollment forms were identified by the project logo placement in upper right corner of the form. If a participant called the 800 number, the registry keeper asked how the caller heard about the registry. If “church” was mentioned as the method of hearing about the registry, the keeper then checked the caller’s church name against the list of churches in the Body & Soul Clinical Trials Project. Website enrollment was tracked through unique URLs created for the intervention and comparison churches. The registry keeper and web master provided the study team with a list of church members who enrolled by mail, phone, or website. Church members were then matched to their baseline questionnaire. The informed consent document noted that participant surveys and enrollment in the registry would be linked.

2.10 Posttest Self-Reported Enrollment

This item was worded as, “Have you ever signed up for the University of Michigan Clinical Studies Registry (aka ENGAGE or UMClinicalStudies.org)?” Response options were yes and no. This same question was asked both at baseline and at posttest.

2.11 Willingness to Participate in a Clinical Trial

Willingness to participate in a CT was assessed at baseline and posttest by asking, “On a scale from 1 to 10, with 1 being not at all willing and 10 being very willing, how willing would you be to participate in a clinical trial in the future?” Response anchors were; not at all willing, somewhat unwilling, neutral, somewhat willing, and very willing.

2.12 Independent Variables

2.13 Demographics

Demographic measures included age (categorized as 18–39, 40–59, and 60+); sex (male or female); household income (categorized as \$40K, \$40,001–\$80K, and \$80,001+); education (categorized as <4 year college degree and 4 year college degree); and work status (categorized as not working, part-time, and full-time).

2.14 Data Analysis

Self-reported enrollment and verified enrollment, as well as post-test willingness to participate in a future CT were the dependent variables, with church included as a random effect to adjust for clustering within churches. All procedures were run within SPSS version 21 using the MIXED procedure to assess willingness to participate in a CT (linear) and the GENLINMIXED procedure used to assess self-reported and verified enrollment (binary). Odds ratios and confidence intervals are reported for binary variables and adjusted betas are reported for willingness. Cases with missing data were removed using list-wise deletion.

3. Results

As shown in Table 1, intervention church members were significantly older than those in the comparison group (51 vs. 45 years respectively). With regard to education and household income, the intervention group had a significantly higher percentage of members with 4 year college degrees (42% vs. 30%), and those who reported more than \$80K per year (25% vs. 13%) than comparison participants. In terms of sex, work status, and baseline willingness to participate in a CT, there was no significant difference between intervention and comparison church members.

3.1 Post-Test Willingness to Participate in a Clinical Trial

As shown in table 2, post-test willingness to participate in a future CT was higher in the intervention churches compared to comparison churches ($\beta=.74$, $p=.02$) after controlling for baseline willingness, age, sex, household income, education, and work status. Regarding income, those with a household income of \$40,001 – \$80,000, were significantly more willing to participate in a CT compared to those with an income $\leq$ \$40K ($\beta=.54$, 95% CI: .02 – 1.05, $p=.02$). Compared to those with a baseline willingness <7 , those with a score of 7 were significantly more willing at post-test to participate in a CT ($\beta=1.9$, 95% CI: 1.48 – 2.34, $p<0.001$). Finally, compared to those aged 18–39, participants aged 60+ were significantly less willing to participate in a CT ($\beta= -0.8$, 95% CI: $-1.42 - -0.19$, $p=0.01$).

3.2 Posttest Self-Reported Enrollment in Registry

As shown in table 3, after controlling for baseline self-reported enrollment, sex, age, education, work status, and household income, those in the intervention group were significantly more likely to report enrolling in the registry than comparison group members (OR=1.94, 95% CI: 1.08–3.47, $p=.03$). The other significant predictors were age and baseline self-reported enrollment in the registry. Compared to 18–39 year olds, those aged 40–59 had higher odds of self-reported enrollment in the registry (OR=3.16, 95% CI: 1.38 – 7.26, $p=.01$). Compared to those who reported no to having enrolled in the registry at baseline, those who reported yes at baseline had higher odds of posttest self-reported enrollment in the registry (OR= 7.74, 95% CI: 3.11 – 19.3, $p<0.001$).

3.3 Verified Enrollment

As shown in Table 4, after controlling for baseline self-reported enrollment, sex, age, education, work status, and household income, the odds of verified enrollment were significantly higher in the intervention than the comparison group (OR= 2.95, 95% CI: 1.32 – 6.52, $p=.01$). In terms of demographic predictors, compared to those not working, church members with full-time work status had lower odds of verified enrollment in the registry (OR= .42, 95% CI: .19–.94, $p=.03$).

4. Discussion and Conclusion

4.1 Discussion

The goal of the Body & Soul Clinical Trial project was to examine the effect of a culturally tailored CT program on willingness to participate in a future CT and enrollment in a

university-based CT registry. To our knowledge, this was the first randomized intervention trial designed to increase enrollment in a university-based registry. By the end of the project, 60 participants had verified enrollment in the registry, with church members in the intervention group having higher odds of verified enrollment. Self-reported enrollment was also significantly higher in the intervention churches. These effects are likely attributed to the culturally tailored CT education program that the church members in the intervention group received, which included a locally produced video created for this project that featured AA doctors, pastors, and a CT participant from a diabetes study. Posttest willingness to participate in future CT higher was also significantly higher for church members in the intervention group. Additionally, independent of treatment condition, church members with a household income of \$40,001 – \$80,000 compared to those with a household income of less than \$40K had higher posttest willingness to participate in a CT. More research is needed to better understand the relationship between household income and CT participation.

For the full study sample, church members between the ages of 40–59 had higher odds of *self-reported* enrollment into the registry. This group may have been more likely to utilize health services due to existing health conditions or routine preventative screenings (e.g., mammograms, colonoscopy) that lead to increased exposure to CT opportunities. Additionally, among church members with *verified* enrollment in the registry, those with full-time work status had lower odds of enrolling in the registry. This finding is not surprising given that CTs can be time consuming and physically demanding, hence those who work full-time may find it difficult to participate in studies that require frequent visits or procedures that need to be conducted during regular business hours.

There was a discrepancy between *self-reported* enrollment (n=76) and *verified* enrollment (n=60). Using chi square tests, we found 53% agreement between those who self-reported a yes to enrolling in the registry and those who had a verified yes for enrolling in the registry. These discrepancies may be due to several factors. First, it is possible that some church members joined the registry via the general University of Michigan website or by returning a standard enrollment form disseminated to the public at community events (versus the project branded forms disseminated at the data collection sessions at the churches). This would result in a positive self-report and a negative verified report. Additionally, church members were asked whether they had *ever* joined our registry on both the pretest and posttest. While we did control for baseline self-reported enrollment in the analyses, we could have been more precise with the wording of the question (e.g., In the last 6 months, did you sign up for the registry). There was also some confusion among the participants about the difference between participating in a specific CT at the university (which some church members had done) and being enrolled in our registry (which is independent from joining specific CTs and not required for participation in health studies), which may also account for the discrepancy.

4.2 Strengths and Limitations

Several limitations should be noted. Because the intervention entailed multiple elements that differed from the comparison group (e.g., video, website, print materials, e-mail invitations

to join the registry, and content of workshops), it is difficult to determine which of these may have accounted for the effects observed. Additionally, there was not an equal dose of CT educational messages for the comparison churches, which limits internal validity. Additionally, there was a modest final number of individuals who enrolled ($n=60$). However, if this intervention would be brought to scale, it could result in a large number of AAs involved in CTs. The sample of churches and church members invited to participate in this study were not randomly selected (this was a convenience sample); therefore, there may be selection bias both at the individual and church level. It should also be noted that enrollment in a CT registry is *not* equivalent to enrolling into a CT. Actual CT enrollment requires additional actions, which may have different determinants than enrollment in a registry. Motivation to enroll in an actual trial may be influenced not only by general attitudes toward medical research but specific aspects of the actual trial such as time requirement and potential risks and discomfort. It is possible that registry enrollment is more determined by general attitudes and experiences than enrollment in specific trials.

Attrition is also a concern. We over recruited at baseline in part to account for anticipated attrition, especially given that CTs may not be as salient as other health topics such as nutrition, physical activity, stress management, and weight loss. While we had few challenges recruiting participants into the study, at one year follow up, we were able to obtain follow up questionnaires on 575 participants out of 745 (77%). While this attrition rate is in the expected range, it does nonetheless limit generalizability. Using chi square tests, no differences in dropout rates were observed by intervention and comparison churches (24% vs 26%, $p=.45$). Reasons for attrition included participants who passed away, moved out of the area, left the church, and/or did not want to complete the final survey for unspecified reasons. More work is needed to better understand how to engage the faith community in discussions about medical research and how to keep interest in CTs over time to reduce attrition.

Our study was conducted in mid-west black churches; thus, generalizability to other geographic areas, other denominations (e.g., Muslims), and religiously unaffiliated AAs may be limited. Although the intervention currently includes some faith-based messaging, with minor editing it can be readily adapted for a secular audience.

4.3 Conclusions

Our study provides evidence that a culturally tailored education program about CTs can increase enrollment in a university-based clinical trials registry.

4.4 Practical Implications

CT registries have the potential to improve recruitment strategies for AAs and other underrepresented racial/ethnic groups by providing a mechanism for researchers to promptly identify interested volunteers across a variety of studies and health conditions. As more health organizations implement registries and advertise the need for *all* people to participate in research as a way to maximize population health and scientific knowledge, registries may attract a larger pool of minority participants, thus mitigating the current challenges with CT recruitment. However, strategies to cultivate relationships between healthcare organizations

and racial/ethnic subgroups may still be needed. Such strategies may include community engagement and health education workshops that highlight the potential role that CTs may play in better understanding how to prevent, treat, and manage health conditions; especially health conditions that disproportionately affect persons of African descent.

Regarding costs, the research project was staffed by three graduate students supported by a grant; however, a similar program could be duplicated in organizations that have existing community outreach and/or patient education programs. Other direct costs included refreshments at data collection sessions, educational materials, printing of surveys, and incentives for participants. Although we did not conduct a formal cost effectiveness analysis, implementation costs for future projects, if brought to scale, would be more affordable. In other words, if disseminated widely, the cost per enrollee would be lowered and the overall return on the investment would be increased.

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Highlights

- Participants received information about clinical trials (intervention) or healthy eating (comparison).
- We evaluated an intervention to increase enrollment in a clinical trial registry.
- Main outcomes were enrollment and willingness to participate in a clinical trial.
- Intervention group had higher enrollment and willingness than comparison group.
- Culturally tailored education may increase participation in clinical trials.
- Limitations include a modest final number of individuals who enrolled (n=60) and that enrolling in a registry is not equivalent to enrolling in a specific CT.

Table 1

Demographics of church members by treatment condition (N=745).

	Comparison	Intervention
Age (mean) *	45	51
Age Categorized (%) *		
18 – 39	36	24
40 – 59	40	40
60 +	24	36
Sex (%)		
Female	67	69
Male	33	31
Education (%) *		
< 4 Year College	70	58
4 Year College	30	42
Work Status (%)		
Not working (includes retirees)	51	50
Part-Time	11	10
Full-Time	38	40
Household Income (%) *		
\$40K	58	43
\$40,001 to \$80,000	29	32
\$80,001 +	13	25
Baseline willingness to participate in a clinical trial (Mean)	7.23	7.23

* Statistically significant, $p < .05$

Table 2

Posttest willingness to participate in a clinical trial by demographic correlates (n=474).

	Beta	95% CI	P-value
Treatment Condition (comparison, ref)	0.74	0.13 – 1.35	0.02
Baseline Willingness (<7, ref) *	1.9	1.48 – 2.34	<0.001
Sex (males, ref)	0.03	–.43 – .48	0.9
Age			
18 – 39 (ref)	1.0		
40–59	–0.19	–0.72 – 0.34	0.48
60+	–0.8	–1.42 – 0.19	0.01
Education (< 4 year degree, ref)	0.22	–0.26 – 0.7	0.37
Work Status			
Not working (ref)	1.0		
Part-time	–0.07	–0.82 – 0.69	0.86
Full-time	0.05	–0.46 – 0.57	0.84
Household Income			
\$40,000 (ref)	1.0		
\$40,001 – \$80,000 *	0.54	0.02 – 1.05	0.04
\$80,001 plus	0.1	–0.54 – 0.74	0.74

* Statistically significant, $p < .05$

Table 3

Posttest self-reported enrollment in a clinical studies registry (n=454).

	Odds Ratio	95% CI	P-value
Treatment Condition (comparison, ref) *	1.94	1.08 – 3.47	0.03
Baseline Self-Reported Enrollment (no, ref) *	7.74	3.11 – 19.3	<0.001
Sex (males, ref)	0.81	0.43 – 1.5	0.49
Age			
18 – 39 (ref)	1.0		
40–59 *	3.16	1.38 – 7.26	0.01
60+	1.67	0.63 – 4.44	0.3
Education (< 4 year degree, ref)	1.19	0.64 – 2.26	0.58
Work Status			0.12
Not working (ref)	1.0		
Part-time	0.95	0.35 – 2.62	0.93
Full-time	0.56	0.27 – 1.15	0.11
Household Income			0.13
\$40,000 (ref)	1.0		
\$40,001 – \$80,000	1.57	0.79 – 3.11	0.2
\$80,001 plus	1.08	0.44 – 2.63	0.87

* Statistically significant, $p < .05$

Table 4**Verified enrollment**

in a clinical studies registry (n=577).

	Odds Ratio	95% CI	P-value
Treatment Condition (comparison, ref) *	2.95	1.33 – 6.52	0.01
Baseline Self-Reported Enrollment (no, ref)	1.05	0.33 – 3.37	0.94
Sex (males, ref)	1.69	0.8 – 3.57	0.17
Age			
18 – 39 (ref)	1.0		
40–59	2.52	1.0 – 6.23	0.05
60+	1.75	0.64 – 4.79	0.27
Education (< 4 year degree, ref)	0.8	0.41 – 1.59	0.52
Work Status			
Not working (ref)	1.0		
Part-time	1.08	0.4 – 2.9	0.88
Full-time *	0.42	0.19 – 0.94	0.03
Household Income			
\$40,000 (ref)	1.0		
\$40,001 – \$80,000	1.65	0.8 – 3.42	0.18
\$80,001 plus	0.99	0.38 – 2.57	0.98

* Statistically significant, $p < .05$