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The Role of Gender in Moderating Treatment Outcome in Collaborative Care for Anxiety

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Abstract

Objective—The aim of this study was to test whether gender moderates intervention effects in the Coordinated Anxiety Learning and Management (CALM) intervention, a 12-month, randomized controlled trial of a collaborative care (CC) intervention for anxiety disorders (panic disorder, generalized anxiety disorder, posttraumatic stress disorder, and social anxiety disorder) in 17 primary care clinics in California, Washington, and Arkansas.

Methods—Participants (n = 1004) completed measures of symptoms (Brief Symptom Inventory; BSI) and functioning (Mental and Physical Health Components of the Short Form-12; (MCS and PCS), and Healthy Days, Restricted Activity Days Scale) at baseline, 6, 12, and 18 months. Data on dose, engagement, and beliefs about psychotherapy were collected for patients in the CC group.

Results—Gender moderated the relationship between treatment and its outcome on the BSI, MCS and Healthy Days but not on the PCS. Women who received CC showed clinical improvements on the BSI, MHC, and Healthy Days that were significantly different from women in Usual Care. There were no differences for men in CC compared to Usual Care on any measures. In the intervention group, women attended more sessions of psychotherapy, completed more modules of therapy, expressed more commitment and viewed psychotherapy as more helpful than men.

Dr. Stein reports that he has consulted for Janssen Pharmaceuticals. Dr. Roy-Byrne reports having stock options with Valant Medical Solutions.

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Conclusions—These findings contribute to the broader literature on treatment heterogeneity, in particular the influence of gender, and may inform personalized care for persons seeking anxiety treatment in primary care settings.

Collaborative Care (CC) interventions utilize proactive, time-limited, patient follow-up by care managers to track outcomes, identify intervention non-responders and facilitate engagement in evidence-based psychotherapy and pharmacotherapy. CC interventions improve clinical outcomes for anxiety and depression with minimal incremental cost (1–9). However, a substantial proportion of patients receiving CC do not respond. Understanding which factors influence treatment heterogeneity is essential to continued quality improvement efforts.

Moderation analysis can highlight which patient characteristics influence intervention effects and can be used to personalize care and improve treatment effectiveness (10,11). For example, demographic characteristics such as ethnicity, age, and socio-economic status have been identified as moderators of CC interventions for anxiety and depression (12). In two studies, minority status predicted greater CC intervention effects with regard to access, adherence and symptoms (1,13) for depression, but not anxiety (14). In another study, older age predicted longer engagement in CC and higher rates of adequate pharmacotherapy (15). In a study of CC for anxiety, lower socio-economic status did not moderate the intervention effect (16).

The moderating effect of gender has received little attention in studies of CC. Patients and care managers in CC collaboratively determine the composition of care, including amount and type of psychotherapy and/or medication. It is likely that patient views on treatment could influence the decision-making process, and subsequent intervention effect. Gender is well studied as a moderator of outcomes in efficacy trials of Cognitive Behavioral Therapy (CBT) (17,18) and pharmacotherapy (19). After receiving a comparable number of CBT sessions for anxiety and depression, men and women show similar clinical outcomes(17). However, prior research has indicated that there are gender differences in engagement in CBT (20), treatment preference (21), therapeutic alliance (22), self-efficacy(23), and outcome expectancy (24), which could all impact the effectiveness of CBT delivered within the context of a CC trial. The impact of gender on outcome for pharmacotherapy for anxiety and depression is inconsistent with some studies suggesting that women respond more favorably and drop out less often during medication trials (19).

To date, evidence about the moderating effect of gender on CC for depression has been mixed and no evidence exists for anxiety (4,12,25–27). Five large effectiveness trials of CC evaluated whether gender is predictive of intervention effects. Two studies, each with increased resources for pharmacotherapy and psychotherapy found that gender had no association with depression (12,25). A third study reported that CC for depression (with increased resources for pharmacotherapy only) was more cost-effective for women than for men, resulting in a greater number of quality adjusted life years (QALY) (4). A fourth reported that women undergoing collaborative care with increased resources for pharmacotherapy were more likely to achieve remission from depression than men (27). The Partners in Care Project found that the effect of gender on outcomes was mixed, varying by

intervention arm (i.e., increased resources for pharmacotherapy and increased resources for psychotherapy) and outcome measure (26,28). In Partners in Care, pharmacotherapy-focused CC reduced depression burden and improved the mental health quality of life among women, but not men. Psychotherapy-focused CC reduced the depression burden for both men and women, and improved the mental health quality of life for men, but not women. Thus, increased resources for pharmacotherapy seems to be more effective for women than men, while the psychotherapy-focused CC appears to be mixed.

No previous studies have examined gender as a moderator of CC for anxiety. We tested gender as a moderator of treatment outcome in the Coordinated Anxiety Learning and Management (CALM) intervention, a 12-month CC intervention for anxiety (6). We hypothesized that gender would moderate the relationship between intervention and clinical outcomes over the course of treatment (6 months, 12 months and 18 months) and that females would report more positive responses to CC. We also explored whether there were gender differences in dose, engagement and beliefs about the core elements of the intervention.

Method

Participants (n=1004) ranged in age from 18 to 75 years old and were diagnosed with panic disorder (PD), generalized anxiety disorder (GAD), posttraumatic stress disorder (PTSD), or social anxiety disorder (SAD) referred by physicians from 17 clinics at 4 sites (Little Rock, Los Angeles, San Diego, and Seattle). All sites provided Institutional Review Board approval and all participants provided written informed consent. Details about the intervention and the evaluation methodology are described elsewhere (6,29).

Study Arms

Patients were referred to the study and following initial screening, were randomized to receive either usual care (n = 501) or CC (n = 503). Usual Care (UC) participants were treated by their primary care physician (i.e., medications or referral to specialty mental health providers). At baseline many UC participants reported that they used psychotropic medication (62%) or attended counseling (47%) with low rates of adequate pharmacotherapy (31%) and CBT usage (5%).

Collaborative Care—The CC intervention tested in this study was based on the IMPACT depression intervention(30). Participants worked with care managers to choose the best treatment approach. Patients could select: medication, CBT, both, or neither. Care managers monitored the pharmacotherapy or delivered CBT face-to-face. Most of the care managers had master's degrees in social work or nursing. All were supervised by licensed clinical psychologists (CBT) and study psychiatrists (medication), who interacted with the patient's primary care physicians either in writing or in-person (29). The psychotherapy was computer-assisted, modularized CBT. The patient and care manager worked together during the session using the computer guided protocol. Modules included psychoeducation, breathing retraining, cognitive restructuring and exposure. Eight sessions of CBT was considered a full course of psychotherapy. A few participants experienced interruptions in

CBT due to life events or emerging substance dependence. Participants also received optional monthly relapse prevention sessions by telephone following completion of CBT.

Measures

The RAND Survey Research Group assessed outcomes of all participants using telephone surveys at baseline, 6, 12, and 18 months. Interviewers were blind to treatment condition.

The *Brief Symptom Inventory* (BSI(31)) is a shortened version of the Symptom Checklist-90 (SCL-90) and is a 53-item measure of a range of symptoms in 9 subscales and 3 global scales. Only the anxiety and somatization subscales are reported in this study. Items assessed degree of distress rated on a 5-point Likert-type scale with responses ranging from 0 (not at all) to 4 (extremely) (32). Higher scores indicate more severe symptoms. The measure has good internal consistency (α = .71–.85) and test-retest reliability ranging from .68–.91 on all scales. Subscales demonstrate construct and criterion validity in a variety of settings (31, 33–35).

The *Short Form-12 Version 2* (SF-12(36)) is a brief version of the SF-36 comprised of Mental Health Composite Score (MCS) and Physical Health Composite Score (PCS). Composite scores (range = 0–100) are computed using all items on the scale with each weighted such that the MCS and PCS are oblique (37) and higher scores represent better functioning.

Healthy Days, Restricted Activity Days scale (38)is a one-item estimate of number of days in the previous 30 days in which activities were restricted by physical or mental health problems. Higher scores represent more restricted activity.

Beliefs about Mental Health and CBT were assessed for the subset of patients randomized to CC in seven domains: (1) intention to seek treatment, (2) comfort talking to a mental health professional, (3) stigma (4) helpfulness of treatment (5) potential for spontaneous recovery (6) outcome expectancy and (7) self-efficacy.

Dose of CBT and CBT engagement data were entered by the care manager following each clinical encounter for the subset of patients randomized to CC. CBT dose included number of sessions, participation in relapse prevention calls, interruption in treatment, number of CBT modules completed and total number of exposure exercises completed. Engagement was measured by clinicians at the completion of each session and included homework adherence (4-point scale) and commitment to CBT (0–10 point scale).

Data Analysis

All analyses were conducted using SAS 9.3 (39). Chi-square for categorical variables and nonparametric Wilcoxon's rank sum tests for continuous variables were used to compare demographic and baseline clinical characteristics. Using the MacArthur Moderation model (11), we examined whether gender moderated the effect of CC on clinical outcomes to test the main hypothesis. The dependent variables included scores on the BSI, PCS, MCS and Health days at 6, 12 and 18-month follow-ups. Mixed models were used to account for the repeated measures. General linear model for repeated measures using a restricted maximum

likelihood approach was used to fit the models using PROC MIXED in SAS. A strength of this approach is that it can be used when data are missing at random (40,41). Each regression model was specified to include group, gender and the two-way interaction of group by gender plus covariates. For each model covariates included baseline score on the target measure and casemix demographic (education, race, age, and income) and clinical (chronic conditions, GAD, PTSD, and MDD) variables to adjust for baseline differences. We chose not to center for gender or intervention because we were interested in estimating the specific effect of the intervention for women rather than the average effects for both genders. Predicted least squares means (LSMEANS in SAS) were calculated for the intervention and control groups by gender with continuous covariates set at their mean values and categorical covariates set at one divided by the number of categories. Type III tests of significance were used to determine the effect of a given variable after controlling for all other variables in the model and are analogous to the F-statistic in logistic regression.

For CC participants only, dose (number of CBT modules completed and total number of exposure exercises completed during the course of treatment), engagement (homework adherence and commitment to CBT), and beliefs about CBT (OE, SE and five items on beliefs about treatment) were compared between men and women using statistical techniques appropriate for the distribution for each item. Three items had a normal distribution (outcome expectancy, self-efficacy, CBT anxiety commitment), two had a binomial distribution (Interrupted Treatment, Relapse prevention), three variables had a negative binomial distribution (Number of CBT sessions, total number of CBT sessions, total number of modules completed), one had a gamma distribution (CBT homework adherence), and five had a multinomial distribution (intention to seek treatment, comfort talking to a provider, stigma, helpfulness of treatment, spontaneous recovery). For each analysis we also controlled for baseline differences in site, education, race, number of chronic conditions, presence of GAD, PTSD, MDD, age and income.

Results

Demographic and baseline data

As shown in Table 1, a majority of the sample was female (n = 714, 71%). Demographic and baseline clinical characteristics at baseline are reported in Table 1. Women were less likely to be white, were less educated and earned a lower income than males in spite of being employed at similar rates. Women endorsed a greater number of chronic medical conditions and were more frequently diagnosed with GAD (77% vs. 70%, $\chi^2 = 5.38$, $df = 1$, $p = .02$) and major depression (67% vs. 60%, $\chi^2 = 4.26$, $df = 1$, $p = .04$) and had poorer physical health status on the SF-12 ($z = 3.49$, $p < .001$).

Clinical Outcomes

The results for BSI showed a two-way interaction effect of intervention and gender (F = 8.24, $df = 1,890$, $p = .004$). Women's casemix adjusted predicted means were significantly lower (i.e., better) for CC than those for UC whereas, for men, there were no significant differences between CC and UC.

For the MCS, there was also a significant two-way interaction between the intervention and gender (F =8.13, *df* = 1,889, *p* = .005). As shown in Table 2, women's casemix-adjusted predicted means (indicating better mental health functioning) were higher in than those in UC . For men there were no significant differences between CC and UC. For the PCS, no significant main effect or interaction effects were found.

On the Healthy Days scale, the two-way interaction between intervention and gender was significant (F = 5.03, *df* = 1,884, *p* = .03). Women in CC had significantly lower casemix adjusted predicted means (restricted activity days) than those in UC. For men there were no significant differences at any time point between CC and UC. Table 2 summarizes the casemix adjusted predicted means for each measure by gender.

Dose, Engagement and Beliefs about CBT

A majority (87%) of the sample received CBT. A third (33%) received CBT alone, 54% received CBT and pharmacotherapy, 9% received pharmacotherapy only, and 4% received no services. Casemix adjusted means for CBT dose, engagement and belief scores for the subset of patients randomized to CC are reported in Table 3. On average, women attended a greater number of CBT psychotherapy sessions than men, (7.3 vs. 6.5;O.R. = 1.18, *p* = .01) although the mean number of sessions for each group were within the recommended range (6–8 sessions). There were no differences in frequency of interrupted treatment or participation in relapse prevention, however, total number of CBT modules completed (O.R. = 2.44, *p* = .01) was greater for women. The clinician-rated measure of commitment (O.R. = 1.26, *p* = .04) was significantly higher for women and women estimated that a larger proportion of people who see a professional help for a serious emotional problem would benefit (63% vs. 59%; O.R. = 0.63 *p* = .02).

Discussion

This is the first study to evaluate gender as a moderator in CC for anxiety, and contributes to the growing literature on treatment heterogeneity and personalized medicine. Women had less access to economic and social resources (e.g., lower income, limited education) and suffered from more chronic health conditions than the men but benefited more from the intervention. These findings support our hypotheses that women would respond more favorably to the CC intervention. Females who received CC showed larger reductions in anxiety than females who received UC. Likewise, females who received CC showed greater improvements in mental health functioning and larger reductions in restricted activity days than females who received UC, whereas males who received CC did not show any differences compared to CC.

In order to understand the relative differences in response between men and women undergoing CC, we focused on gender differences in attitudes about mental health in patients who received CC while controlling for gender differences in baseline characteristics. Women reported a higher commitment to therapy and a stronger belief in the helpfulness of psychotherapy than men. These dimensions are thought to partially predict motivation and effort in treatment and have been found to be predictive of more positive clinical outcomes in CBT (42). With regard to dose of psychotherapy, women attended

approximately one more session of CBT than men and completed more exposure activities. Exposure activities are highly predictive of treatment outcome across studies of CBT for anxiety (20). Women were also judged by their providers to have a greater commitment to CBT which is also associated with better responses (20). It is possible that any one of these dose, engagement or belief factors could have contributed to the overall positive effect of CC for women or that the cumulative effect of several factors influenced the observed positive clinical outcomes.

There may also be unmeasured factors that contribute to the positive response among women. Prior work has found that women are responsive to social relationships and respond positively to therapy environments that foster empowerment and collaboration (43). In CC, the relationship with care managers is collaborative, with sessions focused on treatment decision-making. This may have reduced the complexity of the treatment environment, which has been shown to create barriers for women in treatment (44) and may have increased the patient's commitment to CBT (20). Women report that empowerment and assistance navigating the health care system are instrumental in achieving a positive treatment response, whereas men do not find these features as salient (43,45).

A major implication for continued improvement of CC interventions is to more effectively engage men in treatment beyond simply increasing attendance. One example of this is the National Institutes of Mental Health (NIMH)'s "Real Men, Real Depression" campaign, which is a public media campaign designed to communicate directly with men about their experiences of depression. The approach acknowledges that males in western culture are more likely to value their own self-reliance and less likely to ask for help when they experience problems (46). The goal of "Real Men, Real Depression" was to decrease stigma and to increase mental health treatment utilization by directly addressing the cultural barriers males face in choosing whether or not to get help (47). Relatively little attention, however, has focused on adapting psychotherapy protocols to incorporate strategies to address cultural barriers that interfere with dose, engagement and beliefs about mental health treatment. Based on data focus group data on male attitudes about mental health treatment, some potential adaptations could include discussion of typical male symptom profiles (e.g., fatigue, irritability and anger), strategies to reduce help-seeking apprehension and mental health stigma, and efforts to reduce apprehension about disclosure of distress during psychotherapy(46).

The following limitations should also be considered. This study is a secondary analysis and the study was not originally designed to test our specified hypotheses therefore, the risk of a Type 1 error is slightly higher due to multiple comparisons. Randomization was not stratified by gender. Many of the questions assessing attitudes and behavior were limited to a single, face valid item. Furthermore, gender was constrained to male and female, and did not account for the fluidity of gender and other dimensions of gender identity (e.g., transgender, bisexual, lesbian, or gay). Although we controlled for income, education, race/ethnicity, and diagnostic variables, it is likely that we did not capture all of the gender-based inequities (48). Lastly, belief, dose and engagement data are limited to the treatment group and therefore unavailable for moderation analysis.

Our findings contribute to the field of personalized medicine for both women and men. Future research will need to investigate which features of CC facilitate improvement among women and more importantly identify ways to tailor CC to meet the needs of males. For example, it would be beneficial to identify ways to increase men's confidence in the efficacy of psychotherapy and to develop strategies that increase engagement in therapy. Mixed-methods studies involving quantitative and qualitative research could explore the determinants that influence response to CC among genders in greater detail.

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Table 1

Baseline demographics and clinical characteristics by gender

Variable	Female				Male				Total		p-value
	N=714		71%		N=290		29%		N=100	100%	
	Control		Intervention		Control		Intervention				
	N	%	N	%	N	%	N	%	N	%	
	355	35%	359	36%	146	15%	144	14%	1004	100%	
Ethnicity											
Hispanic	71	20%	85	24%	21	14%	19	13%	196	20%	<.001
African American	58	16%	46	13%	7	5%	5	4%	116	12%	
Other	37	10%	47	13%	18	12%	22	15%	124	12%	
White	189	53%	181	50%	100	68%	98	68%	568	57%	
Education											
<12	21	6%	23	6%	5	3%	6	4%	55	5%	.15
=12	65	18%	64	18%	22	15%	14	10%	165	17%	
>12	269	76%	272	76%	119	82%	124	86%	784	78%	
Currently working	244	69%	253	71%	106	73%	105	73%	708	71%	.74
Insurance	309	87%	308	86%	128	88%	116	81%	861	86%	.32
Number of Medical Conditions											
0	59	17%	69	19%	34	23%	41	28%	203	20%	.11
1	82	23%	82	23%	29	20%	26	18%	219	22%	
≥2	214	60%	208	58%	83	57%	77	53%	582	58%	
Panic Disorder	166	47%	167	47%	74	51%	68	47%	475	47%	.85
Generalized Anxiety Disorder	268	75%	284	79%	98	67%	106	74%	756	75%	.04
Social Anxiety Disorder	137	39%	151	42%	58	40%	59	41%	405	40%	.82
Posttraumatic Stress Disorder	70	20%	69	19%	19	13%	23	16%	181	18%	.27
Major Depression	232	65%	243	68%	86	59%	87	60%	648	65%	.19
Number of Anxiety Disorders											
1	151	43%	139	39%	69	47%	62	43%	421	42%	.61
2	135	38%	142	40%	55	38%	55	38%	387	39%	

Variable	Female				Male				Total		p-value
	N=714		71%		N=290		29%		N=100	100%	
	Control		Intervention		Control		Intervention				
	N	%	N	%	N	%	N	%	N	%	
	355	35%	359	36%	146	15%	144	14%	1004	100%	
3–4	69	19%	78	22%	22	15%	27	19%	196	20%	
Any SUD	3	1%	3	1%	3	2%	1	1%	10	1%	.58
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	p-value
Age (Mean/SD)	43.30	13.83	42.86	13.52	44.53	13.44	44.34	12.29	43.47	13.44	0.43
Income (Mean/SD)	3.94	7.66	4.06	3.82	5.46	5.37	5.67	13.51	4.45	7.53	<.001
Sheehan (mean/SD)	17.3	7.18	16.88	7.62	16.69	6.90	16.52	6.96	16.96	7.27	.57
PCS 12 (mean/SD)	48.88	11.68	48.00	11.36	50.43	11.23	51.64	11.10	49.19	11.47	.0002
MCS12 (mean/SD)	31.88	9.83	31.51	9.83	32.47	10.80	32.00	10.36	31.85	10.04	.80
BSI12 (mean/SD)	16.17	8.81	16.90	9.13	16.42	9.28	15.11	8.48	16.32	8.96	.25
HD (mean/SD)	11.06	9.81	11.58	9.51	11.40	10.18	11.10	10.54	11.30	9.85	.65

The income variable is the adjusted income by age, family size and number of kids.

Table 2

Mean scores on the Brief Symptom Inventory, Healthy Days and Mental Composite Score by gender

	Male					Female				
	Intervention	**Control**	***df***	***F***	***p value***	**Intervention**	**Control**	***df***	***F***	***p* value**
Brief Symptom Inventory	9.78	10.32	1,890	0.49	*.48*	8.45	11.57	1,890	42.40	<.0001
Health Days	5.60	6.16	1,884	0.53	.46	4.63	7.23	1,884	28.63	<.0001
Mental Composite Score	43.62	41.75	1,889	2.80	.09	45.54	39.90	1,889	64.27	<.0001

Table 3

Parameter estimates for CBT dose, engagement and beliefs among Collaborative Care participants

Variable	Odds Ratio	F	*p*-value
Dose			
Number of CBT sessions [a]	1.18	6.31	.01
Interrupted Treatment [b]	1.04	0.01	.92
Relapse Prevention [c]	1.38	1.82	.18
CALM CBT Modules [d]	1.17	3.24	.07
CALM CBT Exposures [e]	2.44	5.96	.02
Engagement			
CBT Homework Adherence [f]	.93	3.34	.07
CBT Anxiety Commitment [g]	1.26	4.36	.04
Beliefs			
Outcome Expectancy [h]	1.20	2.51	.11
Self-Efficacy [i]	1.20	3.13	.08
Intention to Seek Treatment [j]	1.42	2.94	.09
Comfort talking to provider [k]	1.15	0.49	.48
Stigma [l]	.78	1.59	.21
Helpfulness of treatment [m]	.64	5.37	.02
Spontaneous Recovery [n]	1.04	0.03	.85

[a] Number of CBT sessions attended

[b] Number of participants with interruptions in CBT treatment due to life events or substance use

[c] Number of participants who received relapse prevention phone calls following the completion of CBT

[d] Mean number of CBT modules completed during the course of treatment with the care manager

[e] Mean of the total number of exposure modules completed during the course of treatment

[f] Mean homework adherence (1 = *missed most*; 2= *missed half*; 3 = *missed few*; 4 = *missed none*)

[g] Mean commitment rating (range = 1–10; 1 = *none*, 10 = *complete*)

[h] *How likely is it that your anxiety can be successfully treated?* (range = 0–8; 0 = *not at all*, 8 = *certainly*)

[i] *How likely is it that you will be able to do what is necessary to make your anxiety treatment successful?* (range = 0–8; 0 = *not at all*, 8 = *certainly*)

[j] *If you had a serious emotional problem, would you go for professional help?* (range = 1–4; 1 = *definitely*; 4 = *definitely not*)

[k] *How comfortable would you feel talking about personal problems with a professional?* (range = 1–4; 1 = *very comfortable*, 4 = *not at all comfortable*)

[l] *How embarrassed would you be if your friends knew you were getting professional help for an emotional problem?* (range = 1–4, 1 = *very embarrassed*, 4 = *not at all embarrassed*)

[m] *Of the people who see a professional for serious emotional problems, what percent do you think are helped?* (range = 0%–100%)

[n] *Of those who do not get professional help, what percentage do you think get better even without it?* (range = 0%–100%)