Randomized Trial of a Telephone Care Management Program for Outpatients Starting Antidepressant Treatment

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Objective: **This study evaluated the effectiveness of a structured telephone-based care management program for patients in a prepaid health plan receiving new antidepressant prescriptions from psychiatrists.** ***Methods:*** **Potential participants were identified with computerized medical records and contacted by telephone. Eligible and consenting participants were randomly assigned to continued usual care (N=104) or to a three-session telephone care management program (N=103). Care management contacts included assessment of depressive symptoms, medication adherence, and medication side effects with structured feedback to treating psychiatrists. Effectiveness was assessed three and six months after randomization by blinded telephone assessments (depression scale on the Hopkins Symptom Checklist [SCL] and patient-rated global improvement). Computerized records were used to assess medication adherence and frequency of in-person follow-up visits.** ***Results:*** **Compared with usual care, the care management intervention had no significant effect on the mean score of the SCL depression scale at six months, on the probability of 50 percent improvement in depressive symptoms (41 percent for care management and 37 percent for usual care), or on the probability of patient-rated improvement (57 percent for care management and 52 percent for usual care). Patients assigned to care management made significantly more medication management visits over six months (2.4 visits compared with 2.0 visits; p=.035), but there were no significant differences in rates of adequate medication treatment.** ***Conclusions:*** **This study found that a low-intensity telephone care management program did not appear to significantly improve clinical outcomes for patients starting antidepressant treatment. Compared with findings from earlier primary care studies, this study found that patients receiving care from a psychiatrist received more intensive treatment, although many still experienced poor outcomes. (*Psychiatric Services* 57:1441–1445, 2006)**

Abundant research has identified major shortcomings in the process and outcomes of antidepressant treatment. Nearly one-third of patients discontinue medication in the first month of treatment (1). Only a minority receive recommended levels of follow-up care. Fewer than half achieve a satisfactory clinical outcome. Although most research has examined treatment in primary care, medication adherence and clinical outcomes appear nearly as unfavorable in psychiatric practice (2).

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During the past decade, several randomized trials have demonstrated the effectiveness of low-intensity telephone care management programs for primary care patients beginning antidepressant treatment (3–6). These programs included scheduled telephone outreach, structured assessment, support for treatment adherence, and coordination of care with treating primary care physicians. The Texas Medication Algorithm Project (7) examined the benefits of a more intensive quality improvement program—including physician education, treatment algorithms, and structured clinical assessment by study staff at every visit—in public-sector mental health clinics. That program yielded significant improvements in depressive symptoms and functional impairment. However, a low-intensity care management program has not been tested in psychiatric practice.

We describe here a randomized trial of a telephone-based care management program for patients receiving new antidepressant prescriptions from psychiatrists. A representative sample of patients was randomly assigned to a three-session telephone care management program or continued usual care.

Methods

Participants were enrolled in 2002 at four group-model behavioral health clinics of Group Health Cooperative, a prepaid health plan serving approximately 500,000 members in Washington and Northern Idaho. Group Health provides general medical and specialty mental health care on a pre-

paid (capitated) basis, with specialty mental health staffing levels similar to those at other group-model managed care organizations (8). Enrollees in Group Health are similar to the area population except Group Health enrollees tend to have a higher educational level, and the proportion of high-income residents is larger than in the general public (9). Although primary care physicians write a majority of new antidepressant prescriptions, Group Health members may self-refer to psychiatrists or other mental health providers.

Computerized pharmacy and visit registration data were used to identify potential participants who were aged 18 years or older, received a new antidepressant prescription from a psychiatrist (that is, no antidepressant use in the past 90 days according to computerized pharmacy data), received a visit diagnosis of a depressive disorder in the past 30 days, and had no recorded diagnosis of bipolar disorder or schizophrenia in the past two years. As in usual care, potential participants might or might not be receiving psychotherapy along with antidepressant medication.

Potential participants received an invitation letter including all elements of informed consent (description of study purpose, study procedures, study risks, potential benefits, and voluntary nature of participation). Approximately seven days later, potential participants were contacted by telephone to assess eligibility and conduct a baseline interview. The structured interview included the depression scale of the Hopkins Symptom Checklist (SCL) (10) and the Patient Health Questionnaire (PHQ) (11). Exclusion criteria assessed during the baseline interview included a score on the SCL depression scale that was less than .5 (that is, remission of depression), regular use of antidepressant medication in the prior 90 days (that is, the index prescription was not actually a new prescription), and cognitive, language, or hearing impairment severe enough to preclude participation.

After the baseline interview, eligible participants were invited to participate in the randomized trial. A documented oral consent procedure included all elements of informed consent: study objectives, description of study procedures, description of potential risks, advice that participation was completely voluntary, and description of procedures for withdrawing consent. Group Health's human subjects review committee waived the requirement for written documentation of consent because risk was considered minimal and mailing of consent forms would increase the risk of violating confidentiality. The consent procedure included a description of the intervention program, but willingness to participate in care management was not a condition for enrollment. Once each week, the study database administrator used computer-generated random numbers to assign new participants to either continued usual care or to the care management intervention. Participants assigned to the intervention were notified by a telephone call from the care manager. Participants assigned to the usual-care control group were not contacted until the first blinded outcome assessment.

Care managers contacted participants assigned to the program within two weeks of randomization (typically four weeks after the initial antidepressant prescription). Two additional telephone contacts occurred four and 12 weeks later. As in our earlier care management programs with primary care samples (3,4), each contact included a brief, structured assessment of current depressive symptoms, current use of antidepressant medication, and antidepressant side effects. During phone contacts, care managers followed specific scripts to address concerns regarding side effects and used scripted motivational enhancement techniques to address common reasons for discontinuing medication. The treating psychiatrist received a structured report of each contact, including a summary of the clinical assessment and algorithm-based recommendations regarding antidepressant medication adjustment. If a change in treatment was recommended, the care manager contacted the psychiatrist to facilitate doctor-patient communication and follow-up. Care managers also provided as-needed crisis intervention and care coordination. Most care manager time was spent in outreach to patients (for example, five or more telephone attempts to complete a contact and repeated mailings to patients not responding to phone calls) and coordination with treating psychiatrists. All care management activities (caseload tracking, structured assessment, adherence to medication algorithms, provider reports, and supervision) were organized and supported by an electronic decision support system.

Care managers were registered nurses with a minimum of five years' experience in inpatient or outpatient mental health practice. Specific training for this study included four hours of didactic instruction and role play followed by completion of at least five observed care manager contacts before any patient contact. Care managers received approximately 30 minutes of supervision each week from a psychiatrist (GS) and a psychologist (EL).

All participants were contacted for blinded telephone outcome assessments three and six months after being randomly assigned to the study groups. All assessments included a patient-rated measure of global improvement since entering the study and repeat administration of the SCL depression scale. Global improvement was scored on a 7-point scale ranging from 1, very much improved, to 7, very much worse, and possible scores on the SCL depression scale range from 0 to 4.0, with higher scores indicating more severe depression. To preserve blinding of telephone interviewers, participants were repeatedly advised to offer no information regarding treatment received. Interviewers had at least one year of experience in conducting similar assessments (3,12). Training for interviewers included six hours of didactic instruction and role playing followed by weekly supervision by the principal investigator. Previous research supports the reliability and convergent validity of depression assessments conducted via telephone (13).

Health plan administrative data were used to identify outpatient visits to primary care or specialty mental health providers. Computerized pharmacy records were used to compute the proportion of patients receiving adequate medication treatment (that is, continuing antidepressant medication for 90 days or more at a minimally adequate dose—for example, at least 75 mg per day of sertraline or 10 mg per day of fluoxetine) (14).

Table 1

Baseline characteristics of participants receiving new antidepressant prescriptions from psychiatrists, by treatment assignment

Characteristic	Care management (N=103)		Usual care (N=104)		Test statistic	df	p
	N	%	N	%			
Age (M±SD)	41±15		45±13		t=1.98	205	.05
Female	71	69	63	61	χ^2=1.58	1	.21
Caucasian	92	89	93	89	χ^2=.00	1	.98
Married or cohabiting	42	41	46	44	χ^2=.25	1	.62
College graduate	48	47	53	51	χ^2=.39	1	.53
Score (M±SD)							
SCL depression scale[a]	1.61±.68		1.57±.71		t=.39	205	.69
PHQ[b]	16.0±6.2		15.8±6.1		t=.20	205	.84

[a] Depression scale on the Hopkins Symptom Checklist. Possible scores range from 0 to 4, with higher scores indicating more severe depression.
[b] Patient Health Questionnaire. Possible scores range from 0 to 27, with higher scores indicating more severe depression.

All analyses were based on original treatment assignment (intent to treat) and used all available data at each time point. Primary analyses (defined a priori) compared rate of change in the score on the SCL depression scale over six months as well as categorical outcomes assessed at six months (50 percent or greater improvement in the score on the SCL depression scale since baseline and self-rating of "much improved" or "very much improved"). Comparisons of mean scores on the SCL depression scale over time were performed by using mixed linear models to accommodate cases with missing assessments. Power calculations indicated that a sample size of approximately 100 per group was necessary to detect a difference of .25 in mean scores on the SCL depression scale.

Results

Of the 479 persons who were mailed a letter inviting them to participate in the study, 37 (8 percent) could not be contacted by telephone, 101 (21 percent) declined to complete the baseline assessment, and 124 (26 percent) were found ineligible to participate at the baseline assessment. Of the 217 eligible persons, 207 (95 percent) enrolled in the randomized trial. Baseline characteristics of participants are shown in Table 1. Those assigned to usual care were slightly older than those in the care management group. Otherwise, the two treatment groups did not differ in demographic or baseline clinical characteristics.

As Figure 1 shows, 91 percent of participants randomly assigned to a group completed at least one blinded outcome assessment, and 94 percent remained enrolled in Group Health long enough to contribute utilization data. Compared with those contributing clinical outcome data, those missing both assessments did not differ significantly in age, sex, baseline depression severity, or treatment group assignment. Enrollment was not significantly related to age, sex, baseline severity, or treatment group assignment.

Of 103 patients assigned to the intervention program, 98 (95 percent)

Figure 1

Progress of participants receiving new antidepressant prescriptions from psychiatrists throughout the randomized trial

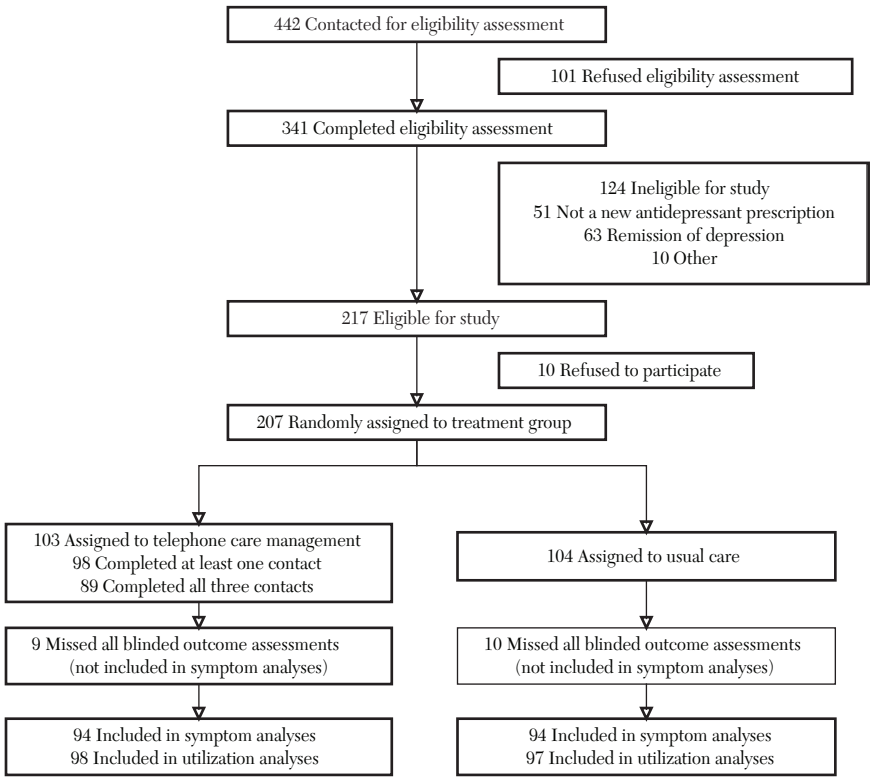
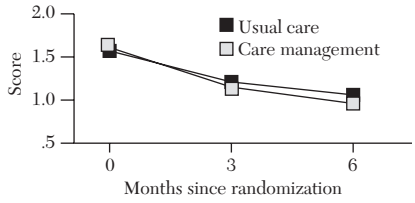


Figure 2

Mean scores on the depression scale on the Hopkins Symptom Checklist, by treatment assignment[a]



[a] Sample includes all participants providing data at each time point (207 at baseline, 188 at three months, and 185 at six months). Possible scores range from 0 to 4, with higher scores indicating more severe depression.

completed at least one telephone care management contact, and 89 (86 percent) completed all three planned contacts. The mean±SD duration of care management contacts was 18±12 minutes (range of ten to 35 minutes).

As shown in Figure 2, mean scores on the SCL depression scale in both groups improved from the moderate range at baseline to the mild depression range at follow-up. A mixed-effects repeated-measures model including adjustment for age and sex found no significant difference in rate of improvement between groups. After adjustment for age, sex, and baseline values, mean scores on the SCL depression scale at six months were 1.08 in the usual-care group and .95 in the care management group (adjusted difference=.13, 95 percent confidence interval=–.07 to .31). At the six-month assessment a 50 percent decrease in score on the SCL depression scale since baseline was shown by 37 of 91 persons (41 percent) in the care management group and 35 of 94 persons (37 percent) in usual care; these proportions were not statistically significant. A self-rating of "much improved" or "very much improved" since baseline was shown by 52 of 91 persons (57 percent) in the care management group and 49 of 94 persons (52 percent) in usual care; these proportions were not statistically significant. Secondary analyses stratified participants according to baseline depression severity (score on the SCL depression scale higher or lower than 1.5). Results were unchanged; no statistically significant intervention effects were observed in either stratum.

As shown in Table 2, the proportion of patients receiving adequate acute-phase antidepressant treatment was not significantly greater in the care management group.The patients assigned to the care management program made significantly more medication follow-up visits to the mental health clinic. The two groups did not differ in either the mean number of psychotherapy visits or the mean number of depression follow-up visits in primary care.

Discussion

A telephone-based care management program to improve acute-phase depression treatment in psychiatric practice proved feasible and acceptable, with participation rates of more than 95 percent. The program, however, had no statistically significant effect on either medication adherence or clinical outcomes over six months.

Our failure to demonstrate benefits of the low-intensity care management program does not reflect a lack of room for improvement. Only 40 to 50 percent of patients in the usual-care group experienced a satisfactory response to acute-phase depression treatment, as measured by symptom scales or patient ratings.

Two previous randomized trials have evaluated a similar care management program in the same health care system among primary care patients who began antidepressant treatment. The first trial evaluated a two-session telephone program between 1996 and 1998 and found that compared with usual primary care, the care management intervention yielded a .2-point reduction in mean scores on the SCL depression scale and a 15 percent increase in treatment response rate (3). The second primary care study was conducted in 2001 and 2002 in parallel with the psychiatry-based trial reported here (4). The study found that compared with usual primary care, a three-session telephone care management program yielded a .15-point reduction in mean scores on the SCL depression scale and an 8 percent increase in response rate. We speculated that improvements in usual-care follow-up over time might account for

Table 2

Process of care measures for participants receiving new antidepressant prescriptions from psychiatrists during the six months after randomization, by treatment assignment[a]

Variable	Care management (N=98) N	Care management (N=98) %	Usual care (N=97) N	Usual care (N=97) %	Test statistic[b]	df	p
Adequate pharmacotherapy[c]	63	64	53	55	χ^2=1.88	1	.17
Number of mental health specialty visits (M±SD)							
Medication management	2.4±1.6		2.0±2.0		z=2.11		.035
Nonprescribing therapist	2.0±3.3		2.1±3.3		z=.12		.91
Primary care with mental health diagnosis	.3±.7		.4±.7		z=1.52		.13

[a] Sample limited to persons continuously enrolled for six months

[b] The z statistic was computed by using the Mann-Whitney nonparametric test.

[c] Filled prescriptions for at least 90 days of continuous antidepressant treatment at a minimally adequate dose

the smaller benefits of care management in the second primary care study.

In the study presented here, we observed still smaller (and not statistically significant) effects of a care management intervention among patients treated by psychiatrists. Compared with the usual-care group in the parallel primary care study (4), the usual-care group in the study presented here was more likely to receive a larger number of antidepressant medication follow-up visits (2.4 visits compared with 1.1 visits), a larger number of psychotherapy visits (2.1 visits compared with .2 visits), and a higher rate of adequate antidepressant use for 90 days (55 percent compared with 41 percent). Other measures of the intensity of medication treatment (probability of high-dose treatment and probability of medication switch or augmentation) were also higher in this sample than in the primary care sample (details available on request).

However, despite this more intensive treatment in specialty practice, the proportion experiencing a 50 percent or greater improvement in depression severity was lower among patients in usual care in our study than among patients in the usual-care sample in the parallel primary care study (37 percent compared with 43 percent). The finding of more intensive baseline treatment in specialty care suggests that a low-intensity care management program may not be adequate to significantly improve treatment quality. The finding of poorer outcomes despite more intensive treatment suggests that patients treated by psychiatrists experience more persistent or treatment-resistant depression. For both of these reasons, a low-intensity care management program added to usual psychiatric care might not be expected to significantly improve outcomes.

The Texas Medication Algorithm Project found that a systematic care improvement program significantly improved outcomes of depression treatment in public-sector mental health clinics (7). The discrepancy between those results and ours could be explained by differences in intervention programs, differences in patients studied, and differences in usual-care treatment in the two settings. The more intensive Texas intervention included physician training, explicit and specific treatment algorithms, and frequent in-person contact with treatment coordinators. Patients treated in public-sector clinics may have a poorer prognosis in usual care because of socioeconomic disadvantage or more chronic depression. Persons receiving usual-care treatment in public-sector clinics may have poorer medication adherence and less regular follow-up, so that a systematic care program would demonstrate even greater benefits.

The sample size in this study was not adequate to detect small differences in clinical outcomes. Confidence limits for our observed results, however, do exclude a difference in scores on the SCL depression scale greater than .3 (equivalent to an effect size of .4).

These data were collected within a single prepaid health system, and we cannot be certain how results would generalize to other settings or patient populations. Quality-of-care indicators, however, suggest that antidepressant medication adherence and frequency of depression follow-up visits in this health system were both near the national average for managed care organizations (2,15).

Conclusions

Among patients receiving antidepressant prescriptions from psychiatrists, a low-intensity telephone care management program offered no significant advantage over usual care. Alternative, and probably more intensive, interventions will be necessary for the half of patients who still experience disappointing outcomes.

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