

Collaborative Care Management of Late-Life Depression in the Primary Care Setting

A Randomized Controlled Trial

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MAJOR DEPRESSION AND dysthymic disorder affect between 5% and 10% of older adults seen in the primary care setting.¹⁻³ Late-life depression is often chronic or recurrent⁴⁻⁸ and is associated with substantial suffering, functional impairment, and diminished health-related quality of life.⁹ Depressed, older primary care patients are frequent users of general medical services^{3,10-12} and may have poor adherence to medical treatments.¹³ They are also at increased risk of death from suicide¹⁴ and medical illnesses.¹⁵⁻¹⁷ Although late-life depression can be suc-

Context Few depressed older adults receive effective treatment in primary care settings.

Objective To determine the effectiveness of the Improving Mood–Promoting Access to Collaborative Treatment (IMPACT) collaborative care management program for late-life depression.

Design Randomized controlled trial with recruitment from July 1999 to August 2001.

Setting Eighteen primary care clinics from 8 health care organizations in 5 states.

Participants A total of 1801 patients aged 60 years or older with major depression (17%), dysthymic disorder (30%), or both (53%).

Intervention Patients were randomly assigned to the IMPACT intervention (n=906) or to usual care (n=895). Intervention patients had access for up to 12 months to a depression care manager who was supervised by a psychiatrist and a primary care expert and who offered education, care management, and support of antidepressant management by the patient's primary care physician or a brief psychotherapy for depression, Problem Solving Treatment in Primary Care.

Main Outcome Measures Assessments at baseline and at 3, 6, and 12 months for depression, depression treatments, satisfaction with care, functional impairment, and quality of life.

Results At 12 months, 45% of intervention patients had a 50% or greater reduction in depressive symptoms from baseline compared with 19% of usual care participants (odds ratio [OR], 3.45; 95% confidence interval [CI], 2.71-4.38; $P<.001$). Intervention patients also experienced greater rates of depression treatment (OR, 2.98; 95% CI, 2.34-3.79; $P<.001$), more satisfaction with depression care (OR, 3.38; 95% CI, 2.66-4.30; $P<.001$), lower depression severity (range, 0-4; between-group difference, -0.4; 95% CI, -0.46 to -0.33; $P<.001$), less functional impairment (range, 0-10; between-group difference, -0.91; 95% CI, -1.19 to -0.64; $P<.001$), and greater quality of life (range, 0-10; between-group difference, 0.56; 95% CI, 0.32-0.79; $P<.001$) than participants assigned to the usual care group.

Conclusion The IMPACT collaborative care model appears to be feasible and significantly more effective than usual care for depression in a wide range of primary care practices.

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cessfully treated with antidepressant medications or psychotherapy,¹⁸⁻²¹ few depressed older adults receive adequate trials of such treatments in primary care²²⁻²⁸ or see a mental health spe-

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cialist.^{25,29-35} Efforts to improve late-life depression treatment using screening and health care practitioner feedback and education have not resulted in consistent improvements in depression.^{22,23} A more comprehensive intervention strategy may be needed to improve outcomes for this population.

We enrolled 1801 depressed, older adults from 18 primary care clinics across the United States in a randomized trial of a primary care-based collaborative care model for late-life depression, the Improving Mood—Promoting Access to Collaborative Treatment (IMPACT) program,³⁶ compared with care as usual. The IMPACT intervention includes key components of evidence-based models for chronic illness care^{37,38}: collaboration among primary care practitioners, patients, and specialists on a common definition of the problem, development of a therapeutic alliance, a personalized treatment plan that includes patient preferences, proactive follow-up and outcomes monitoring by a depression care manager, targeted use of specialty consultation, and protocols for stepped care. Intervention patients had access to an IMPACT care manager for up to 12 months. Usual care patients could use any primary care

or specialty mental health care services available to them in usual care. After 12 months, all study participants continued with their regular primary care practitioners as usual.

This article examines health outcomes throughout 12 months. We hypothesized that patients assigned to the IMPACT intervention would have higher rates of depression treatment, greater satisfaction with depression care, greater improvements in depression, less health-related functional impairment, and higher quality of life than usual care patients.

METHODS

The IMPACT study is a multisite randomized controlled trial of a collaborative intervention program for late-life depression in primary care.^{36,39-41} Study protocols were developed in collaboration with all participating organizations, reviewed by a study advisory board, and approved by the institutional review boards at all sites and the study coordinating center. All participants gave written informed consent.

Sample

Seven study sites representing 8 diverse health care organizations with a total of 18 primary care clinics in 5 states

participated in the study (TABLE 1). We estimated that 650 participants each were required in the intervention and control groups to have a 95% chance of detecting as significant (at the 2-sided .05 level) a difference of 0.10 (SD, 0.50) in the mean score of the 20 depression items from the Symptom Checklist-90 (SCL-20)⁴² depression scores. To compensate for patient attrition, we planned to enroll 875 patients per group. To identify a sample of depressed, older adults who could participate in a quality improvement intervention such as IMPACT under real-world practice conditions, each site used a 2-pronged strategy to recruit study participants from July 1999 to August 2001 (FIGURE 1).³⁶

The first strategy relied on referrals of depressed older adults from primary care practitioners, other clinic staff, or patients themselves in response to clinic promotions of the program. The second method consisted of systematic depression screening of English-speaking, older adults who used the participating primary care clinics with a 2-item depression screener adapted from the PRIME-MD study. These screens were administered either in person or by telephone.⁴³ Of the 32908 patients approached for screening, 5246 (16%) either refused to be screened or participated in the initial

Table 1. Characteristics of Participating Organizations*

Characteristics	Health Care Organization								
	All	1	2	3	4	5	6	7	8
No. of patients enrolled	1801	70	188	254	235	258	245	280	271
No. of primary care clinics	18	1	3	3	2	1	5	1	2
Organization type		PGP	VA	AGP	AGP	HMO	HMO, IPA	HMO	HMO
Urban or rural		Urban	Mixed	Mixed	Urban	Urban	Mixed	Urban	Urban
Capitated, %		<25	NA (VA)	<10	<10	100	95	100	100
No. of primary care practitioners†	324 (170)	7	29 (80)	20	28 (90)	64	94	35	47
Family medicine physicians, %		0	0	0	0	0	47 (50)	22 (63)	36 (77)
Internal medicine physicians, %		5 (71)	86 (79)	17 (85)	117 (99)	54 (84)	42 (45)	6 (17)	0
Nurse practitioners or physician assistants, %		2 (29)	23 (21)	3 (15)	1 (1)	10 (16)	5 (5)	7 (20)	11 (23)
Mental health care financing		Mixed	Carved in	Mixed	Carved in	Carved in	Carved out	Carved in	Carved in
Mental health care practitioner available on site		No	Some	No	No	Yes	No	No	Yes
No. of older adults (>60 years) served		3250	7250	7000	12 000	33 373	20 734	17 500	12 000

*Organizations 1 and 2 belong to the same study site but represent different provider organizations. All other organizations represent different study sites. PGP indicates private group practice; VA, Department of Veterans Affairs; AGP, academic group practice; HMO, health maintenance organization; IPA, independent provider association; and NA, not applicable.

†Numbers of physicians in training are in parentheses.

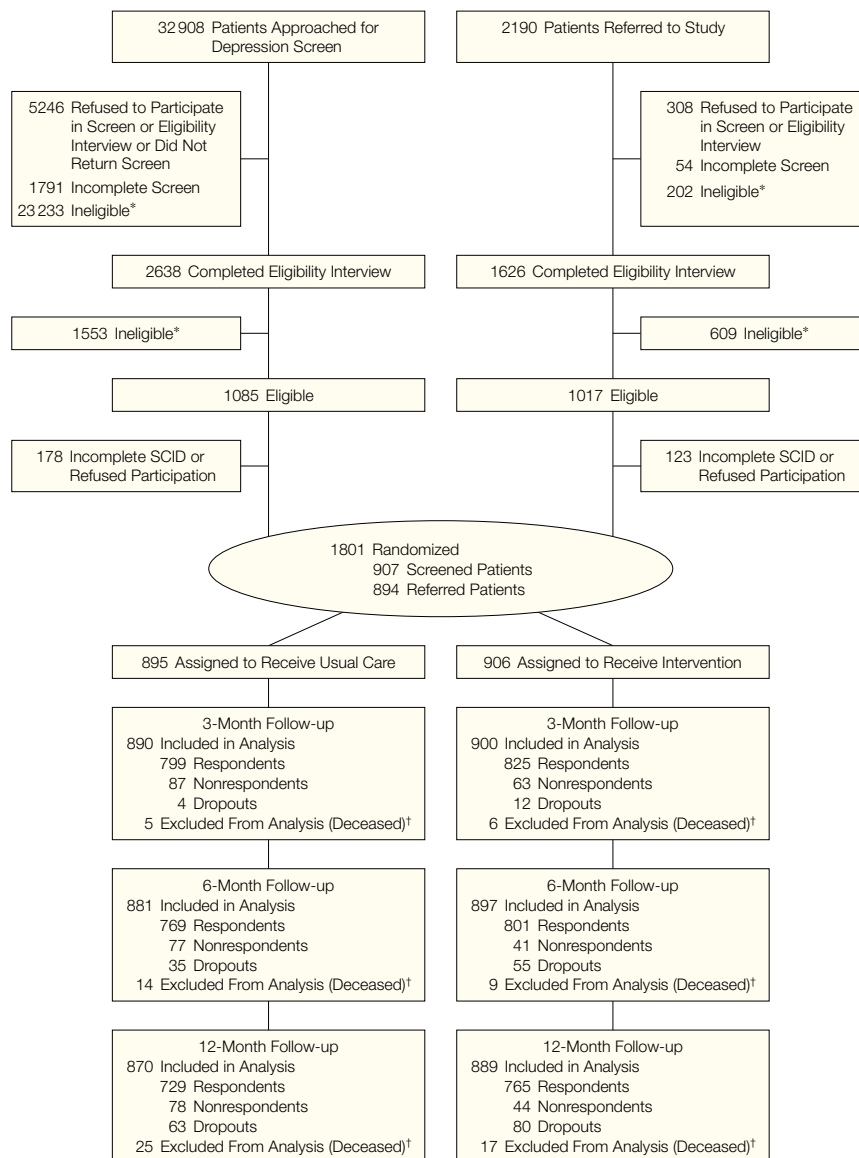
screening but refused further interviews. A total of 1791 (5%) of the initial screens were incomplete, and 23 233 (71%) of those screened were not eligible because they did not endorse one of the core depression symptoms (95% of those ineligible) or because of logistic reasons, such as lack of transportation or access to a telephone (5% of

those ineligible). Of the 2190 patients referred to the study, 308 (14%) refused the initial eligibility screen or further interviews. Fifty-four (3%) had incomplete initial screens, and 202 (9%) were ineligible because they were younger than 60 years or they did not plan to use the participating clinic during the coming 12 months.

The remaining 2638 (8%) of those screened and 1626 (74%) of those referred underwent a 30- to 60-minute structured, computer-assisted interview by trained lay interviewers to determine study eligibility.³⁶ This interview included the structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (SCID) to assess whether patients met research diagnostic criteria for major depression or dysthymia.^{44,45} Inclusion criteria were age 60 years or older, plans to use one of the participating clinics as the main source of general medical care in the coming year, and a diagnosis of current major depression or dysthymic disorder according to the SCID. Approximately 2% (n=99) of otherwise eligible patients were excluded because of current drinking problems (a score of ≥ 2 on the CAGE questionnaire)⁴⁶; 3% (n=145) were excluded because of a history of bipolar disorder or psychosis³⁶; 2% (n=85) were excluded because they were in ongoing treatment with a psychiatrist; and approximately 1% (n=44) were excluded because they met screening criteria for severe cognitive impairment defined by a score of less than 3 on a 6-item cognitive screen.⁴⁷ Less than 1% were excluded because they were found to be at acute risk for suicide and needed immediate care. Our 2-pronged recruitment method identified 2102 eligible older adults with major depression or dysthymic disorder (approximately 2% of all older adults served at the participating clinics); 1801 (86% of those eligible) enrolled in the study and completed a structured baseline interview.³⁶

After the baseline interview, participants were randomly assigned to the IMPACT intervention or usual care. The random assignment was stratified by recruitment method (screening or referral) and clinic. Within each stratum, participants were assigned according to a random number sequence that was developed using a computer random number generator at the coordinating center. Random assignment information was contained in a set of numbered, sealed envelopes for each stra-

Figure 1. Flowchart of Participants in the Trial



Asterisk indicates that most (90%-95%) of the ineligible subjects did not meet screening or research diagnostic criteria for depression. Dagger indicates the cumulative number of participants who were deceased and who were therefore excluded from analysis; analyses included all other patients after multiple imputation of unit-level missing data. SCID indicates structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.

tum that were used sequentially for newly enrolled patients at each clinic.³⁶

Intervention

The IMPACT intervention has been described in detail elsewhere.^{36,39,40,48} Intervention participants received a 20-minute educational videotape and a booklet about late-life depression^{49,50} and were encouraged to have an initial visit with a depression care manager at the primary care clinic. Care managers were nurses or psychologists who were trained for the study as a depression clinical specialist (DCS).^{36,39,40} During the initial visit, the DCS conducted a clinical and psychosocial history, reviewed the educational materials, and discussed patient preferences for depression treatment (antidepressant medications or psychotherapy). New cases and cases needing treatment plan adjustments were discussed with a supervising team psychiatrist and a liaison primary care physician during a weekly team meeting. The DCS then worked with the patient and his/her regular primary care practitioner to establish a treatment plan according to a recommended treatment algorithm, but patients and their primary care practitioners made the actual treatment choices.³⁶ The IMPACT treatment algorithm suggested an initial choice of an antidepressant medication (usually a selective serotonin reuptake inhibitor) or a course of Problem Solving Treatment in Primary Care (PST-PC), a 6- to 8-session, brief, structured psychotherapy for depression,⁵¹⁻⁵⁵ delivered by the DCS in the primary care setting. For patients who were already taking antidepressant medications but who were still depressed, the recommendation was to increase the dose or to augment the antidepressant with a trial of PST-PC (for partial responders) or to switch to a different medication or PST-PC (for non-responders). Patients' regular primary care practitioners were asked to write all antidepressant prescriptions. The DCSs also encouraged patients to schedule pleasant life events and referred them to additional health or social services as clinically indicated.

As care managers, DCSs attempted to follow up patients for up to 12 months, monitoring treatment response with the Patient Health Questionnaire 9³⁶ and a Web-based clinical information system.⁵⁷ During the acute treatment phase, in-person or telephone follow-up contacts were suggested at least every other week. Patients who achieved recovery from depression ($\geq 50\%$ reduction in the Patient Health Questionnaire 9 score and fewer than 3 of 9 symptoms of major depression) were engaged in developing a relapse prevention plan and then followed up monthly by the DCS. Patients who did not respond to initial treatment were discussed with the IMPACT team and a "step 2" treatment plan was developed that could include augmentation of an antidepressant medication, a switch to a different antidepressant, a switch from medications to PST-PC, or vice versa. Team psychiatrists were encouraged to see patients who presented diagnostic challenges or who had persistent depression for in-person consultations in the primary care setting. Patients who did not respond after 10 weeks of step 2 treatment were again reviewed by the team, and additional treatments, such as further medication changes, psychotherapy, hospitalization, or electroconvulsive therapy, were considered.

Data Collection

We used baseline and 3-, 6-, and 12-month follow-up data from all 1801 study participants. Baseline interviews were conducted by trained lay interviewers using structured computerized interviews³⁶ before randomization; thus, the interviewers were blind to study assignment. Blind follow-up interviews were performed at 3, 6, and 12 months by trained interviewers at a telephone survey research group using computer-assisted telephone interviews,³⁶ with survey response rates of 90% at 3 months, 87% at 6 months, and 83% at 12 months (Figure 1).

Baseline interviews assessed sociodemographic characteristics, the severity of depressive symptoms using the SCL-20,⁴² SCID diagnoses of major de-

pression or dysthymia,^{44,45} and health-related functional impairment using an index developed from the Sheehan disability scale that incorporates impairments in work, family, and other social functioning.^{58,59} Respondents rated their overall quality of life in the past month (including physical and mental well-being) on a scale from 0 (about as bad as dying) to 10 (life is perfect) and indicated whether they had been diagnosed as having or had been treated for any of 10 common chronic medical problems in the past 3 years. The Cornell Services Index⁶⁰ and additional questions about the use of antidepressant medications, counseling, or psychotherapy assessed health services use in the past 3 months.⁶¹ Earlier research at one of our study sites found high rates of agreement between self-reported antidepressant use and prescription fill data from a pharmacy database.^{62,63}

Outcomes Examined

Dependent variables in our analyses included self-reported use of antidepressants or psychotherapy, satisfaction with depression care (percentage who answered "excellent" or "very good"), mean SCL-20 depression scores, treatment response ($\geq 50\%$ decrease in SCL-20 score from baseline), complete remission of depression symptoms (SCL-20 score < 0.5), major depression as assessed by the SCID, health-related functional impairment, and quality of life. We estimated the costs of providing IMPACT intervention services based on detailed study records of all patient contacts, mean salary and benefit costs of DCSs plus 30% overhead costs, and the cost of supervision and consultation from team psychiatrists and primary care experts.

Analyses

We conducted bivariate analyses to compare demographic and clinical characteristics of intervention and usual care patients at baseline (TABLE 2). For each dependent variable, we conducted an intention-to-treat analysis of repeated measures. We fitted mixed-effects regres-

sion models for continuous variables or mixed-effects logistic regression models for dichotomous variables using baseline and 3-, 6-, and 12-month follow-up data with regression adjustment for recruitment method (screening or referral) and participating study organizations. In the mixed-effects models, we treated time as a categorical variable and examined the fixed effects for time, intervention condition, and their interactions. We specified the covariance structure within patients using an unstructured model to account for the

within-patient correlation over time.⁶⁴ For predicting depression severity and major depression at follow-up, we performed additional analyses that tested the interaction of intervention status with recruitment method (referral or screening), participating organizations, and depression diagnosis (major depression or dysthymia). Because of multiple comparisons, we used a conservative *P* value of less than .01 to detect statistically significant differences. All analyses were conducted using SAS software, version 8 (SAS Institute Inc, Cary, NC).

We used an extended hot deck multiple imputation technique that modifies the predictive mean matching method^{65,66} to impute item-level missing data.⁶⁷ Rates of item-level missing data were less than 2% for all variables discussed in this article. The results across 5 imputed data sets were combined by averaging, and SEs were adjusted to reflect both within-imputation variability and between-imputation variability.⁶⁷ Although there were no significant differences in the completion rate of follow-up interviews between the intervention and usual care groups, we found somewhat different predictors of follow-up response in intervention and usual care patients. We used an approximate Bayesian bootstrap multiple imputation method⁶⁸ to impute unit-level missing data and adjust for these differences. Imputations were conducted separately in the intervention and usual care groups.

Table 2. Baseline Patient Characteristics*

Sample Characteristics	All (N = 1801)	Usual Care (n = 895)	Intervention (n = 906)	Group Test <i>P</i> Value†
Referred	894 (50)	444 (50)	450 (50)	.98
Female	1168 (65)	587 (66)	581 (64)	.52
Mean (SD) age, y	71.2 (7.5)	71.4 (7.6)	71 (7.4)	.33
Married or living with partner	834 (46)	432 (48)	401 (44)	.09
Ethnic minority	415 (23)	218 (24)	197 (22)	.20
At least high school graduate	1425 (79)	709 (79)	716 (79)	.90
Medicare coverage	1380 (77)	686 (77)	694 (77)	.96
Prescription medication coverage	1621 (90)	809 (90)	812 (90)	.57
Depression status (SCID diagnosis)				
Major depression	306 (17)	146 (16)	160 (18)	.35
Dysthymia	542 (30)	283 (32)	259 (29)	
Major depression and dysthymia	953 (53)	466 (52)	487 (54)	
Two or more prior episodes of depression	1274 (71)	632 (71)	642 (71)	.90
Mean (SD) SCL-20 depression score (range, 0-4)	1.7 (0.6)	1.7 (0.6)	1.7 (0.6)	.75
Thoughts of suicide	105 (6)	49 (5)	56 (6)	.52
Treatment preferences				
Prefer antidepressant medications	682 (38)	339 (38)	343 (38)	.88
Prefer counseling or psychotherapy	920 (51)	458 (51)	462 (51)	
Prefer neither	78 (4)	36 (4)	42 (5)	
No preference	121 (7)	63 (7)	59 (6)	
Positive result on cognitive impairment screening	683 (35)	323 (36)	315 (35)	.54
Positive result on anxiety screening	518 (29)	260 (29)	258 (28)	.79
Mean (SD) chronic disease count (of a list of 10)	3.2 (1.7)	3.2 (1.7)	3.2 (1.8)	.95
Significant chronic pain	1178 (65)	583 (65)	596 (66)	.78
Mean (SD) health-related functional impairment (range, 0-10)	4.6 (2.6)	4.6 (2.6)	4.7 (2.6)	.43
Mean (SD) overall quality of life (range, 0-10)	5.3 (2)	5.3 (1.9)	5.4 (2)	.83
Any antidepressant use in the past 3 months	769 (43)	378 (42)	391 (43)	.69
Any specialty mental health visits or psychotherapy in the past 3 months	151 (8)	69 (8)	82 (9)	.29
Satisfaction with depression care (% excellent, very good)‡	304 (51)	140 (49)	164 (53)	.38

*Data are presented as No. (%) unless otherwise indicated. SCID indicates structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; SCL-20, 20 depression items from the Symptom Checklist-90.

†Comparing differences across intervention conditions for multiple imputed data sets.

‡Assessed only in individuals who reported depression care in past 3 months (n = 598).

RESULTS

The enrolled sample was clinically and sociodemographically diverse (Table 2). The mean age of participants was 71.2 years (SD, 7.5 years), and 65% were women. With 23% of participants from ethnic minority groups (12% African Americans, 8% Latinos, and 3% other ethnic minorities), we had a somewhat greater representation of ethnic minorities than a national sample of older adults.⁶⁹ Most participants (53%) met diagnostic criteria for major depression and dysthymic disorder, and 71% reported 2 or more prior depressive episodes. The mean SCL-20 depression score⁴² was 1.7 (SD, 0.6), indicating moderate to severe depression. Six percent of participants reported thoughts of suicide in the past month. One third (35%) showed some evidence of cognitive impairment, and 29% screened positive for panic disorder or posttraumatic stress disorder. Participants reported a mean of 3.2 (SD, 1.7) of 10 common comorbid medical conditions. About half (46%) reported depression treatment (antidepressant medication or psychotherapy) in the past 3 months.⁶³ We found no signifi-

Table 3. Depression Care

	Unadjusted Estimates, No. (%)		Adjusted Analysis for Intervention vs Usual Care*		
	Usual Care	Intervention	OR (95% CI)	t	P Value
Any antidepressant use					
Baseline (past 3 months)	378 (42.21)	391 (43.16)	1.04 (0.86-1.25)	0.386	.70
3-Month follow-up	396 (44.49)	556 (61.82)	2.02 (1.66-2.44)	7.168	<.001
6-Month follow-up	461 (52.3)	618 (68.87)	2.02 (1.66-2.47)	6.957	<.001
12-Month follow-up	497 (57.17)	649 (73)	2.03 (1.60-2.57)	5.87	<.001
Any psychotherapy or specialty mental health visits†					
Baseline (past 3 months)	69 (7.66)	82 (9.05)	1.23 (0.87-1.73)	1.182	.24
3-Month follow-up	158 (17.78)	400 (44.42)	3.77 (3.02-4.70)	11.77	<.001
6-Month follow-up	112 (12.76)	352 (39.22)	4.47 (3.47-5.77)	11.55	<.001
12-Month follow-up	135 (15.56)	380 (42.7)	4.13 (3.19-5.36)	10.73	<.001
Any use of antidepressant medications or psychotherapy					
Baseline (past 3 months)	404 (45.18)	422 (46.58)	1.06 (0.88-1.28)	0.60	.55
3-Month follow-up	451 (50.67)	695 (77.24)	3.33 (2.68-4.13)	10.92	<.001
6-Month follow-up	478 (54.21)	696 (77.57)	2.93 (2.34-3.67)	9.406	<.001
12-Month follow-up	530 (60.97)	731 (82.25)	2.98 (2.34-3.79)	9.108	<.001
Satisfaction with depression care (excellent/very good)‡					
Baseline	140 (48.95)	164 (52.63)	1.23 (0.88-1.72)	1.192	.24
3-Month follow-up	312 (50.29)	642 (76.59)	3.26 (2.52-4.22)	9.007	<.001
12-Month follow-up	272 (47.42)	597 (75.59)	3.38 (2.66-4.30)	9.993	<.001

*Mixed-effects logistic regression adjusted for recruitment method and study site. OR indicates odds ratio; CI, confidence interval.

†Increases in the intervention group are mostly accounted for by Problem Solving Treatment in Primary Care.

‡Satisfaction with depression care was not assessed at 6 months and was only assessed at baseline in participants who reported depression care in the past 3 months (n = 598).

cant differences in sociodemographic and clinical characteristics between the intervention and control groups.

Intervention Implementation

Most (98%) of the 906 intervention participants completed an initial visit with a DCS. Intervention participants had a mean of 9.15 (SD, 6.17) in-person visits and 6.10 (SD, 5.13) telephone contacts with a DCS, and 11% were seen for a consultation by a team psychiatrist. The majority (80%) had at least 1 trial of an antidepressant, and approximately one third (30%) received PST-PC. The mean number of PST-PC sessions was 6.34 (SD, 4.26).

Process of Care

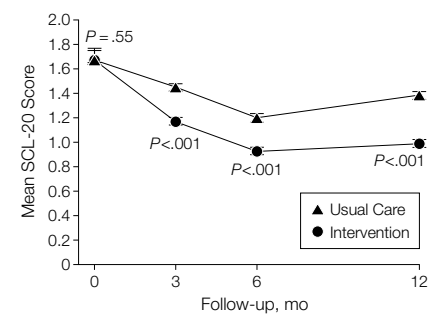
Intervention patients were significantly more likely to use antidepressants or psychotherapy than usual care participants at all follow-ups (TABLE 3). Intervention patients reported antidepressant use for 6.6 months (SD, 4.9 months) of the 12-month study period compared with 4.6 months (SD, 5.0 months) in the usual care group ($t=8.12$, $P<.001$). They also reported greater satisfaction with depression care

at 3 and 12 months (satisfaction was not assessed at 6 months). Four patients in the usual care group and 5 intervention patients reported psychiatric hospitalizations during the 12-month study period.

Clinical Outcomes

Intervention patients had significantly lower depression severity (measured by SCL-20 depression scores) during all follow-up points, with the difference between intervention and usual care increasing from the 3- to the 12-month follow-up (FIGURE 2). Intervention patients also had significantly higher rates of treatment response (at least 50% reduction in the SCL-20 score from baseline) and of complete remission of depressive symptoms (SCL-20 score of <0.5)⁷⁰ than usual care participants (TABLE 4). We are not aware of any attempted or completed suicides in either group.

We observed significant main effects of participating organizations on depression. For example, the proportion of patients who met criteria for major depression across the participating sites ranged from 57% to 84% at base-

Figure 2. Mean SCL-20 Depression Score

Scores on the 20 depression items from the Symptom Checklist-90 (SCL-20) ranged from 0 to 4. Error bars indicate SEs.

line and from 18% to 36% at 6 months. We did not find any significant interaction effects of intervention status with organization ($F=1.61$; $P=.13$), intervention with recruitment method ($t=1.17$; $P=.24$), or intervention with baseline depression diagnosis (major depression or dysthymia, $t=-1.12$; $P=.26$). Across all sites, intervention patients had a significantly greater reduction in rates of major depression (from a mean of 71% at baseline to 22% at 6 months) than usual care participants

(from 68% to 35%; the SCID to assess major depression was not administered at 3 or 12 months).

Intervention patients also reported less health-related functional impairment ($P < .001$ at 3 and 12 months, $P = .02$ at 6 months) and greater overall quality of life in the past month ($P < .001$ at all follow-ups) than usual care participants (Table 4). We conducted sensitivity analyses using design-based permutation tests. For each outcome variable, we used the imputation version least favorable to the intervention. These conservative analyses gave similar results and are not presented in this article.

Intervention Costs

We estimate the mean costs of providing IMPACT services to be \$553 per intervention patient for a 12-month period. These costs include \$7 for the educational brochure and videotape, \$418 for DCS services, \$70 for supervision and in-person consultations with team psychiatrists, and \$58 for supervision of DCSs by primary care experts. All visits with DCSs and team psychiatrists were provided free of charge to the patients. Patients and their insurers were responsible for all other health care costs, including antidepressant medications. Information on these costs will be reported in a subsequent article.

COMMENT

Recent studies^{69,71-73} have reported significant increases in rates of antidepressant use during the past 10 years. Almost half of our patients reported depression treatment during the 3 months before the study and more than half of our usual care patients reported antidepressant use or psychotherapy during the 12-month study period. Our findings suggest that despite this recent increase in antidepressant use, treatment of late-life depression in primary care remains challenging. At the 12-month follow-up, only 19% of usual care patients reported at least a 50% reduction in depressive symptoms from

Table 4. Clinical Outcomes*

	Unadjusted Estimates, Mean (SD) or No. (%)		Adjusted Analysis for Intervention vs Usual Care†		
	Usual Care	Intervention	Between-Group Difference or OR (95% CI)	t	P Value
SCL-20 depression score (range, 0-4)					
Baseline	1.67 (0.61)	1.68 (0.61)	0.02 (-0.04 to 0.07)‡	0.593	.55
3-Month follow-up	1.46 (0.66)	1.18 (0.67)	-0.28 (-0.34 to -0.21)‡	-8.33	<.001
6-Month follow-up	1.21 (0.72)	0.93 (0.67)	-0.28 (-0.35 to -0.19)‡	-7.06	<.001
12-Month follow-up	1.39 (0.67)	0.99 (0.67)	-0.4 (-0.46 to -0.33)‡	-11.5	<.001
Overall functional impairment (range, 0-10)					
Baseline	4.58 (2.56)	4.68 (2.64)	0.10 (-0.12 to 0.35)‡	0.975	.33
3-Month follow-up	4.50 (2.64)	3.83 (2.73)	-0.67 (-0.9 to -0.4)‡	-5.06	<.001
6-Month follow-up	4.23 (2.67)	3.88 (2.76)	-0.35 (-0.6 to -0.05)‡	-2.3	.02
12-Month follow-up	4.52 (2.73)	3.58 (2.80)	-0.94 (-1.19 to -0.64)‡	-6.65	<.001
Overall quality of life in past month (range, 0-10)					
Baseline	5.34 (1.94)	5.36 (2.01)	0.02 (-0.17 to 0.19)‡	0.083	.93
3-Month follow-up	5.74 (2.23)	6.23 (2.15)	0.49 (0.27 to 0.69)‡	4.457	<.001
6-Month follow-up	5.82 (2.17)	6.23 (2.08)	0.41 (0.17 to 0.63)‡	3.508	<.001
12-Month follow-up	6.02 (2.13)	6.58 (2.15)	0.56 (0.32 to 0.79)‡	4.731	<.001
Response (at least 50% decrease in SCL-20 depression score from baseline), No. (%)					
3-Month follow-up	131 (14.76)	286 (31.8)	2.73 (2.10 to 3.54)§	7.53	<.001
6-Month follow-up	272 (30.92)	443 (49.34)	2.21 (1.76 to 2.76)§	6.863	<.001
12-Month follow-up	167 (19.22)	398 (44.67)	3.45 (2.71 to 4.38)§	10.14	<.001
Complete remission of depression symptoms (SCL-20 score <0.5), No. (%)					
Baseline¶	20 (2.235)	15 (1.61)	0.67 (0.32 to 1.42)§	-1.04	.30
3-Month follow-up	44 (4.90)	142 (15.76)	3.63 (2.46 to 5.38)§	6.452	<.001
6-Month follow-up	147 (16.66)	270 (30.08)	2.16 (1.69 to 2.76)§	6.201	<.001
12-Month follow-up	72 (8.30)	223 (25.01)	3.72 (2.69 to 5.15)§	7.91	<.001
Major depression (SCID), No. (%)¶¶					
Baseline	612 (68.36)	647 (71.41)	1.22 (0.99 to 1.50)§	1.91	.06
6-Month follow-up	312 (35.39)	199 (22.14)	0.50 (0.40 to 0.62)§	-6.41	<.001

*OR indicates odds ratio; CI, confidence interval; SCID, structured clinical interview for *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; and SCL-20, 20 depression items from the Symptom Checklist-90.

†Mixed-effects linear regression and logistic regression adjusted for recruitment method and study site.

‡Data are the between-group difference for mean SCL-20 depression score, overall functional impairment, and overall quality of life.

§Data are ORs for the response, complete remission of depression symptoms, and major depression.

¶A small number of individuals (n = 35; 20 in usual care and 15 in the intervention group) met SCID eligibility criteria for major depression or dysthymic disorder but had self-reported

SCL-20 scores of less than 0.5 at the baseline interview.

¶¶Not assessed at 3- and 12-month follow-up.

baseline and only 8% were completely free of depression symptoms.

Compared with these relatively modest effects of usual care treatment, intervention patients had significantly higher rates of depression treatment, greater satisfaction with depression care, and greater improvements in depression. Our findings are similar to earlier studies of collaborative care for mixed-aged adults with depression that integrated psychiatrists or psychologists into primary care settings and found greater improvements in depression in intervention than usual care patients.^{74,75} Our treatment effects in terms of number needed to treat to achieve a treatment response at 12 months (number needed to treat, 4; 95% confidence interval, 3-5) are similar to a number needed to treat of 4 reported in a Cochrane review of antidepressants compared with placebo or no treatment in medically ill adults.⁷⁶ Subjects assigned to the IMPACT intervention also reported less health-related impairment in work, family, and social functioning and better quality of life than usual care patients, suggesting that the effects of this intervention on health extend beyond reducing depressive symptoms. We are particularly encouraged by the observation that differences between intervention and control patients in all health outcomes examined increased during the 12-month follow-up period. Longer-term follow-up will be needed to determine if these differences persist after discontinuation of the intervention resources at 12 months.

Our sample was recruited from 8 diverse health care organizations nationally, representing a wide variety of practices and patients.³⁶ For example, the median household income of participants from the 8 organizations varied 5-fold (\$8400 to \$40000 per year), and the proportion of patients with a high school education varied 3-fold (32% to 93%). We observed substantial intervention effects on depression at each of the 8 health care organizations, indicating that the IMPACT care model is feasible and effective in a range of

primary care clinics that serve patients with widely diverse sociodemographic and clinical characteristics. We did not find significant interactions between intervention status and baseline depression diagnosis (major depression or dysthymic disorder) or between intervention status and recruitment method (screening or referral). We believe that our screening procedures identified a number of depressed older adults who might not have been recognized by their primary care practitioners and agree with the recent recommendation by the US Preventive Services Task Force that screening for depression in primary care is effective when coupled with systematic depression treatments such as those offered in our study.⁷⁷

Despite substantial improvements in depression and quality of life, only approximately half of the intervention patients experienced a 50% reduction in depressive symptoms and only 25% to 30% became completely free of depressive symptoms. This may be due to greater medical comorbidity (a mean of 3.2 chronic medical illnesses and 65% with chronic pain), greater ambivalence about depression treatment among patients and practitioners, and lower treatment intensity in this effectiveness study conducted under naturalistic practice conditions compared with treatment efficacy studies with select samples in academic medical centers.³⁶ It is also questionable whether complete freedom from symptoms, such as fatigue or lack of energy, is a realistic goal in older adults with multiple chronic medical illnesses. Further research is needed to examine the long-term outcomes of persistently depressed patients, to identify factors associated with treatment participation, adherence, and treatment resistance, and to develop effective interventions for this group. Possible strategies might include earlier and more aggressive use of in-person psychiatric consultation for nonresponders to antidepressants or psychotherapy in primary care or more aggressive use of additional treatments such as electroconvulsive therapy.

Most participants (51%) stated a preference for psychotherapy during the baseline interview before randomization, and 30% of intervention patients received a course of PST-PC in primary care. Given that only 8% of patients reported receiving counseling or psychotherapy in the 3 months before the baseline interview, it appears that the intervention program substantially increased the likelihood that patients received psychotherapy by offering this service in the primary care setting. However, when confronted with the need to travel to the clinic for PST-PC sessions, some patients may have opted to try antidepressants instead of PST-PC.

Our estimated 12-month intervention cost of \$553 is consistent with cost estimates from an earlier study of collaborative care for depression using nurse care managers.⁷⁸ It seems relatively modest given total annual Medicare spending of \$5506 per enrollee in 1998^{12,79} and the fact that health care costs for depressed, older adults are up to 50% higher than for older adults without depression.^{5,12} We plan to examine differences in total health care costs using administrative data from the participating organizations to compare the cost-effectiveness of the intervention to usual care.

Our study design may have biased our comparisons in favor of the usual care group.³⁶ Referring practitioners were notified if a patient meeting study criteria was assigned to usual care, possibly resulting in treatment that would not have occurred in true usual care. Practitioners treated both intervention and usual care patients from 1999 to 2002; a spillover effect in which primary care practitioners applied improved skills learned from exposure to the intervention to the treatment of their usual care patients may have resulted. However, earlier studies^{23,80} have not found substantial effects of notification about depression status or physician training on usual care. Finally, we used a protocol to identify patients with thoughts of suicide during the follow-up interviews and referred them to appropriate clinical evaluation regard-

less of group assignment, possibly resulting in additional mental health care for the most depressed usual care participants. These biases may contribute to an underestimation of the effectiveness of the intervention compared with usual care outside a research setting. Additional limitations include our reliance on self-reports of chronic medical conditions and antidepressant and psychotherapy use. However, earlier research at 2 of our study sites^{61,62,81} found high rates of agreement between self-reported antidepressant use and prescription fill data from a pharmacy database.

The IMPACT model, a collaborative, stepped care management intervention for late-life depression, appears to be feasible and significantly more effective than usual care in a wide range of primary care practices.

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