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Does a Quality Improvement Intervention for Anxiety Result in Differential Outcomes for Lower Income Patients?

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Abstract

Objective—This study examined the effects of a collaborative care intervention for anxiety disorders in primary care on lower income participants relative to those with higher incomes. The authors hypothesized that lower income patients might show less improvement or improve at a lower rate given that they experience greater economic stress over the treatment course. Alternatively, lower income patients could improve at a higher rate because the intervention facilitates access to evidence-based treatment, which typically is less available to persons with lower incomes.

Method—The authors compared baseline demographic and clinical characteristics of patients with lower (n=287) and higher (n=717) income using t-tests and chi-square tests for continuous and categorical variables respectively. For the longitudinal analysis of intervention effects by

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income group, the authors jointly modeled the outcomes at the four assessment times by study site; income; time; intervention; time and intervention; income and time; income and intervention; and time, intervention and income.

Results—Although lower-income participants were more ill and disabled at baseline than those in the higher income group, the two income groups were very similar in their clinical response. The lower income participants experienced a comparable degree of clinical improvement, despite receiving fewer treatment sessions, less relapse prevention, and less continuous care.

Conclusions—These findings contribute to the ongoing discussion as to whether or not, and to what extent, quality improvement interventions work equally well across income groups or require tailoring for specific vulnerable populations.

INTRODUCTION

Ideally, interventions to improve the quality of mental health care should be broadly effective across populations, including those with lower socioeconomic status. Quality improvement programs tailored for lower income groups have been shown to be effective. For example, cognitive behavioral therapy (CBT), antidepressants, and extensive outreach and support were effective for low income depressed Latina and African American women (1); group support and antidepressants were effective for impoverished Chilean patients (2); and medication and problem-solving therapy were effective for low income depressed patients with cancer (3). But more universal quality improvement interventions designed for broader segments of the population may or may not have equivalent effects across vulnerable subpopulations. Some universal quality improvement interventions have been shown to benefit all participants uniformly (4) and others have been shown not only to be broadly clinically effective but to have a differentially positive effect on vulnerable populations, namely ethnic minorities (5, 6). For example, Partners in Care, a primary care effectiveness quality improvement study, found greater outcome improvement for minorities than whites and reduced outcome disparities for minorities relative to whites compared to enhanced usual care, over 9 years of follow-up (1, 7, 8). Such interventions serve a dual purpose in that they improve quality broadly while, at the same time, reducing disparities in outcomes.

Attention has focused on racial or ethnic disparities but other factors that increase risk for substandard treatment, such as lower socioeconomic status, warrant further exploration. Researchers cite poverty's contributions to the development of poor mental health, in particular the environmental toxins, food insecurity, geographic barriers to health care, violence, limited economic opportunities, crime, and increased stress. But less is known about how lower socioeconomic status impacts mental health treatment outcomes. Anxiety is more prevalent in the disadvantaged (9, 10) and poorer persons have been shown to have poorer outcomes (11, 12). Chronic economic deprivation increases levels of both anxiety and depression (13). Having fewer resources, such as funds for transportation, child care, or health insurance may also indirectly impact clinical outcomes and continued engagement in care or adherence to treatment (14-16).

Recently, we found evidence that a flexible treatment-delivery model for primary care anxiety disorders was superior to usual care (17). The Coordinated Anxiety Learning and Management (CALM) intervention, a collaborative care intervention for anxiety disorders in primary care, resulted in greater improvement in anxiety symptoms, functional disability and quality of care over 18 months relative to treatment as usual. In this paper we examine the clinical effectiveness of the CALM intervention relative to income. While more work has been done for depression, evidence for the impact of quality improvement programs for anxiety disorders on lower income populations is lacking. Our prior work with persons with

panic disorder found a comparable clinical response of lower income individuals relative to higher income individuals in a collaborative care intervention (medication and CBT) over 12 months of follow-up (4). Other than this prior work, we know of no other study of quality improvement or collaborative care interventions specifically for anxiety disorders that has focused on the potentially moderating effect of income on clinical outcomes. Since our study population was relatively wealthy and about 50% of lower income patients were white, this study offers an opportunity to examine the association between incomes and clinical outcomes without substantial confounding by race. In addition, since most poorer persons receive mental health treatment in primary care rather than in specialty care settings (18), data from the CALM study are broadly relevant to the examination of lower income and clinical outcomes.

The purpose of this analysis is to examine the effect of the CALM collaborative care intervention on lower income participants relative to those with higher incomes. We hypothesized that lower income patients might show less improvement with CALM or might improve at a lower rate than higher income patients. We reasoned that they would not only be more ill at baseline but would be likely to have more continual economic stress over the course of the 12 month treatment program, placing them at risk for a less robust clinical response. On the other hand, it is also possible that lower income patients could improve at a higher rate since CALM facilitates access to evidence-based treatment, which may be less available to persons with lower incomes in the usual care group. These findings contribute to the ongoing discussion as to whether or not, and to what extent, quality improvement interventions should be universal vs. targeted or tailored for specific vulnerable populations (19).

Methods

Sample

We enrolled 1004 primary care patients with panic disorder, social anxiety disorder, generalized anxiety disorder or posttraumatic stress disorder between June 2006 and April 2008 in the Coordinated Anxiety Learning and Management (CALM) study. CALM is the largest randomized trial of collaborative care for anxiety disorders conducted to date (17, 20).

Four sites coordinated patient recruitment: University of Washington, Seattle, University of California at San Diego and Los Angeles, and the University of Arkansas for Medical Sciences at Little Rock, Arkansas. Each of the four sites selected clinics in their geographic area to participate. Candidate clinics were evaluated and 17 were purposively selected based on a number of considerations, including provider interest, space availability, size and diversity of the patient population, and insurance mix (public and private) with the goal of recruiting a diverse population of patients and clinics.

A “facilitated referral” approach was used to recruit participants. Primary care providers and clinic nursing staff directly referred potential participants. In addition, sites actively publicized the study within each clinic, allowing for self-referral. Referred participants met with a study anxiety clinical specialist to determine eligibility for CALM. Eligible participants had to be patients at one of the participating clinics, be at least 18 years old, meet DSM-IV criteria for generalized anxiety disorder, panic disorder, social anxiety disorder, or posttraumatic stress disorder (based on the Mini International Neuropsychiatric Interview (21)), score at least 8 (moderate but clinically significant anxiety symptoms on a scale ranging from 0-20) on the Overall Anxiety Severity and Impairment Scale (22), be willing to participate in CALM, and be able to provide written, informed consent. Exclusion criteria included serious alcohol or drug use (specifically, alcohol or marijuana dependence

or any other drug abuse or dependence, including methadone – 4% were excluded for this reason), unstable medical conditions, marked cognitive impairment, active suicidal intent or plan, psychosis, or bipolar I disorder. Individuals already receiving ongoing CBT and persons without routine access to a telephone, or who could not speak English or Spanish were excluded.

Of 1620 patients referred and interviewed for eligibility, 1062 were eligible and, after the study procedures were explained, 1036 provided written informed consent for the study. After a baseline interview, 1004 participants were randomized to CALM or usual care using an automated computer program at RAND. The RAND Survey Research Group conducted all baseline and follow-up assessments (at 6, 12, and 18 months) by phone. Randomization was stratified by clinic and presence of co-morbid major depression using a permuted block design. Block size was masked to all clinical site study members.

Intervention Design

CALM is a flexible, collaborative care delivery model for primary care anxiety treatment that addresses any of four common anxiety disorders in primary care; provides strategies to enhance patient engagement in treatment, including allowing choice of CBT, medication, or both; and provides the option for additional treatment over the course of a year. It utilizes a web based outcomes system to optimize treatment decisions and a computer-assisted program to allow CBT-inexperienced care managers to optimize delivery of CBT and to optimize fidelity to the CBT model. Medication is prescribed by primary care physicians with care manager assistance in promoting adherence, dose optimization, and medication switches/augmentation. Although the CALM intervention was not specifically tailored for special groups of participants, an ethnicity advisory group reviewed all materials and content of the intervention to assure that it was appropriate for African-Americans, Asians, Latinos, and whites.

CALM patients initially received their preferred course of treatment over 10 to 12 weeks. The CBT program included five generic modules (education, self-monitoring, hierarchy development, breathing training, relapse prevention) and three modules (cognitive restructuring, exposure to internal and external stimuli) tailored to the four specific anxiety disorders. Patients who had multiple anxiety disorders (about 2/3 of the participants) were asked to choose the most disabling or distressing disorder to focus on within CBT with the expectation that their co-morbid disorders would also improve. CBT was administered by the care manager, called the anxiety clinical specialist. A local study psychiatrist provided single session medication management training to providers, as needed consultation by phone or e-mail, and occasionally a face-to-face assessment for complex patients. The algorithm emphasized first line use of SSRI or SNRI antidepressants, dose optimization, and side effect monitoring. If needed these were followed by second and third step combinations of two antidepressants or an antidepressant and benzodiazepine. The anxiety clinical specialist monitored adherence and related medication suggestions from the supervising psychiatrist to the primary care provider.

Patient outcomes were tracked by the anxiety clinical specialist on a web-based system. The goal was either clinical remission, defined as an anxiety scale score of <5 or sufficient improvement such that the patient did not want further treatment (23). Symptomatic patients could receive additional treatment with CBT or medication for up to twelve months. After treatment was completed, patients received monthly relapse prevention follow-up phone calls to reinforce CBT skills and/or medication adherence. Most CALM participants completed the treatment course in six months, but occasionally the course of treatment was interrupted, usually by life events or the emergence of substance abuse or dependence. Usual

care patients were treated by their physicians in the usual manner which could include referral to a mental health specialist.

Measures

Mental Health Outcomes—An assessment battery was administered at baseline, 6, 12 and 18 months via telephone. The primary outcome for the secondary analyses reported here included two key components of all anxiety disorders, psychic (psychological symptoms) and somatic (physical symptoms) aspects of anxiety as measured by the Brief Symptom Inventory-12 subscales for anxiety and somatization. Lower Brief Symptom Inventory-12 scores indicate fewer symptoms. Other measures included the global mental health and physical health scales of the Medical Outcomes Study 12-Item Short-Form Health Survey (24), and the Center for Disease Control and Prevention's (CDC) Healthy Days Measure, a single-item estimate of restricted activity days or days (in the past 30) in which poor physical or mental health kept the participant from doing usual activities (25). For the global mental health and physical health scales, higher scores indicate better functioning, while on the CDC healthy days measure, lower scores reflect better functioning.

Income—Income was assessed at baseline. We derived a dichotomous measure of high and low income by first calculating weighted average income thresholds based on Federal Poverty Guidelines (26) adjusted for family size, age of respondent and number of children less than 18 years. Family income divided by this threshold value created a poverty ratio. We divided the sample into those with incomes at or below 200%of the poverty level and those with incomes higher than this. Among CALM participants, 287 were designated low income, including 133 in the intervention group and 154 in the control group, and the remaining 717 were designated high income, including 370 in the intervention group and 347 in the control group.

Statistical Analysis

We compared baseline demographic and clinical characteristics of patients with lower and higher income using t-tests and chi-square tests for continuous and categorical variables respectively. For the longitudinal analysis of intervention effects by income group, we jointly modeled the outcomes at the four assessment times (baseline and 6, 12, and 18 month follow-ups) by study site, income, time, intervention; the two way interactions of time and intervention, income and time, income and intervention; and the three-way interaction of time, intervention and income. We fitted the models using a restricted maximum likelihood approach, which produces valid estimates under the missing-at-random assumption. This approach uses all available data to obtain unbiased estimates of model parameters. The statistical software used was SAS version 9.3. All P values were 2-tailed.

Results

Persons in the lower income group (n = 287) were younger, less educated, and less likely to have health insurance compared to those in the higher income group (n = 717) (table 1). Lower income patients tended to be sicker at baseline, as reflected by more medical and anxiety comorbidities, and had higher disability scores on both anxiety-specific (Sheehan Disability Score) and generic (global medical health scale) functioning measures, indicating poorer physical and mental functioning. While they were no more likely to meet criteria for panic disorder, generalized anxiety disorder or social anxiety disorder than higher income participants, they demonstrated a higher prevalence of both posttraumatic stress disorder and comorbid depression at baseline compared to those in the higher income group.

Figures 1-3 show baseline and follow-up predicted mean scores for low and high income patients in the CALM and usual care conditions from general linear mixed models using repeated measures for the three outcomes. In all three models, the three-way interaction of time, intervention and income was non-significant. Nor were the two-way interactions between time and income and between income and intervention significant; however the two-way interaction between time and intervention was significant in all three models ($p<.0001$, $p<.0001$ and $p=.0025$ respectively for Brief Symptom Inventory-12, global mental health scale, and restricted activity days).

Low income participants reported more symptoms at baseline on the Brief Symptom Inventory-12, regardless of whether or not they were assigned to CALM or usual care groups, than high income participants, but those low income patients assigned to CALM had higher Brief Symptom Inventory-12 scores at baseline. The CALM intervention lowered symptoms significantly more for both low and high income patients, relative to usual care over 6 and 12 months, but by 18 months there was no significant difference in Brief Symptom Inventory-12 scores between the two low-income groups (CALM vs. usual care) although the difference in Brief Symptom Inventory-12 scores between the two high income groups (CALM vs. usual care) persisted (figure 1). This may be due to fewer subjects followed in the low income group at eighteen months, especially for the CALM group. A similar pattern was seen for the global mental health scale score (figure 2), although the intervention effect was comparable and significant for both low and high income patients over all 18 months. At 6 months, the CALM intervention brought low income patients' global mental health scale scores to the level of high income controls. The pattern for restricted activity days, shown in figure 3, is similar to the Brief Symptom Inventory-12 scores (figure 1). High income participants had fewer restricted activity days than low income participants at all times for both CALM and usual groups. There was no difference in the restricted activity days between CALM and usual care groups at baseline; however at follow-ups, the CALM group had significantly fewer restricted activity days than the usual care group for both lower and higher income groups, except at the twelve month interview for the low income group, where the difference became non-significant. Again, this may be due to fewer subjects followed in the low income group at this interview, especially for the CALM intervention group.

To examine whether or not lower income participants in the CALM intervention group differed in terms of treatment patterns, we assessed whether or not participants experienced interrupted treatment and whether they participated in the relapse prevention component of the program. (This information was available only for the intervention participants (n=503).) We also compared the number of completed CBT sessions across income groups. Lower income participants (n = 126) were significantly more likely to have interrupted treatment compared to higher income participants (n = 356) (12.7% vs. 7.0%, chi-square = 3.85; p = 0.0497); were significantly less likely to have participated in relapse prevention (61.9% vs. 72.2%, chi square = 4.65; p =0.0311); and completed fewer CBT sessions (mean=6.00 compared to mean=7.39; chi-square=10.42, p=0.0012 from Kruskal-Wallis Test). (These data were available for participants in the intervention group only.)

Discussion

As expected, lower income participants in the CALM study were more ill and disabled at baseline than those in the higher income group. At baseline, they were not only more burdened with symptoms but also more functionally impaired.

At the same time, the lower and higher income groups were very similar in terms of their clinical response to the CALM intervention, as depicted by the comparable slopes of the

lines in Figures 1 - 3. The lower income participants began the study sicker and ended the study sicker than the high income group. They experienced a comparable degree of clinical improvement but the disparities related to income were not eliminated. These findings are similar to those in our previous study of collaborative care for panic disorder (4) as well as to the findings of Arean et al in the IMPACT collaborative care intervention for older adults (12). It is possible that the persistent differential in clinical outcomes across income groups results from having fewer resources available (e.g., child care, transportation) to assure continued access to treatment. But it could also relate to differential beliefs or attitudes about the relevance of CBT given very realistic life stressors in the lower income group. Regardless of the explanation, it is quite conceivable that had the lower income group received comparable numbers of CBT sessions, relapse prevention, and continuous care, they may have had a *more robust* clinical response relative to those with higher incomes.

Most participants in the CALM study completed treatment within the initial 6 month period but could be actively followed by the study clinicians for 12 months, after which they received only one follow-up assessment by phone from the survey group but no clinical interventions. Therefore, one might expect the greatest clinical response to occur at 6 months and to potentially deteriorate after that point, a pattern reflected in our data. However, given that the lower income group would continue to be subject to more economic stress, it may be especially remarkable that the lower income group did not experience significantly greater deterioration of clinical improvements after 6 months relative to the high income participants. This suggests that the effect of the CALM intervention was sustained equally well across participants regardless of income level and in spite of presumed differences in treatment intensity and continuity, at least over the first 12 months. This is in contrast to a recently reported depression intervention for low income women with co-morbid cancer in which marked recurrence of depression occurred post-intervention (3).

Our study suggests that if the goal is to obtain an equivalent clinical response across lower and higher income patients, clinic-based collaborative care for anxiety disorders as delivered in the CALM study is adequate and effective. It is possible, however, that the low income group might have benefited to a greater extent from tailored supplements to treatment, such as assistance with transportation or child care or even novel delivery approaches, such as treatment delivered in the home. Providing such features for lower income participants might be more likely to result in an intervention that not only improves quality of care but also even further reduces disparities in clinical outcomes. Studies are needed to address significant barriers to building collaborative care teams in safety net care populations, including approaches to facilitate communication across mental health and medical providers via newer health technologies.

Limitations

Because CALM participants were recruited from primary care settings, most had health insurance and the resources needed to get to the primary care clinics. Before entering the CALM study, 57% of participants were already receiving medication, much of it clinically appropriate. Hence, participants represent a select group that had failed to improve with first line medication treatment administered by the primary care provider. Participants as a whole were better off economically than many segments of the population who may not have ready access to primary care or who may live in even more stressful living situations in which meeting daily needs for survival are paramount. Our findings, therefore, should not be interpreted as applying to all groups of lower income persons. In addition, while the study used common and widely-accepted outcome measures, these measures capture symptoms at only one point in time and may, therefore, fail to reflect the often episodic nature of anxiety disorders.

In conclusion, this analysis illustrates that a collaborative care intervention for anxiety in primary care worked equally well for those with lower and higher incomes but did not eliminate baseline disparities in mental health status associated with economic disadvantage. Our findings should reduce the tendency to be nihilistic about the impact of mental health treatments for lower income individuals. Even when treatments were delivered with less intensity and frequency than desirable, clear and meaningful benefits were obtained.

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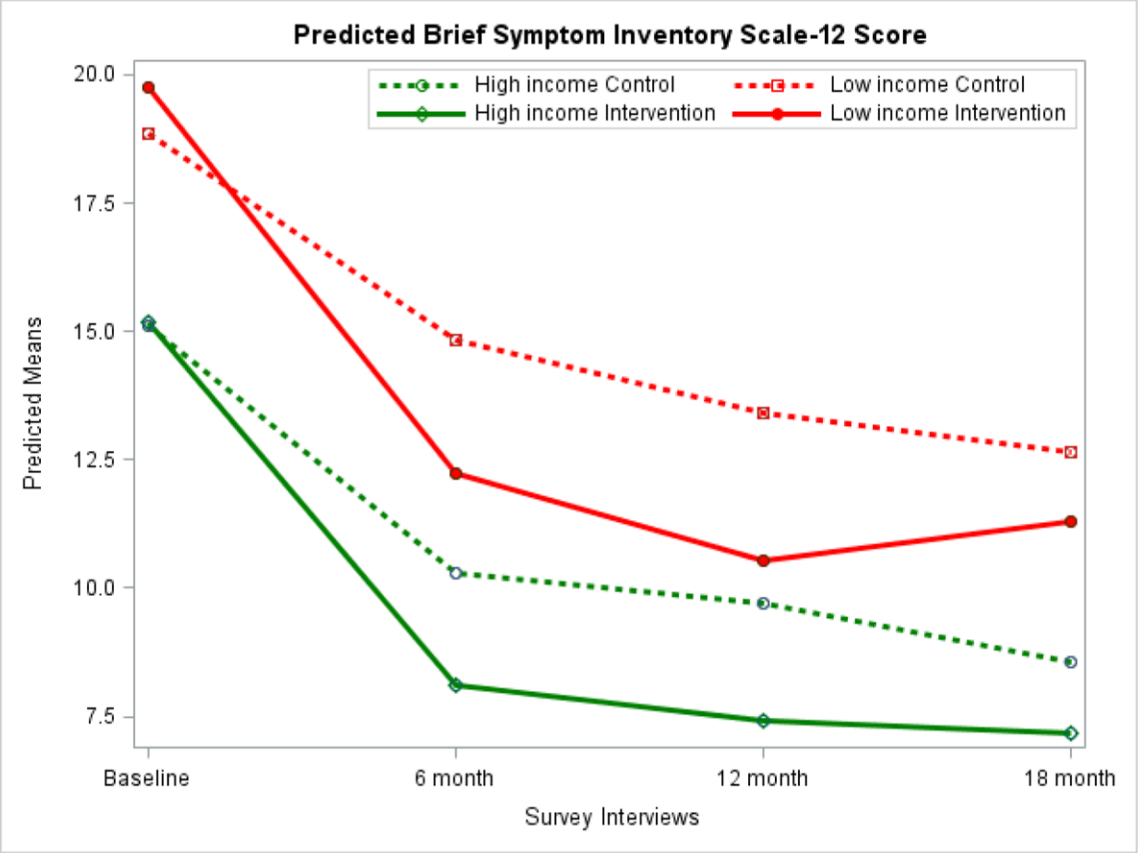

Figure 1. Predicted Brief Symptom Inventory Scale-12 Score

Among low income participants there was a significant difference in Brief Symptom Inventory-12 scores between intervention and control (usual care) groups at 6 ($p = .012$) and 12 ($p = .007$) months. Among high income participants there was a significant difference at 6 ($p < .0001$), 12 ($p < .0001$), and 18 ($p = .031$) months.

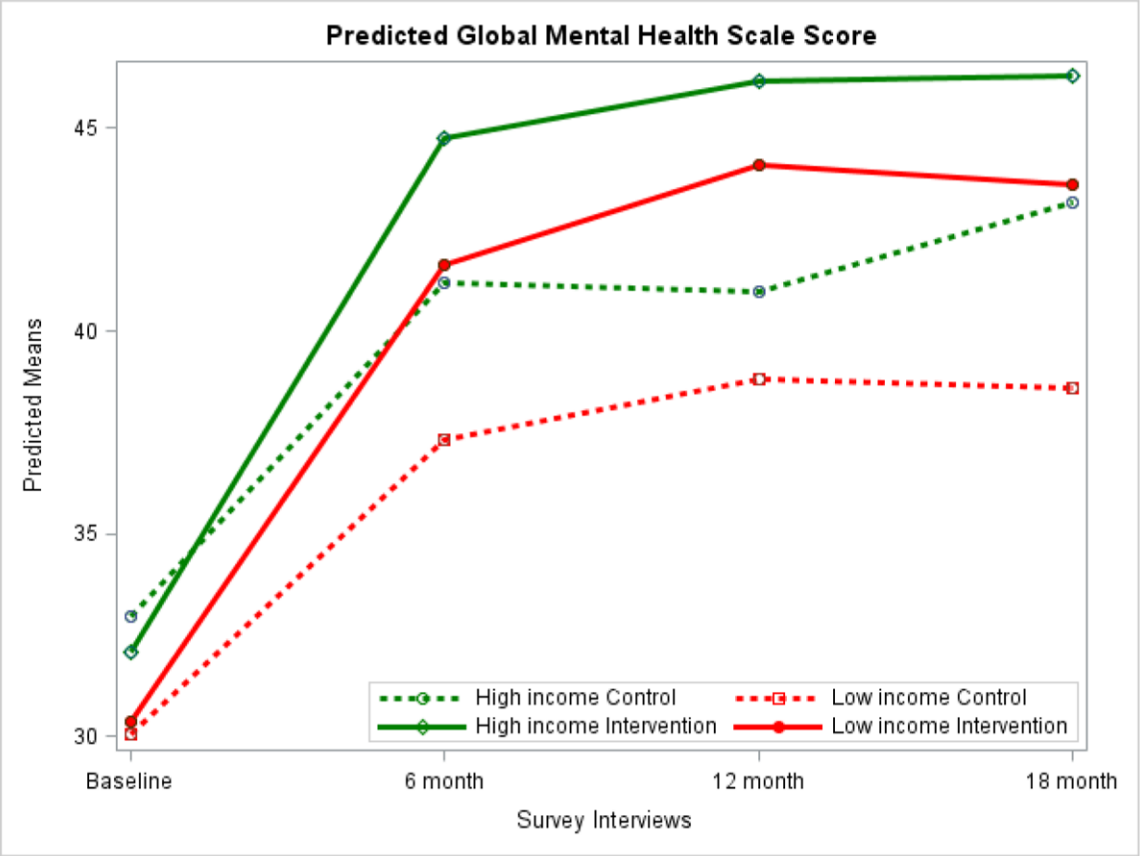

Figure 2. Predicted Global Mental Health Scale Score

Among low income participants there was a significant difference in the Mental Health Component Scale Score at 6 ($p = .002$), 12 ($p < .001$) and 18 ($p < .001$) months. Among high income participants there was a significant difference at 6 ($p < .0001$), 12 ($p < .0001$), and 18 ($p < .0001$) months.

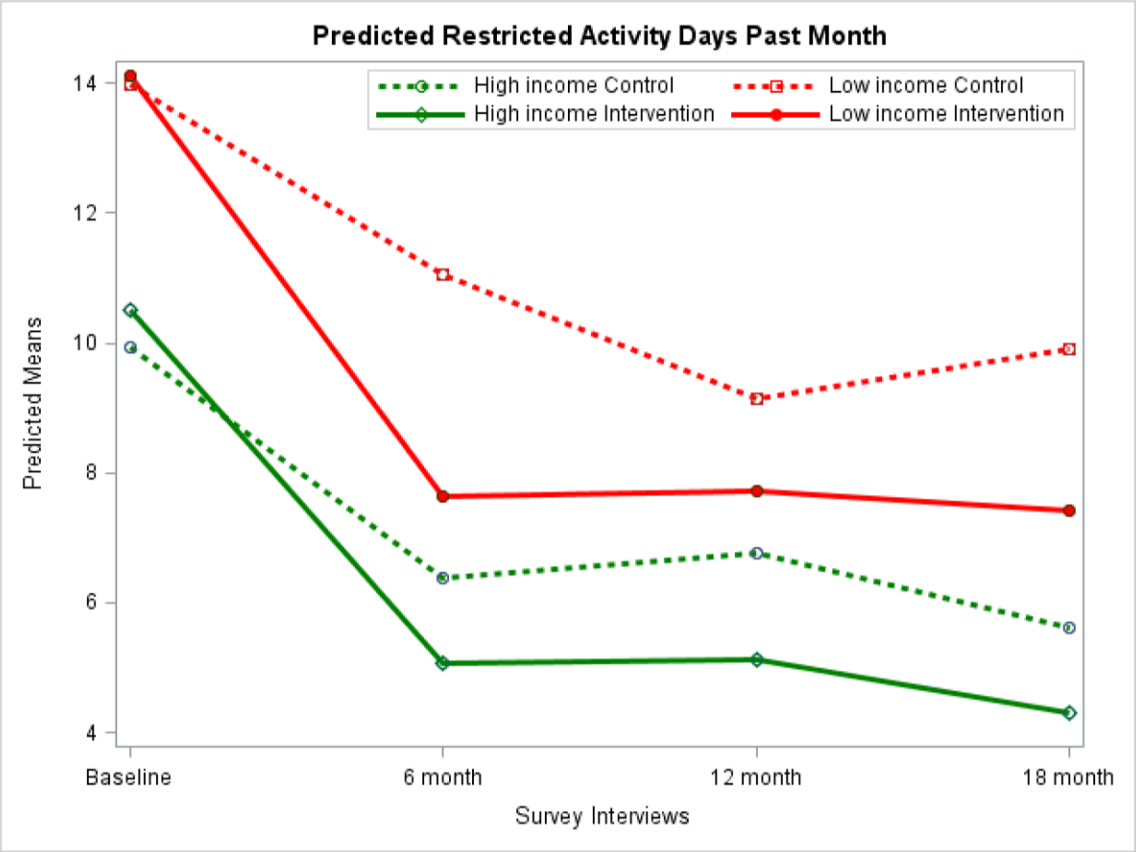

Figure 3. Predicted Restricted Activity Days Past Month

Among low income participants there was a significant difference in CDC Healthy Days score at 6 (p = .001) and 18 (p = .022) months. Among high income participants there was a significant difference at 6 (p = .047), 12 (p = .018), and 18 (p = .045) months.

Table 1

Baseline Patient Characteristics

Characteristic	Participant Group						
	Low Income N = 287 (27.5)		High Income N = 717 (72.5)		Total N = 1004		
	N	%	N	%	N	%	p-value
Female	212	73.9	502	70.0	714	71.1	0.224
Education**							
< High school	33	11.5	22	3.0	55	5.5	<0.001
High school	62	21.6	103	14.4	165	16.4	
> High school	192	66.9	592	82.6	784	78.1	
Ethnicity							
Hispanic	61	21.3	135	18.8	196	19.5	0.068
African American	43	15.0	73	10.2	116	11.6	
White	146	50.9	422	58.9	568	56.6	
Other	37	12.9	87	12.1	124	12.4	
Health insurance**							
Yes	221	77.3	640	89.4	861	85.9	<0.001
Number of chronic medical conditions							
0	50	17.4	153	21.3	203	20.2	0.185
1	58	20.2	161	22.5	219	21.8	
≥ 2	179	62.4	403	56.2	582	58.0	
Anxiety disorder							
Panic	148	51.6	327	45.6	475	47.3	0.087
Generalized anxiety	214	74.6	542	75.6	756	75.3	0.733
Social anxiety	125	43.6	280	39.1	405	40.3	0.189
Post-traumatic stress**	75	26.1	106	14.8	181	18.0	<0.001
Major depressive disorder**	215	74.9	433	60.4	648	64.5	<0.001
Number of anxiety disorders*							<0.001
1	99	34.5	322	44.9	421	41.9	<0.001

Characteristic	Participant Group						
	Low Income N = 287 (27.5)		High Income N = 717 (72.5)		Total N = 1004		
	N	%	N	%	N	%	p-value
2	110	38.3	277	38.6	387	38.6	
3-4	78	27.2	118	16.5	196	19.5	
	Mean	SD	Mean	SD	Mean	SD	p-value
Age *	42.25	14.24	43.96	13.09	43.47	13.44	0.048
Sheehan Disability Score ** *a*	18.52	7.44	16.34	7.11	16.96	7.27	<0.0001
Global Physical Health Scale Score ***b*	45.28	13.27	50.75	10.28	49.19	11.47	<0.0001
Global Mental Health Scale Score ***b*	29.91	9.69	32.62	10.08	31.85	10.04	0.0001
CDC Healthy Days Score ***c*	14.28	10.56	10.14	9.32	11.30	9.85	<0.0001

*p<.05

**p<.0001

*a*Higher scores indicate greater disability

*b*Higher scores indicate better functioning

*c*Lower scores indicate better functioning