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Practice Based Versus Telemedicine Based Collaborative Care for Depression in Rural Federally Qualified Health Centers: A Pragmatic Randomized Comparative Effectiveness Trial

John C. Fortney, PhD[1,2,3], **Jeffrey M. Pyne, MD**[1,2,3], **Sip B. Mouden, MS, CRC**[4], **Dinesh Mittal, MD**[1,2,3], **Teresa J. Hudson, PharmD**[1,2,3], **Gary W. Schroeder, PhD**[1], **David K. Williams, PhD**[5], **Carol A. Bynum, PhD**[6], **Rhonda Mattox, MD**[7], and **Kathryn M Rost, PhD**[8]

[1]Division of Health Services Research, Department of Psychiatry, College of Medicine, University of Arkansas for Medical Sciences, Little Rock, AR, 72205

[2]South Central Mental Illness Education and Clinical Center, Central Arkansas Veterans Healthcare System, North Little Rock, AR, 27114

[3]Health Services Research and Development, Central Arkansas Veterans Healthcare System, North Little Rock, AR, 27114

[4]Community Health Centers of Arkansas Inc. North Little Rock, AR, 72114

[5]Department of Biostatistics, College of Public Health, University of Arkansas for Medical Sciences, Little Rock, AR, 72205

[6]Center for Distance Health, University of Arkansas for Medical Sciences, Little Rock, AR, 72205

[7]United Family Services, Little Rock, AR 72202

[8]Department of Mental Health Law and Policy, College of Behavioral and Community Sciences, University of South Florida, Tampa, FL 33612

Abstract

Objective—Practice Based Collaborative Care is a complex evidence-based practice that is difficult to implement in smaller primary care practices lacking on-site mental health staff. Telemedicine Based Collaborative Care virtually co-locates and integrates mental health providers into primary care settings. The objective of this multi-site randomized pragmatic comparative effectiveness trial was to compare the outcomes of patients randomized to Practice Based versus Telemedicine Based Collaborative Care.

Method—From 2007–2009, patients at Federally Qualified Health Centers serving medically underserved populations were screened for depression, and 364 patients screening positive were enrolled and followed for 18 months. Those randomized to Practice Based Collaborative Care received evidence-based care from an on-site primary care provider and nurse care manager. Those randomized to Telemedicine Based Collaborative Care received evidence-based care from an on-site primary care provider and off-site telephone nurse care manager, telephone pharmacist, tele-psychologist and tele-psychiatrist. The primary clinical outcomes were treatment response, remission and changes in depression severity

Contact Information for Primary Author: John Fortney, 4301 W. Markham St., Department of Psychiatry #755, University of Arkansas for Medical Sciences, Little Rock, AR, 72205, 501.526.8131, FortneyJohnC@UAMS.edu.

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Results—There were significant group main effects for both response (OR=7.74, CI_{95}=3.94–15.20, p<0.0001) and remission (OR=12.69, CI_{95}=4.81–33.46, p<0.0001) and a significant overall group by time interaction effect for Hopkins Symptom Checklist depression severity (χ^2_3=40.51, p<0.0001) with greater reductions in depression severity observed over time for those randomized to Telemedicine Based Collaborative Care. Improvements in outcomes appeared to be attributable to higher fidelity to the collaborative care evidence-base in the Telemedicine Based group.

Conclusions—Contracting with an off-site Telemedicine Based Collaborative Care team yields better outcomes than implementing Practice Based Collaborative Care with locally available staff.

INTRODUCTION

Complex evidence-based practices are difficult to implement with fidelity in routine care. One such evidence-based practice, Practice Based Collaborative Care (PBCC), involves co-located primary care (PC) providers, mental health (MH) specialists and care managers working together on-site in the PC setting. PBCC has been shown to improve depression outcomes in numerous randomized effectiveness trials.[1–7] However, implementation in smaller PC practices presents challenges where it is typically not feasible to employ on-site MH specialists or full-time care managers. Only 25% of U.S. PC practices have on-site MH specialists.[8] Two previous studies have demonstrated that depression outcomes can be improved in small PC clinics lacking on-site MH specialists by training on-site nurses to be depression care managers, however the effect sizes have been small to medium.[3, 9] Moreover, based on the results of a meta analysis of randomized trials of PBCC, Gilbody concluded that collaborative care interventions with more MH specialist involvement have larger effect sizes.[10]

Telemedicine technologies now make possible the virtual co-location of MH specialists and PC providers. Telemedicine Based Collaborative Care (TBCC) involves an off-site team of MH specialists collaborating with on-site PC providers, from a centralized location, using telephones, interactive video and electronic health records. A multi-site randomized trial conducted in the Department of Veterans Affairs demonstrated that TBCC is more effective than usual care in small satellite PC clinics.[11, 12] TBCC has also been adopted and sustained as part of routine care in small satellite PC clinics within the Department of Veterans Affairs.[13] Compared to PBCC, TBCC has the potential to be implemented with higher fidelity in smaller PC clinics because the off-site team can include an array of MH specialists, and full-time care managers can practice under more intensive clinical supervision and dedicate their time to care-coordination activities (resulting in higher fidelity to care manager protocols). However, there are also potential disadvantages to TBCC. Off-site care managers cannot build upon established relationships with patients and may have difficulty establishing therapeutic alliances from a distance. Likewise, if off-site care managers lack access to on-site medical records, they may have difficulties integrating behavioral and physical aspects of care and face barriers communicating with on-site PC providers. In addition, the stepped care elements of the collaborative care model (e.g., psychiatric consultation) may be less effective when delivered via telemedicine. However, patients and providers uniformly report high levels of satisfaction with interactive video,[14–17] and there is good evidence documenting the clinical equivalency of psychiatric[18–21] and psychological[22–26] treatments delivered via interactive video compared to face to face.

Given that: 1) PBCC without the involvement of on-site MH specialists improves outcomes, 2) PBCC with involvement from on-site MH specialists improves outcomes more, and 3) the potential disadvantages of TBCC, an important policy relevant question is whether it is more effective for small remote PC clinics to implement PBCC without the involvement of on-site

MH specialists or to implement TBCC in partnership with an off-site team of tele-MH specialists. Therefore, the objective of this Pragmatic [27] Comparative Effectiveness Trial [28] (NCT00439452) was to compare the process outcomes and clinical outcomes of patients randomized to TBCC versus PBCC in small remote PC clinics lacking on-site MH specialists, thereby comparing two organizational approaches (with clinical equipoise) to delivering collaborative care for depression.[29] We chose to conduct a pragmatic trial design in order to compare two viable competing strategies to delivering an evidence-based practice rather than an explanatory trial designed to determine why one approach was superior to the other. Compared to patients randomized to PBCC, we hypothesized that patients randomized to TBCC would receive higher fidelity care management, more specialty MH services (e.g., tele-psychiatry and tele-psychology), and higher quality pharmacotherapy, and therefore would experience greater symptom improvement. Secondary outcomes examined included health status, quality of life, and satisfaction with care.

We partnered with five Federally Qualified Health Centers (FQHCs) serving medically underserved populations in Arkansas' Mississippi delta and Ozark highlands. With federal oversight from Health Resources and Services Administration (HRSA), FQHCs make up the nation's largest and fastest growing network of PC providers, with 8,000 clinics providing services to 20 million Americans.[30, 31] Three quarters of FQHC patients live in poverty, half live in rural areas, a third are uninsured, and a third are from minority populations. MH problems are the most commonly reported reasons for visits to FQHCs.[32] Yet, only 5.5% of encounters are with on-site MH specialists.[33] Research conducted in partnership with FQHCs has direct applicability to a large segment of the US population at risk for experiencing health disparities.

METHODS

Design Overview

This multi-site randomized trial employed a comparative effectiveness research design. [28] Patients were randomized to one of two active treatment arms, both of which represented potentially feasible approaches to adapting the evidence-based collaborative care model for routine delivery in medically underserved areas. The study design also included many elements of pragmatic trials[27] including: 1) applying relatively few exclusion criteria, 2) enrolling a diverse sample of patients, 3) monitoring but not controlling intervention fidelity, 4) defining the primary outcome as changes in *patient-reported* symptoms , and 5) using intent-to-treat analyses to examine group differences.

Setting and Participants

We approached six FQHCs, and five (83.3%) agreed to participate. Participating FQHCs employed between 1.3 and 9.7 PC physician FTEs, served between 5,362 and 13,050 unique PC patients, and operated one to six clinics across multiple locations. None of the participating clinic locations had an on-site MH specialist. Between November 2007 and June 2009, 19,285 patients were screened for depression by FQHC staff using the PHQ9 (see Consort Diagram). Fifteen percent of patients (n=2,863) screened positive (PHQ9 ≥10); FQHC staff obtained informed consent from 62% of potentially eligible patients (n=829); and 55% (n=364) were found to be eligible and completed the baseline telephone interview. We excluded patients that PC providers would not be comfortable treating. These exclusion criteria included pregnancy, schizophrenia, acute suicide ideation, substance dependence, bipolar disorder, recent bereavement and already receiving specialty mental health treatment. We also excluded patients who were unable to participate in research. These exclusion criteria included cognitive impairment, court-appointed guardian, non-English

speaking, no telephone, or life event preventing participation. Screening and eligibility results were entered into the medical record.

Randomization and Interventions

Randomization—Patients were the unit of randomization. Eligible patients were computer randomized using a 2×2 Latin Square Design (stratified by clinic) to either TBCC or PBCC. It was not feasible to blind patients or providers to randomization status.

Practice-Based Collaborative Care (PBCC)—The PBCC intervention was designed to be the same as the model of care supported by HRSA, known as the Depression Health Disparities Collaborative,[34, 35] and represents more intensive treatment than usual care. PBCC involved two types of providers: on-site PC providers and on-site nurse depression care managers (DCM). Each clinic location employed a half-time Depression Care Manager (DCM) funded by the study. DCMs were RNs or LPNs who had no prior MH experience. They received one day of training in depression care management, a care manager training manual, and access to a web-based patient registry and DCM decision support system (https://www.netdss.net/).[36] Patients could choose either watchful waiting or antidepressant treatment. DCM encounters were conducted either face-to-face or by telephone depending on the preference of the patient. The initial DCM encounter included: 1) PHQ9 symptom monitoring; 2) education/activation; 3) barrier assessment/resolution; and 4) establishing self-management goals, including planning physical, rewarding, and social activities. Follow-up encounters, scheduled every two weeks during acute treatment and every four weeks during continuation treatment, included the monitoring of: 1) PHQ9 symptoms, 2) medication adherence, 3) side-effects and 4) engagement in planned self-management activities. DCMs received no clinical supervision from a MH specialist. Progress notes were entered into the patients' paper medical record. A trial was considered to have failed in the acute phase if the patient did not respond (i.e., 50% decrease in PHQ9 score) after eight weeks of treatment. No additional on-site MH support was available for patients failing treatment, although patients could be referred to off-site MH providers (e.g., Community Mental Health Centers). Patients received the intervention for up to 12 months.

Telemedicine-Based Collaborative Care (TBCC)—TBCC involved five types of providers: on-site PC providers, and off-site DCM (RN), pharmacist (PharmD), psychologist (PhD) and psychiatrist (MD). The off-site team was funded by the study and located at the University of Arkansas for Medical Sciences. The full-time DCM was an RN who had no prior MH experience and received the same training and tools as the on-site DCMs. All DCM encounters were conducted by telephone and followed the protocol described above. Progress notes were faxed to the clinic. During weekly meetings, the DCM received clinical supervision and the off-site team discussed new patients and patients failing treatment, and offered treatment recommendations to PC providers via the DCM progress notes. Patients received stepped-care, whereby treatment intensity was increased for patients failing treatment. If the patient did not respond to the initial antidepressant, the telephone pharmacist conducted a medication history and provided medication management as needed. If the patient did not respond to two trials, a psychiatry consultation via interactive video was scheduled. At any time, patients had access to cognitive behavioral therapy (CBT) delivered via interactive video, and patients failing an antidepressant trial were specifically encouraged to initiate and complete CBT.

Outcomes and Follow-up

Fidelity Assessment—Fidelity to the DCM protocol was measured from chart review. Five (1.4%) of the charts could not be located during the site visits. The following fidelity measures were abstracted: number of DCM encounters with documented PHQ9 scores, self-

management activities, antidepressant adherence assessments, and side-effect assessments (for those prescribed antidepressants) and counseling adherence assessments (for those referred to psychotherapy). DCM fidelity was also measured from patient self-report during the 6 and 12 months telephone interviews using items that addressed: education, self-management, symptom monitoring, adherence monitoring and collaboration among providers. To measure fidelity to the stepped care protocol, we examined what proportion of patients randomized to TBCC and failing at least one medication trial had a telephone pharmacist encounter, and what proportion of those failing two trials had a tele-psychiatry consultation. We also examined what proportion of those randomized to TBCC attended at least one tele-psychotherapy session and completed ≥8 sessions.

Baseline Interviews—Data were collected at baseline via blinded telephone interview. At baseline, socio-demographic and clinical casemix factors were collected using the Depression Outcomes Module,[37, 38] Mini International Neuropsychiatric Interview,[39, 40] Duke Social Support and Stress Scale,[41, 42] Quality Improvement for Depression Treatment Acceptability scale,[3, 4] and the Depression Health Beliefs Inventory.[43] Zip codes were used to categorize patient's residence as rural or urban according to Rural Urban Commuting Area (RUCA) classification scheme C.

Follow-up Interviews—Blinded follow-up telephone interviews were completed for 87% (n=318) at 6 months, 79% (n=287) at 12 months and 78% (n=283) at 18 months. In addition to the fidelity measures described above, the other primary process measures included self-reported MH service utilization, antidepressant prescriptions, antidepressant dose (categorized as starting, usual or high[44]) and antidepressant adherence (taking the full prescribed dosage at least 80% of days in previous month). The primary clinical outcomes were changes in depression severity, and treatment response and remission. Depression severity was measured continuously using the Hopkins Symptom Checklist SCL-20.[45, 46] Response was measured dichotomously as a 50% improvement in SCL-20 score between baseline and follow-up. Remission was measured dichotomously as a SCL-20 score <0.5. Secondary outcomes included health status (PCS and MCS scores from the SF12),[47, 48] quality of life (Quality of Well Being - QWB),[49–52] and satisfaction with care (CAHPS).[53]

Statistical Analysis

Patients were the unit of the intent-to-treat analysis. Clinic level intraclass correlation coefficients for SCL-20 change scores were not significant. Provider level intraclass correlation could not be calculated because patients could have multiple PC providers. For the hypotheses examining fidelity, separate logistic regressions were specified for the first six months and the second six months. For the hypotheses examining other outcomes, we used mixed models and included data from all completed research assessments.[54] Casemix variables were selected using the method of purposeful selection.[55, 56] Casemix variables with missing values were imputed using the PROC MI procedure in SAS9.3. PROC MIXED and PROC GLIMMIX were used with the PROC MIANALYZE procedure to model outcomes with linear (e.g., SCL20), binomial (e.g., response), negative binomial (e.g., visits) or ordinal (dosage categories) distributions. All models specified clinic as a random effect to control for ICC. Time was included as a fixed effect. The model specifications included main effects for group and time (with PBCC assigned as the reference group), and interaction effects for group by time. The main group effect was used to test the hypotheses for dependent variables not measured at baseline (e.g., response). For dependent variables measured at baseline (e.g., SCL-20), group by time interaction effects were used to test the hypotheses that the rate of improvement differed across the two groups. Because there were multiple group by time interaction terms, an omnibus test was used to determine whether these variables collectively explained a significant amount of the variance in the dependent

variable.[57] If the omnibus test was significant at the conservative alpha <0.10 level, we report group differences and significance tests for each time period. Otherwise, we report group differences averaged across the time periods and one significance test. There was 85% power to detect a 15% difference (e.g., 30% versus 45%) in response rates.

RESULTS

The socio-economic and clinical characteristics of study participants are provided in Table 1. Two thirds (64.5%) were unemployed, 69.7% had annual household incomes <$20,000, 50.8% were uninsured, and 68.1% lived in a rural area. At baseline, 83.2% met diagnostic criteria for major depressive disorder, and the mean SCL-20 score was 1.9, indicating moderately severe depression. The mean number of chronic physical health disorders was 4.6 (sd=2.6), and psychiatric comorbidity was common. Mean PCS and MCS scores were nearly two standard deviations below the general population. Nearly half (48.4%) were already receiving depression treatment at enrollment, indicating treatment resistance.

Care Manager Fidelity

Table 2 describes care manager fidelity. At the 6 and 12 month follow-ups, significantly more patients randomized to TBCC compared to PBCC reported that a health care professional other than their PC provider: 1) gave them helpful information about depression or depression treatment (6 months: OR=2.77, CI_{95}=1.67–4.61, p=<0.0001; 12 months: OR=2.32, CI_{95}=1.37–3.94, p=0.0018), 2) made helpful suggestions about things they could do to help depression, such as exercise or becoming more socially active (6 months: OR=3.47, CI_{95}=2.15–5.62, p<0.0001; 12 months: OR=2.50, CI_{95}=1.48–4.23, p=0.0006), 3) asked them about their depression symptoms (6 months: OR=3.60, CI_{95}=2.21–5.86, p<0.0001; 12 months: OR=2.63, CI_{95}=1.54–4.52, p=0.0004), 4) asked them whether there were taking antidepressant medications as prescribed or attending scheduled counseling sessions (6 months: OR=4.70, CI_{95}=2.82–7.84, p<0.0001; 12 months: OR=3.96, CI_{95}=2.22–7.05, p<0.0001), and 5) their PC provider worked collaboratively with a MH specialist (6 months: OR=4.63, CI_{95}=2.08–10.30, p=0.0002; 12 months: OR=9.05, CI_{95}=3.04–26.93, p<0.0001).

Compared to patients randomized to PBCC, patients randomized to TBCC had significantly more DCM encounters with PHQ9 depression severity scores documented in the medical record during the first six months (Incidence Rate Ratio (IR)=4.10, CI_{95}=3.41–4.92, p<0.0001) and second six months (IR=4.64, CI_{95}=3.19–6.74, p<0.0001). Patients randomized to TBCC also had significantly more DCM encounters with documented self-management goals during the first six months (IR=5.62, CI_{95}=4.46–7.07, p<0.0001). Among those patients prescribed an antidepressant, those randomized to TBCC had significantly more DCM encounters with medication adherence documented compared to those randomized to PBCC during the first six months (IR=2.69, CI_{95}=2.20–3.28, p<0.0001) and second six months (IR=2.49, CI_{95}=1.69–3.67, p<0.0001). Likewise, TBCC patients prescribed an antidepressant had significantly more DCM encounters with presence/absence of side effects documented during the first six months (IR=4.22, CI_{95}=3.32–5.36, p<0.0001) and second six months (IR=4.46, CI_{95}=2.75–7.25, p<0.0001). Among those patients referred to counseling, there were no significant group differences in the number of DCM encounters with session attendance documented in the medical record.

Stepped Care Fidelity

Among patients randomized to TBCC and failing at least one medication trial (n=73), 8.2% (n=6) had a telephone encounter with the tele-pharmacist. Among those with at least two failed trials (n=29), 48.3% (n=14) had a tele-psychiatry consultation. Another seven patients

had an ad hoc tele-psychiatry consultation. Also, 16.6% (n=30) attended at least one tele-psychotherapy session and 7.8% (n=14) completed ≥8 sessions.

Treatment Process Outcomes

Table 3 describes the treatment provided to the two groups. There were no significant group differences at baseline, and no significant group by time interactions for number of PC visits (χ^2_3=5.11, p=0.16) or number of depression-related PC visits (χ^2_3=3.74, p=0.29), or MH visits (χ^2_3=5.19, p=0.16). With respect to antidepressant treatment, there were no significant group main effects for being prescribed an antidepressant (OR=1.64, CI_{95}=0.75–3.58, p=0.21), number of prescribed antidepressants (Incidence Ratio=1.19, CI_{95}=0.92–1.56, p=0.19), dose level (starting, usual, high) (OR=1.84, CI_{95}=0.77–4.38, p=0.17), or adherence (OR=1.22, CI_{95}=0.38–3.89, p=0.74).

Clinical Outcomes

Clinical outcomes are presented in Table 4. There was a significant group main effect for both response (OR=7.74, CI_{95}=3.94–15.20, p<0.0001) and remission (OR=12.69, CI_{95}=4.81–33.46, p<0.0001) with patients randomized to TBCC having better outcomes. There was also a significant overall group by time interaction effect for SCL-20 (χ^2_3=40.51, p<0.0001), with greater reductions in severity for those randomized to TBCC (Figure 2). There was also a significant overall group by time interaction effect for MCS (χ^2_3=11.46, p=0.01) and QWB (χ^2_3=6.55, p=0.09), with greater improvements among patients randomized to TBCC. There were no significant overall group by time interaction effects for PCS (χ^2_3=2.61, p=0.46, although this finding is likely an artifact resulting from the orthogonal factor rotation and negative weights used to score the MCS and PCS.[58] There were no group differences in satisfaction at baseline, but the omnibus test of the group by time interactions was significant at the alpha <0.10 level (χ^2_3=6.69, p=0.08), with the TBCC group having higher satisfaction.

DISCUSSION

Study participants were recruited from small remote PC clinics associated with the largest publically-funded healthcare system in the country. The sample was predominantly rural, unemployed, and uninsured. Patients had numerous comorbidities and were treatment resistant. The high degree of treatment resistance likely contributed to the low response/remission rates among those randomized to the PBCC group. Compared to patients randomized to PBCC, patients randomized to TBCC had significantly and substantially greater treatment response rates, remission rates, reductions in depression severity and increases in mental health status and quality of life. Improved outcomes were achieved in the TBCC group without increasing the number of PC visits. Improved outcomes appear to be due to higher fidelity to the care manager protocol in the TBCC model, despite the fact that off-site and on-site DCMs had similar levels of clinical experience at baseline and underwent identical training. The higher fidelity to the care manager protocol in the TBCC model may have been due to the fact that the off-site DCM practiced under more intensive clinical supervision and dedicated 100% of her time to DCM activities.

The greater fidelity to the care manager protocol did not translate into improvements in the quality of pharmacotherapy in the TBCC group. The majority of patients in both groups initiated antidepressant treatment at therapeutic dosages and adherence was high. Likewise, the psychotherapy available to patients in the TBCC group via interactive video was not highly utilized, and was not likely to have contributed substantially to improved outcomes. Our findings were essentially unchanged when patients receiving tele-psychotherapy were excluded from the analytical sample. Because group differences in outcomes are not likely

to be attributable to either pharmacotherapy or psychotherapy , we hypothesize that patients randomized to TBCC were more likely to engage in self-management activities such as physical, rewarding, and social activities. This hypothesis is based on the finding that TBCC patients received more encouragement from the DCM to engage in self-management activities. Previous research has demonstrated that behavioral activation is a clinically effective stand-alone treatment for depression.[59, 60] Also, patients randomized to the PBCC intervention in Project Impact were found to have significantly better treatment response rates if the DCM documented in the medical record that the patient scheduled physical, rewarding, and social activities.[61] This hypothesis needs to be tested using an experimental dismantling study specifically designed to estimate the incremental treatment effect of scheduling self-management activities. Another possibility is that the more frequent DCM encounters provided to the TBCC group resulted in greater social support, which in turn reduced depressive symptoms. This was the conclusion of Hunkeler who similarly reported that a DCM program at Kaiser Permanente did not improve antidepressant management, but did reduce depression symptoms.[62]

An inherent limitation of this pragmatic trial (designed to inform policy), is that results are not conclusive with respect to identifying treatment mechanisms. Explanatory trial designs are needed to determine why patients randomized to TBCC had better outcomes than those randomized to PBCC. However, for policy makers at HRSA and FQHCs lacking on-site MH personnel, these results clearly indicate that contracting with an off-site depression care team yields better depression outcomes than implementing collaborative care with staff available on-site. Future research should also examine whether having on-site nurse care managers supported by off-site tele-psychiatrists, tele-psychologists and tele-pharmacists is an effective organizational approach to delivering collaborative care.

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Figure 1.
Consort Diagram

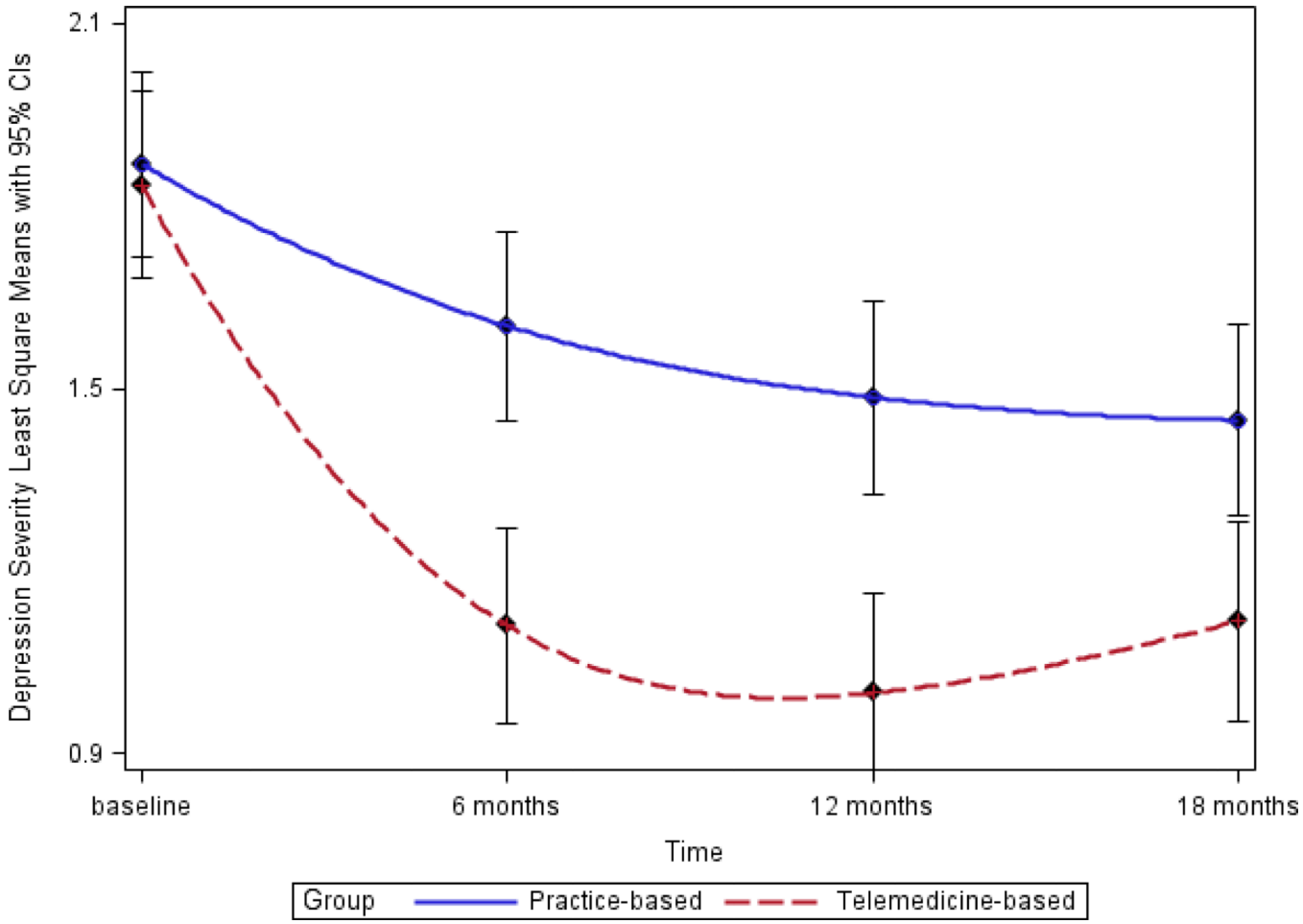

Figure 2.
Adjusted Depression Severity SCL_20 Scores
Least square means, or marginal means, are the estimated group means controlling for the covariates, which are held constant at their mean values.

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Table 1

Group Differences in Baseline Patient Socio-Demographic and Clinical Characteristics[a]

Characteristics		All (N=364)	Telemedicine Based Collaborative Care (N=179)	Practice Based Collaborative Care (N=185)	P value		
Age, mean(SD)		47.2(12.6)	47.7(12.5)	46.8(12.8)	0.50		
Male (%)		67(18.4)	32(17.9)	35(18.9)	0.80		
Race/Ethnicity							
	Caucasian	261(71.7)	128(71.5)	133(71.9)			
	African American	76(20.9)	39(21.8)	37(20.0)	0.79		
	Native American	18(5.0)	7(3.9)	11(6.0)			
	Other	9(2.5)	5(2.8)	4(2.2)			
Income							
	< $10,000	104(29.7)	59(33.7)	45(25.7)			
	$10,000 – $15,000	84(24.0)	42(24.0)	42(24.0)			
	$15,000 – $20,000	56(16.0)	29(16.6)	27(15.4)			
	$20,000 – $30,000	61(17.4)	25(14.3)	36(20.6)	0.58		
	$30,000 – $40,000	24(6.9)	10(5.7)	14(8.0)			
	$40,000 – $50,000	12(3.4)	6(3.4)	6(3.4)			
	>$50,000	9(2.6)	4(2.3)	5(2.9)			
	Rural (%)		248(68.1)	119(66.5)		129(69.7)	0.51
Married (%)		162(44.5)	79(44.1)	83(44.9)	0.89		
High school graduate (%)		265(73.0)	125(70.2)	140(75.7)	0.24		
Employed (%)		129(35.5)	57(31.8)	72(39.1)	0.15		
Insurance[b]					0.09		
	Public_insurance	110(30.2)	64(35.8)	46(24.9)			
	Private_insurance	54(14.8)	28(15.6)	26(14.1)			
	Both_insurance	15(4.1)	7(3.9)	8(4.3)			
	Uinsurance	185(50.8)	80(44.7)	105(56.8)			

Characteristics	All (N=364)	Telemedicine Based Collaborative Care (N=179)	Practice Based Collaborative Care (N=185)	P value
Social support (0–1), mean(SD)	0.4(0.2)	0.4(0.2)	0.4(0.2)	0.88
Perceived barriers (0–9), mean(SD)	3.7(2.0)	4.0(2.1)	3.4(1.9)	0.01
Perceived need (0–6), mean(SD)	3.0(1.5)	3.1(1.5)	3.0(1.5)	0.22
Perceived treatment effectiveness (0–2), mean(SD)	1.3(0.7)	1.3(0.7)	1.3(0.7)	0.75
SCL-20(Depression Severity score: 0–4), mean(SD)	1.9(0.7)	1.9(0.8)	1.9(0.7)	0.73
PCS(Physical Component score: 0–100), mean(SD)	36.9(13.4)	35.7(13.1)	38.0(13.7)	0.11
MCS(Mental Component score: 0–100), mean(SD)	31.3(11.2)	32.4(11.1)	30.3(11.2)	0.08
QWB(Quality of Well-Being score: 0–1), mean(SD)	0.4(0.1)	0.4(0.1)	0.4(0.1)	0.61
Chronic physical illness count, mean(SD)	4.6(2.6)	4.8(2.5)	4.3(2.6)	0.05
Family history of depression (%)	209(58.2)	110(62.5)	99(54.1)	0.11
Age depression onset <18 (%)	144(41.0)	67(39.2)	77(42.8)	0.49
Prior depression episodes count, mean(SD)	4.2(1.6)	4.2(1.6)	4.2(1.6)	0.72
Prior antidepressant(%)	267(73.35)	128(71.51)	139(75.14)	0.43
Prior counseling (%)	107(29.40)	51(28.49)	56(30.27)	0.71
Current depression Treatment (%)	176(48.4)	84(46.9)	92(49.7)	0.59
Antidepressants acceptable (%)	303(85.1)	149(84.7)	154(85.6)	0.81
Counseling acceptability (%)	273(76.9)	136(77.7)	137(76.1)	0.72
Current major depressive disorder (%)	303(83.2)	144(80.5)	159(86.0)	0.16
Current dysthymia (%)	12(3.3)	7(3.9)	5(2.7)	0.52
Current panic disorder (%)	32(8.8)	16(8.9)	16(8.7)	0.92
Current generalized anxiety disorder (%)	231(63.5)	114(63.7)	117(63.2)	0.93
Current post traumatic stress disorder (%)	58(15.9)	30(16.8)	28(15.1)	0.67
Current at–risk drinking (%)	20(5.5)	12(6.7)	8(4.3)	0.32

[a] Some numbers do not add up to total number of patients because of missing data and some percents do not add up to 100 because of rounding.

[b] Percentages do not add up to 100 because some patients had more than one type of insurance.

Table 2

Group Differences in Fidelity to the Care Manager Protocol

Patient Self Report							
			Telemedicine-Based Collaborative Care (%)	Practice-Based Collaborative Care (%)	P value	Adjusted Odds Ratio (95% CI)[a]	P value
Education[b]	6 mo[1]	Frequently	38/153(24.84)	18/165(10.91)	0.0002	2.77(1.67,4.61)	<0.0001
		Occasionally	39/153(25.49)	29/165(17.58)			
		Not at all	76/153(49.67)	118/165(71.52)			
	12 mo[2]	Frequently	24/138(17.39)	11/149(7.38)	0.0102	2.32(1.37,3.94)	0.0018
		Occasionally	31/138(22.46)	26/149(17.45)			
		Not at all	83/138(60.14)	112/149(75.17)			
Self Management[c]	6 mo[3]	Frequently	49/153(32.03)	22/165(13.33)	<.0001	3.47(2.15,5.62)	<.0001
		Occasionally	51/153(33.33)	42/165(25.45)			
		Not at all	53/153(34.64)	101/165(61.21)			
	12 mo[4]	Frequently	35/138(25.36)	12/149(8.05)	0.0004	2.50(1.48,4.23)	0.0006
		Occasionally	25/138(18.12)	31/149(20.81)			
		Not at all	78/138(56.52)	106/149(71.14)			
Symptom Monitoring[d]	6 mo[5]	Frequently	53/153(34.64)	24/165(14.55)	<.0001	3.60(2.21,5.86)	<.0001
		Occasionally	41/153(26.80)	29/165(17.58)			
		Not at all	59/153(38.56)	112/165(67.88)			
	12 mo[6]	Frequently	34/138(24.64)	12/149(8.05)	0.0006	2.63(1.54,4.52)	0.0004
		Occasionally	23/138(16.67)	27/149(18.12)			
		Not at all	81/138(58.70)	110/149(73.83)			
Antidepressant Monitoring[e]	6 mo[7]	Frequently	46/153(30.07)	18/165(10.91)	<.0001	4.70(2.82,7.84)	<.0001
		Occasionally	47/153(30.72)	28/165(16.97)			
		Not at all	60/153(39.22)	119/165(72.12)			
	12 mo[8]	Frequently	33/138(23.91)	11/149(7.38)	<.0001	3.96(2.22,7.05)	<.0001
		Occasionally	27/138(19.57)	18/149(12.08)			
		Not at all	78/138(56.52)	120/149(80.54)			

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Patient Self Report

			Telemedicine-Based Collaborative Care (%)	Practice-Based Collaborative Care (%)	P value	Adjusted Odds Ratio (95% CI)[a]	P value
Collaboration[f]	6 mo[9]	Frequently	22/96(22.92)	8/112(7.14)	0.0012	4.63(2.08,10.30)	0.0002
		Occasionally	13/96(13.54)	9/112(8.04)			
		Not at all	61/96(63.54)	95/112(84.82)			
	12 mo[10]	Frequently	12/91(13.19)	4/111(3.60)	0.0062	9.05(3.04,26.93)	<.0001
		Occasionally	10/91(10.99)	5/111(4.50)			
		Not at all	69/91(75.82)	102/111(91.89)			

Chart Review

		Telemedicine-Based Collaborative Care, Mean (sd)	Practice-Based Collaborative Care, Mean (sd)	P value	Adjusted Incidence Rate Ratio (95% CI)	P value
Education[g]	0–6 mo[11]	0.56(0.65)	0.16(0.48)	<.0001	2.03(1.38,2.98)	0.0003
	6–12 mo[12]	0.02(0.13)	0.02(0.15)	0.7425	1.06(0.27,4.17)	0.9315
Self Management	0–6 mo[13]	4.12(2.56)	0.77(1.47)	<.0001	5.62(4.46,7.07)	<.0001
	6–12 mo[14]	2.08(2.70)	0.26(0.92)	<.0001	8.84(5.44,14.35)	<.0001
Symptom monitoring	0–6 mo[15]	4.85(2.69)	1.19(1.65)	<.0001	4.10(3.41,4.92)	<.0001
	6–12 mo[16]	2.11(2.73)	0.44(1.07)	<.0001	4.64 (3.19,6.74)	<.0001
Antidepressant Monitoring[h]	0–6 mo[17]	5.40(2.29)	1.97(1.81)	<.0001	2.69(2.20,3.28)	<.0001
	6–12 mo[18]	3.94(2.49)	1.47(1.72)	<.0001	2.49(1.69,3.67)	<.0001
Side effect Monitoring[g,h]	0–6 mo[19]	5.18(2.29)	1.24(1.49)	<.0001	4.22(3.32,5.36)	<.0001
	6–12 mo[20]	3.73(2.45)	0.80(1.19)	<.0001	4.46(2.75,7.25)	<.0001
Counseling Monitoring[h]	0–6 mo[21]	3.44(2.68)	2.70(1.64)	0.4166	1.13(0.63,2.05)	0.6643
	6–12 mo[22]	2.57(2.27)	2.00(2.71)	0.6581	2.91(0.08,110.94)	0.4193

[a] Abbreviation: CI, confidence interval.

[b] How often did a health care professional other than your PCP give you helpful information about depression or depression treatment?

[c] How often did a health care professional other than your PCP make helpful suggestions about things you can do to help depression such as exercise or becoming more active socially?

[d] How often did a health care professional other than your PCP ask you about your depression symptoms?

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[e] How often did a health care professional other than your PCP ask you whether you were taking antidepressant medications as prescribed or attending scheduled counseling sessions?

[f] How often did your PCP work together with a mental health specialist to care for your depression symptoms?

[g] Model did not include a random effect to control for ICC because when included the variance-covariance matrix was positive definite indicating not enough variation in the dependent variable attributable to variation in the random effect.

[h] Antidepressant analysis conducted on sub-sample of 187 patients. Counseling analysis conducted on sub-sample of 42 patients.

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Table 3

Group Differences in Services Utilization and Antidepressant Treatment

Service Utilization							
	Telemedicine Based Collaborative Care Mean (sd)	**Practice Based Collaborative Care Mean (sd)**	**Unadjusted difference**	**P value**	**Adjusted Incidence Rate Ratio (95% CI)[a]**	**P value**	**Omnibus test P value**
Primary Care Visits							
Baseline	4.25(3.73)	3.63(3.04)	0.62	0.0813	1.16(0.98,1.36)	0.0807	χ^2_3=5.11, P =0.16
6 mo	3.82(3.34)	3.69(3.98)	0.13	0.7489			
12 mo	3.09(2.71)	3.39(3.44)	−0.30	0.4185			
18 mo	2.72(2.36)	2.98(3.54)	−0.26	0.4626			
Depression Related Primary Care Visits[b]							
Baseline	1.07(1.43)	1.16(1.55)	−0.09	0.5916	0.99(0.72,1.37)	0.9579	χ^2_3=3.74, P=0.29
6 mo	1.07(1.93)	1.17(2.24)	−0.10	0.6580			
12 mo	0.68(1.31)	1.05(1.98)	−0.37	0.0681			
18 mo	0.58(1.17)	0.94(2.06)	−0.36	0.0795			
	Telemedicine Based Collaborative Care (%)	**Practice Based Collaborative Care (%)**	**Unadjusted Odds Ratio (95% CI)**	**P value**	**Adjusted Odds Ratio (95% CI)**	**P value**	**Omnibus test P value**
Any Specialty Mental Health Visits[c]							
Baseline	8/179(4.47)	12/185(6.49)	0.67(0.27,1.69)	0.3985	0.56(0.24,1.82)	0.4253	χ^2_3=5.19, P=0.16
6 mo	31/153(20.26)	21/165(12.73)	1.74(0.95,3.19)	0.0695			
12 mo	20/138(14.49)	13/149(8.72)	1.77(0.85,3.72)	0.1259			
18 mo	13/132(9.85)	18/151(11.92)	0.81(0.38,1.72)	0.5777			
Antidepressant Medications							
	Telemedicine Based Collaborative Care (%)	**Practice Based Collaborative Care (%)**	**Unadjusted Odds Ratio (95% CI)**	**P value**	**Adjusted Odds Ratio (95% CI)**	**P value**	**Omnibus test P value**
Prescribed Any Antidepressant							

Service Utilization								
		Telemedicine Based Collaborative Care Mean (sd)	**Practice Based Collaborative Care Mean (sd)**	**Unadjusted difference**	**P value**	**Adjusted Incidence Rate Ratio (95% CI)[a]**	**P value**	**Omnibus test P value**
Baseline		-	-	-	-	-	-	-
6 mo		100/153(65.36)	100/165(60.61)	1.23(0.78,1.94)	0.3806	1.64(0.75,3.58)	0.2117	χ^2_2=1.98, P=0.37
12 mo		91/138(65.94)	86/149(57.72)	1.42(0.88,2.29)	0.1522			
18 mo		74/132(56.06)	86/151(56.95)	0.96(0.60,1.54)	0.8798			
Adherence[d,e]								
Baseline		-	-	-	-	-	-	-
6 mo		82/92(89.13)	81/95(85.26)	1.42(0.60,3.38)	0.4293	1.22(0.38,3.89)	0.7369	χ^2_2=0.30, P =0.86
12 mo		74/86(86.05)	67/80(83.75)	1.20(0.51,2.80)	0.6793			
18 mo		62/69(89.86)	73/81(90.12)	0.97(0.33,2.83)	0.9565			
Dosage Level[f]								
Baseline		-	-	-	-	-	-	-
6 mo	Starting	44/98(44.90)	45/92(48.91)	-	0.1468	1.84(0.77,4.38)	0.1687	χ^2_2=0.75, P=0.69
		Usual	42/98(42.86)	43/92(46.74)	-			
		High	12/98(12.24)	4/92(4.35)	-			
12 mo	Starting	32/86(37.21)	34/85(40.00)	-	0.5514			
	Usual	40/86(46.51)	42/85(49.41)	-				
	High	14/86(16.28)	9/85(10.59)	-				
18 mo	Starting	27/69(39.13)	37/79(46.84)	-	0.4438			
	Usual	33/69(47.83)	36/79(45.57)	-				
	High	9/69(13.04)	6/79(7.59)	-				
		Telemedicine-Based Collaborative Care Mean(SD)	**Practice-Based Collaborative Care Mean(SD)**	**Unadjusted difference**	**P value**	**Adjusted Incidence Rate Ratio (95% CI)[a]**	**P value**	**Omnibus test P value**
Number of Prescribed Antidepressants								
Baseline		-	-	-	-	-	-	-

Service Utilization							
	Telemedicine Based Collaborative Care Mean (sd)	**Practice Based Collaborative Care Mean (sd)**	**Unadjusted difference**	**P value**	**Adjusted Incidence Rate Ratio (95% CI)[a]**	**P value**	**Omnibus test P value**
6 mo	0.75(0.62)	0.68(0.62)	0.07	0.3392	1.19(0.92,1.56)	0.1911	χ^2_2=1.41, P=0.49
12 mo	0.77(0.65)	0.66(0.63)	0.11	0.1739			
18 mo	0.62(0.60)	0.69(0.68)	−0.07	0.3772			

[a] Abbreviation: CI, confidence interval.

[b] Number of PC visits during which depression symptoms were discussed.

[c] Any visit to a MH specialists; either face-to-face with a provider in the community or via interactive video with a study tele-psychologist or tele-psychiatrist.

[d] Adherence specified to be 1 if taking antidepressant ≥80% of days in past month, or 0 otherwise.

[e] Analysis conducted on the subsample of patients with an active antidepressant prescription, and not reporting antidepressant discontinuation as a result of PCP instruction: (n=187) at the 6-month follow-up, (n=166) at the 12-month follow-up, and (n=150) at the 18-month follow-up.

[f] Analysis conducted on the subsample of patients with an active antidepressant prescription with non-missing dosages: (n=190) at 6-month follow-up,(n=171) at 12-month follow-up and (n=148) at 18-month follow-up.

Table 4

Group Differences in Clinical Outcomes

	Telemedicine Based Collaborative Care (%)	Practice Based Collaborative Care (%)	Unadjusted Odds Ratio (95% CI[a])	P value	Adjusted Odds Ratio (95% CI)	P value	Omnibus test P value
Satisfaction[b]							
Baseline	79/167(47.31)	82/176(46.59)	1.03(0.67,1.57)	0.8946	1.08(0.64,1.83)	0.7654	χ^2_3=6.69, P value=0.08
6 mo	120/150(80.00)	101/159(63.52)	2.30(1.37,3.84)	0.0013	2.76(1.50,5.01)	0.0012	
12 mo	99/133(74.44)	87/140(62.14)	1.77(1.06,2.98)	0.0293	1.99(1.06,3.71)	0.0313	
18 mo	95/128(74.22)	96/148(64.86)	1.56(0.93,2.62)	0.0932	1.67(0.89,3.13)	0.1070	
Response[c]							
Baseline	-	-	-	-	-	-	χ^2_3=1.29, P value=0.52
6 mo	70/153 (45.75)	25/165 (15.15)	4.72(2.78,8.03)	<.0001	7.74(3.94,15.20)	<.0001	
12 mo	73/138(52.90)	31/149(20.81)	4.27(2.55,7.18)	<.0001			
18 mo	63/132(47.73)	33/151(21.85)	3.26(1.95,5.47)	<.0001			
Remission[d]							
Baseline	-	-	-	-	-	-	χ^2_3=2.60, P value=0.27
6 mo	44/153(28.76)	11/165(6.67)	5.65(2.79,11.44)	<.0001	12.69(4.81,33.46)	<.0001	
12 mo	43/138(31.16)	17/149(11.41)	3.51(1.89,6.54)	<.0001			
18 mo	34/132(25.76)	15/151(9.93)	3.15(1.62,6.09)	0.0004			
	Telemedicine Based Collaborative Care mean(SD)	**Practice Based Collaborative Care mean(SD)**	**Unadjusted Difference**	**P value**	**Adjusted Group Difference (95% CI)**	**P value**	**Omnibus Test P value**
Depression Severity (SCL-20: 0–4)							
Baseline	1.88(0.77)	1.90(0.72)	−0.02	0.7317	−0.04(−0.18,0.10)	0.5935	χ^2_3=40.51, P value<.0001
6 mo	1.16(0.90)	1.64(0.75)	−0.48	<.0001	−0.50(−0.65,−0.35)	<.0001	
12 mo	1.04(0.79)	1.53(0.85)	−0.49	<.0001	−0.49(−0.65,−0.33)	<.0001	
18 mo	1.13(0.85)	1.49(0.75)	−0.36	0.0002	−0.33(−0.49,−0.18)	<.0001	
Mental Health Status (SF12 – MCS: 0–100)							

	Telemedicine Based Collaborative Care (%)	Practice Based Collaborative Care (%)	Unadjusted Odds Ratio (95% CI[a])	P value	Adjusted Odds Ratio (95% CI)	P value	Omnibus test P value
Baseline	32.39(11.08)	30.31(11.22)	2.08	0.0758	1.82(−0.65,4.30)	0.1489	
6 mo	44.34(14.22)	37.49(11.98)	6.85	<.0001	6.53(3.91,9.15)	<.0001	χ^2_3=11.46, P value=0.01
12 mo	46.53(12.98)	40.58(13.20)	5.94	0.0002	5.39(2.66,8.12)	0.0001	
18 mo	44.60(13.52)	39.86(12.24)	4.75	0.0021	4.01 (1.26,6.76)	0.0042	
Physical Health Status (SF12 – PCS: 0-100)							
Baseline	35.73(13.09)	37.96(13.68)	−.2.23	0.1123			
6 mo	33.93(12.54)	35.98(13.54)	−.2.05	0.1622	−0.22(−2.26,1.82)	0.8342	χ^2_3=2.61, P value=0.46
12 mo	32.98(13.18)	35.62(12.77)	−2.64	0.0859			
18 mo	34.52(12.53)	35.31(13.22)	-0.79	0.6090			
Quality of Well Being (QWB: 0–1)							
Baseline	0.43(0.15)	0.44(0.14)	−.01	0.6079	0.01(−0.02,0.03)	0.6550	
6 mo	0.49(0.18)	0.46(0.15)	.03	0.0974	0.03(0.003,0.06)	0.0322	χ^2_3=6.55, P value=0.09
12 mo	0.50(0.17)	0.49(0.17)	.02	0.3999	0.03(0.002,0.06)	0.0374	
18 mo	0.50(0.15)	0.48(0.17)	.02	0.2202	0.04(0.02,0.07)	0.0023	

[a]Abbreviation: CI, confidence interval.

[b]Satisfaction is specified to be 1 if patient reported very satisfied or satisfied and 0 if patient reported very dissatisfied, dissatisfied, or neither satisfied or dissatisfied.

[c]Response is specified to be 1 if patient experienced a 50% reduction in depression severity according to SCL-20, and 0 otherwise.

[d]Remission is specified to be 1 if patient reported a SCL-20 score <0.5, and 0 otherwise.