Original Investigation

Patient Engagement Programs for Recognition and Initial Treatment of Depression in Primary Care
A Randomized Trial

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IMPORTANCE Encouraging primary care patients to address depression symptoms and care with clinicians could improve outcomes but may also result in unnecessary treatment.

OBJECTIVE To determine whether a depression engagement video (DEV) or a tailored interactive multimedia computer program (IMCP) improves initial depression care compared with a control without increasing unnecessary antidepressant prescribing.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial comparing DEV, IMCP, and control among 925 adult patients treated by 135 primary care clinicians (603 patients with depression and 322 patients without depression, defined by Patient Health Questionnaire–9 [PHQ-9] score) conducted from June 2010 through March 2012 at 7 primary care clinical sites in California.

INTERVENTIONS DEV targeted to sex and income, an IMCP tailored to individual patient characteristics, and a sleep hygiene video (control).

MAIN OUTCOMES AND MEASURES Among depressed patients, superiority assessment of the composite measure of patient-reported antidepressant drug recommendation, mental health referral, or both (primary outcome); depression at 12-week follow-up, measured by the PHQ-8 (secondary outcome). Among nondepressed patients, noninferiority assessment of clinician- and patient-reported antidepressant drug recommendation (primary outcomes) with a noninferiority margin of 3.5%. Analyses were cluster adjusted.

RESULTS Of the 925 eligible patients, 867 were included in the primary analysis (depressed, 559; nondepressed, 308). Among depressed patients, rates of achieving the primary outcome were 17.5% for DEV, 26% for IMCP, and 16.3% for control (DEV vs control, 1.1 [95% CI, −6.7 to 8.9], $P = .79$; IMCP vs control, 9.9 [95% CI, 1.6 to 18.2], $P = .02$). There were no effects on PHQ-8 measured depression score at the 12-week follow-up: DEV vs control, −0.2 (95% CI, −1.2 to 0.8); IMCP vs control, 0.9 (95% CI, −0.1 to 1.9). Among nondepressed patients, clinician-reported antidepressant prescribing in the DEV and IMCP groups was noninferior to control (mean percentage point difference [PPD]: DEV vs control, −2.2 [90% CI, −8.0 to 3.49], $P = .0499$ for noninferiority; IMCP vs control, −3.3 [90% CI, −9.1 to 2.4], $P = .02$ for noninferiority); patient-reported antidepressant recommendation did not achieve noninferiority (mean PPD: DEV vs control, 0.9 [90% CI, −4.9 to 6.7], $P = .23$ for noninferiority; IMCP vs control, 0.3 [90% CI, −5.1 to 5.7], $P = .16$ for noninferiority).

CONCLUSIONS AND RELEVANCE A tailored IMCP increased clinician recommendations for antidepressant drugs, a mental health referral, or both among depressed patients but had no effect on mental health at the 12-week follow-up. The possibility that the IMCP and DEV increased patient-reported clinician recommendations for an antidepressant drug among nondepressed patients could not be excluded.

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Despite progress, depression in primary care remains underrecognized and undertreated.[1-5] Barriers to improvement include system, clinician, and patient factors. System-level interventions are effective in increasing recognition and treatment of depression, but these interventions are difficult to disseminate.[4,6] Clinician behavior is difficult to change.[7] Patients are potentially attractive targets for intervention,[8] but they may have difficulty articulating their distress and signaling openness to treatment for depression.[9-11] Marketing strategies such as direct-to-consumer advertising encourage patients to report depression symptoms and accept depression treatment,[12,13] but these interventions may also promote overprescribing.[13-17] More selective approaches are needed.

In shaping messages to influence health-related behavior, researchers have applied 2 approaches: targeting and tailoring. Targeting involves segmenting a general population into smaller, more homogeneous units based on observable factors (such as age, sex, or place of residence).[18] Tailoring uses information elicited from the respondent, often through an interactive computerized interface, to craft messages specific to that person.[19]

We examined whether targeted and tailored communication strategies could enhance patient engagement and initial care for patients with depression. We also examined the extent to which each intervention promoted prescribing or recommendation of antidepressant medication, depression-related discussion, and antidepressant requests among patients who were not depressed. We developed 2 interventions for use in primary care: a depression engagement video (DEV) targeted to sex and income and an interactive multimedia computer program (IMCP) tailored to the characteristics, interests, and problems of the individual patient. Enrolled patients were categorized into 2 cohorts (depressed and nondepressed) according to whether they had significant depression symptoms. Within each of these 2 cohorts, we compared the effectiveness of each intervention with a control (sleep hygiene informational video). Among depressed patients, we hypothesized that each intervention would increase the delivery of depression treatments (primary outcome), encourage patients to ask questions about depression, and lead to improved mental health 12 weeks later compared with the control group. Among nondepressed patients, we hypothesized that each intervention would not increase antidepressant prescribing or recommendations (primary outcomes), depression-related discussion, patient requests for antidepressants, or clinician time and burden compared with the control group.

DEV *depression engagement video*
IMCP *interactive multimedia computer program*
PHQ *Patient Health Questionnaire*
PPD *percentage point difference*

Methods

Design Overview

Ethics approval for this trial was obtained from the institutional review boards at all performance sites. Study procedures and protocols have been detailed elsewhere.[20] All patients provided written informed consent. The trial was designed as a randomized clinical trial comparing 3 interventions: a targeted DEV designed to encourage patient participation in depression-related discussion and care, a tailored IMCP, and a sleep hygiene informational video (control). We report separately on the results for depressed and nondepressed patient cohorts. We defined the 2 cohorts with a Patient Health Questionnaire-9 [PHQ-9] scoring system; a score of 5 or greater defined patients with depression and a score of less than 5 defined patients without depression.

Sampling

Patients and clinicians were recruited from 7 clinical sites affiliated with the University of California, San Francisco (UCSF); the San Francisco Veterans Affairs (VA) Medical Center; the University of California, Davis (UCD), Ambulatory Care Center; the UCD Primary Care Network; the Northern California (Sacramento) Veterans Affairs Health System; Kaiser Permanente, Sacramento; and Sutter Medical Group, Sacramento.

We recruited primary care clinicians through e-mail announcements and at in-person presentations. Clinicians were told that the study was a randomized trial of an intervention designed to improve communication about common physical and mental health symptoms in primary care. Although not blinded to patients' participation in the study, clinicians were not alerted to patients' group assignments. All clinicians agreed to enroll up to 12 patients.

Patient Enrollment

Eligible patients were aged 25 to 70 years, could read and understand English, use a computer, and were not currently taking antidepressant medication (with the exception of low-dose tricyclics for pain or sleep). We studied this age group because of the high social and economic burden imposed by depression upon adults in their working years.[21] In all recruitment settings except UCSF urgent care, eligibility screening was conducted by telephoning patients who were scheduled for a routine primary care visit in the next 1 to 2 weeks. Patients were told that the study was designed to improve care for patients with common symptoms including sleep problems, depression, and chronic pain. Research staff made up to 3 attempts to reach each patient. Patients were randomly selected for telephoning from each clinic's appointment lists until daily quotas were filled. Patients with significant depression symptoms based on the PHQ-8[22] (used in lieu of the PHQ-9 for telephone screening) were oversampled. Eligible patients who provided preliminary verbal consent were invited to a research appointment 1 hour prior to the index visit. At the UCSF urgent care clinic, patients were approached directly by research assistants in waiting rooms, without any prior telephone screening. Patients were offered an incentive of $20 to $35 for completing index visit procedures and an additional $10 for completing the 12-week follow-up telephone interview.

Interventions

The targeted DEVs and tailored IMCP were developed based on literature reviews and extensive formative research.[23,24] The

control intervention was a sleep hygiene informational video produced by HealthiNation.[25] Screenshots of the DEV and IMCP are available from the authors on request.

The DEVs, produced in collaboration with a marketing firm, were designed to enhance depression recognition and care-seeking by educating patients about depression; emphasizing the importance of disclosing relevant symptoms; and suggesting ways to start a conversation with their primary care physician.[9,10,23,26] The marketing firm produced 4 DEV variants targeted to sex and household income.[24] By using terms and images likely to resonate with the intended audience, targeted messages are generally better attended to and more thoroughly processed than nontargeted messages.[27]

The IMCP was developed collaboratively by the study investigators, guided by standard software engineering principles. The IMCP provided patients with feedback tailored to their level of depression symptoms (eg, those with PHQ-9 scores <5 were told they were probably not depressed, whereas those with higher scores were told they might be depressed and were advised to talk with their clinician), visit agenda (intention to discuss depression, depression treatment, or both), depression causal attributions (biological, psychosocial, situational, existential),[28,29] treatment preferences (medication, counseling, both, or neither),[28,30,31] self-efficacy for communicating with health care professionals,[32]and depression stigma.[9,33,] The IMCP gave users control over knowledge acquisition (self-tailoring) by offering links to more detailed material.[34] Tailored health messages are better remembered, more frequently read, and more often perceived as relevant compared with nontailored health messages. Tailored health messages are also superior to nontailored interventions in improving various health behaviors and outcomes across a broad array of patient populations and target conditions,[35] including depression.[36,37]

Randomization and Patient Flow

A study research assistant met patients an hour prior to their primary care clinic appointment. Following written informed consent, patients were logged on to a tablet computer for randomization and intervention assignment.

The unit of randomization was the patient. As described previously,[20] the computer randomization program stratified patients into categories defined by self-reported race/ethnicity (because of its association with socioeconomic position [a target of the DEV] and to enhance generalizability), sex, and site. Within each category, patients were randomly allocated in equal proportions to 1 of 3 study groups, in randomly permuted blocks of 9 patients (the size of the blocks was not disclosed to research staff during enrollment). After randomization, patients were again asked about current antidepressant use. Antidepressant users were excluded from participation.

After intervention assignment, patients answered additional questions to measure baseline depressive symptom burden (using the PHQ-9),[38] and to assess baseline health status. Immediately thereafter, patients received their randomly assigned intervention: 1 of 4 targeted DEV variants, the tailored IMCP, or the control video. The DEVs and control video were each approximately 3 minutes long. Patients assigned to the IMCP spent a median of 5 minutes with the program (10th percentile, 2 minutes; 90th percentile, 15 minutes).

Following the office visit, patients completed a computer-based questionnaire, which included questions about the encounter (ie, whether they asked about or discussed depression, depression-related care, or both; whether the clinician recommended an antidepressant or made a mental health referral; and when the clinician arranged for primary care follow-up). Clinicians independently completed a brief questionnaire after the visit. Agreement between patient and clinician for antidepressant recommendation was 87% and for mental health referral 89%. Patients in the depressed cohort were telephoned 12 weeks later to assess depression severity (using the PHQ-8) and health status (using the SF-12).

Outcome Measures

Measures for this study were derived from the patient report immediately following the visit, the clinician report immediately following the visit, and the 12-week patient follow-up by telephone. Among patients categorized as depressed, we focused on patient reports because of the critical role of patient perceptions in driving health behaviors and assessing outcomes. Among patients categorized as nondepressed, we used both patient and clinician reports.

Depressed Cohort

The prespecified primary outcome applied to the depressed cohort of patients was a composite measure of initial depression care, defined as receiving an antidepressant recommendation, a mental health referral, or both during the index visit. Secondary outcomes included patient-clinician communication self-efficacy questionnaire score using a scale modified from Maly and coauthors[32] (the sum of 6 items, each scored from 1 [not at all confident] to 5 [very confident]; scale range, 6-30); whether the patient reported asking the clinician for information about depression during the visit; scores on the PHQ-8 at the 12-week follow-up (sum of 8 items, each scored from 0 [not at all] to 3 [nearly every day]; scale range, 0-24)[22,38-40]; and the 12-Item Short Form Health Survey's (SF-12, version 2.0) Mental Health Component Summary (MCS-12) scores and Physical Health Component Summary (PCS-12) scores at the 12-week follow-up (both scored from 0-100, with higher scores representing better health).[41,42]

Nondepressed Cohort

The prespecified primary outcome applied to nondepressed patients was whether the clinician recommended or prescribed an antidepressant. This was assessed by a clinician report of antidepressant prescribing and by a patient report of whether the clinician recommended a medication for depression. Secondary outcomes among nondepressed patients included (1) whether depression or depression treatment were discussed (each classified as yes, no, or uncertain), (2) whether the patient requested medication for depression during the study visit (yes, no, or uncertain), (3) clinician-reported face-to-face visit time (minutes), and (4) clinician-reported visit burden, computed as the sum of 3 items that rated the visit in terms

of the amount of time required, amount of effort required, and the degree to which the clinician found the patient visit difficult, each on a 0 to 2 scale (0, less than average; 1, about average; and 2, greater than average; Cronbach α, .79).

Statistical Analysis

Details on power calculations, model assumptions, and variable selection have been reported.[20] Briefly, we fitted clustered data regression models that would allow assessment of the pairwise (intervention vs control) contrasts of interest, and accounted for study design–effects arising from the stratified sampling and randomization scheme and for the clustering of patients within clinicians. No adjustments were made for multiple comparisons. The target sample size of 170 patients per group for the analyses involving depressed patients was established to provide 80% power for 2-sided testing (α = 5%) to detect standardized pairwise differences of 0.3 (eg, 15 percentage points for a binary outcome with an expected value of 50%). For analyses of nondepressed patients, the per-group target sample of 102 patients was established to provide 80% power to reject the inferiority null hypothesis that the rate of antidepressant prescribing in the DEV and IMCP groups would be 3.5 percentage points higher than in the control group, under the alternative hypothesis that the true probability was 1%.

Outcomes were analyzed using Stata (StataCorp), version 12.1.[43] Binary outcomes were assessed using random-effects logistic regression models or, for low event counts, generalized estimating equations. Relative comparisons for binary outcomes were expressed as adjusted odds ratios (ORs) from models that adjusted for the study design (to minimize omitted covariate bias).[44] Absolute comparisons were expressed as cluster-adjusted, mean percentage point differences (PPDs) on the original scale of measurement. Cluster-adjusted, mean percentages and differences were estimated via Stata's postestimation command margins, immediately after fitting simple clustered data logistic regression models. For mixed-effects models, margins were estimated with the random effect for each observation set to 0 (the mean value).

Continuous outcomes were assessed using mixed-effects linear regression models with adjustment for stratifiers. In the depressed cohort, all pairwise contrasts were estimated with 95% CIs and tested with 2-sided *P* values. In the nondepressed cohort, 2-sided, 90% CIs are reported, equivalent to 1-sided testing of the inferiority null hypothesis. The significance threshold was a *P* value less than .05 for all contrasts. For harms, we report *P* values for noninferiority for only the antidepressant prescribing and recommendation outcomes, using prespecified noninferiority margins of 3.5 percentage points. When the *P* value for noninferiority is less than .05, the contrast is statistically significant in favor of noninferiority at the specified tolerance margin.

Models adjusting for strata included the following terms: patient sex, race/ethnicity, practice setting [multispecialty group, faculty or resident practice, health maintenance organization, or VA clinic]), and (in analyses of depressed patients) baseline PHQ-9 category (5-9 vs ≥10). The postvisit patient-clinician communication self-efficacy outcome analysis also adjusted for self-efficacy prior to the visit. For 12-week outcomes (PHQ-8, MCS-12, and PCS-12 scores), 3-level mixed-effects models estimated adjusted within-group mean (over time) differences and between-group differences in mean differences. This approach uses all available data, including baseline data from patients who dropped out, to avoid biases that could occur in complete case analysis.[45]

Although not prespecified prior to patient enrollment, we hypothesized on clinical grounds prior to examination of the data that the interventions might be particularly effective among patients with more severe depressive symptomatology. This hypothesis was assessed by conducting analyses stratified by PHQ-9 score. Heterogeneity of treatment effects by baseline depression severity (5-9 vs ≥10) was assessed by fitting a model including the group depression category interaction term (tested with the Wald χ^2 test [2 *df*]).

Results

Patient Flow and Baseline Characteristics

Of 135 consenting clinicians, 124 enrolled at least 1 patient with a PHQ-9 score of 5 or greater, and 106 enrolled at least 1 with a PHQ-9 score of less than 5. The **Figure** depicts the flow of patients from screening through the 12-week follow-up. Of 6191 patients assessed for eligibility, 3650 patients were invited to participate, and 925 patients (603 in the depressed cohort and 322 in the nondepressed cohort) were randomized to the DEV, IMCP, or control group prior to a primary care office visit. Of the 925 randomized patients, 58 were excluded due to ineligibility or withdrawal after randomization, leaving 867 analyzable patients (559 categorized as depressed and 308 as nondepressed). Of the 559, approximately 85% completed the 12-week telephone follow-up survey (Figure). Patients were enrolled from June 16, 2010, through November 8, 2011; follow-up was complete by March 31, 2012.

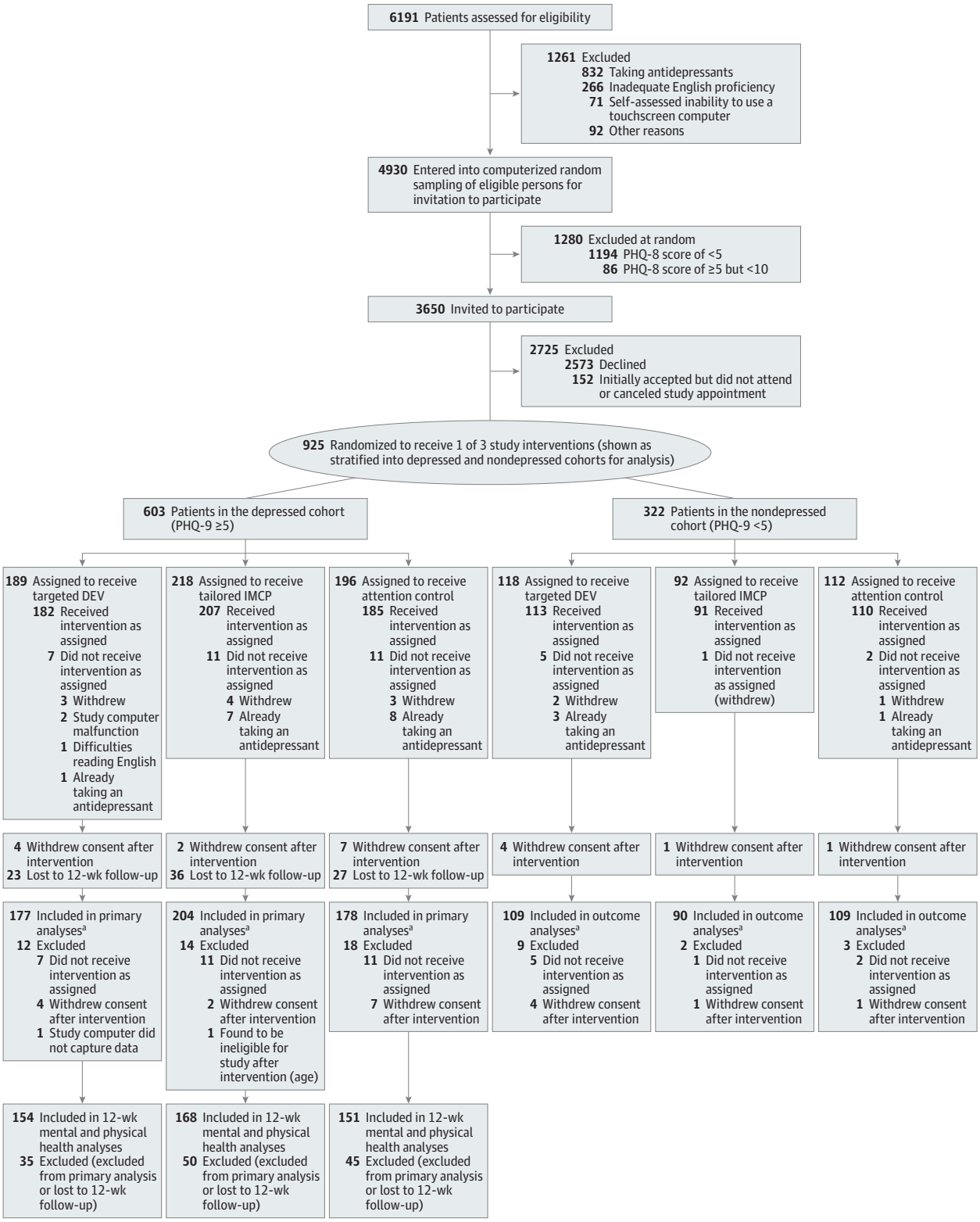
Within both the depressed and nondepressed cohorts, patients assigned to the 3 experimental groups were similar in sex, age, race/ethnicity, family income, depression symptoms, and baseline self-efficacy for communicating with the clinician about mental health issues (**Table 1**). In the depressed cohort, the DEV group had a higher mean baseline MCS-12 score than the IMCP or control group (*P* = .01).

Results in Depressed Patients

Intervention Effects on the Primary Composite Care Outcome

Rates of receipt of the composite care measure were 17.5% for the DEV group, 26% for the IMCP group, and 16.3% for the control group (cluster-adjusted, mean PPD: DEV vs control, 1.1 [95% CI, −6.7 to 8.9], *P* = .79; IMCP vs control, 9.9 [95% CI, 1.6 to 18.2], *P* = .02, **Table 2**). Mixed-effects models confirmed the superiority of the IMCP compared with control (adjusted OR, 1.81 [95% CI, 1.04 to 3.16], Table 2). The adjusted IMCP ORs were of similar magnitude (albeit not statistically significant) with respect to the 2 components of the primary outcome (for antidepressant prescribing, 1.85 [95% CI, 0.95 to 3.59], *P* = .07; for mental health referral, 1.76 [95% CI, 0.97 to 3.18], *P* = .06). In stratified analyses, the IMCP effect was significant in those

Figure. Flow of Patients Through Study



PHQ indicates Patient Health Questionnaire; DEV, depression engagement video; IMCP, interactive multimedia computer program.

[a] In the depressed cohort, 559 patients were included in the primary analysis; nondepressed cohort, 308 patients.

Table 1. Baseline Characteristics of Patients (Depressed Cohort and Nondepressed Cohort)

	Depressed Cohort, No. (%)[a]			Nondepressed Cohort, No. (%)[a]		
	DEV (n = 177)	IMCP (n = 204)	Control (n = 178)	DEV (n = 109)	IMCP (n = 90)	Control (n = 109)
Women	94 (53.1)	110 (53.9)	99 (55.6)	65 (59.6)	52 (57.8)	66 (60.6)
Age, mean (SD), y	50.6 (11.7)	50.5 (12.4)	50.6 (11.1)	54.5 (10.8)	53.7 (12.1)	53.5 (12.0)
Race/ethnicity						
White, non-Hispanic	89 (50.3)	110 (53.9)	90 (50.6)	75 (68.8)	55 (61.1)	67 (61.5)
Hispanic or Latino	32 (18.1)	30 (14.7)	26 (14.6)	8 (7.3)	13 (14.4)	14 (12.8)
Black, not Hispanic	37 (20.9)	49 (24.0)	44 (24.7)	13 (11.9)	12 (13.3)	13 (11.9)
Other	19 (10.7)	15 (7.4)	18 (10.1)	13 (11.9)	10 (11.1)	15 (13.8)
Income level, $						
<35 000	79 (44.6)	89 (43.6)	77 (43.3)	31 (28.4)	17 (18.9)	24 (22.0)
≥35 000	98 (55.4)	115 (56.4)	101 (56.7)	78 (71.6)	73 (81.1)	85 (78.0)
College or graduate degree, No./Total (%)	59/176 (33.5)	75/202 (37.1)	74/178 (41.6)	64/109 (58.7)	51/89 (57.3)	68/108 (63.0)
Living with spouse or partner, No./Total (%)	92/176 (52.3)	109/202 (54.0)	93/178 (52.2)	68/109 (62.4)	53/89 (59.6)	72/108 (66.7)
Practice setting[b]						
Multispecialty group practice	78 (44.1)	81 (39.7)	61 (34.3)	52 (47.7)	38 (42.2)	53 (48.6)
Faculty or resident practice	50 (28.2)	57 (27.9)	69 (38.8)	39 (35.8)	37 (41.1)	36 (33.0)
Health maintenance organization	24 (13.6)	26 (12.8)	19 (10.7)	6 (5.5)	6 (6.7)	5 (4.6)
Veterans Affairs clinic	25 (14.1)	40 (19.6)	29 (16.3)	12 (11.0)	9 (10.0)	15 (13.8)
City of care						
Sacramento	134 (75.7)	152 (74.5)	127 (71.4)	78 (71.6)	59 (65.6)	80 (73.4)
San Francisco	43 (24.3)	52 (25.5)	51 (28.7)	31 (28.4)	31 (34.4)	29 (26.6)
PHQ-9 score at index visit, mean (SD)[c]	10.0 (4.6)	10.8 (4.8)	10.6 (4.5)	1.7 (1.5)	1.9 (1.5)	1.9 (1.5)
PHQ-9 category at index visit						
0-4, Nondepressed				109 (100.0)	90 (100.0)	109 (100.0)
5-9, Mild depression	103 (58.2)	99 (48.5)	89 (50.0)			
10-14, Moderate depression	43 (24.3)	66 (32.4)	56 (31.5)			
≥15, Moderately severe to severe depression	31 (17.5)	39 (19.1)	33 (18.5)			
SF-12 at enrollment, No.	172	201	178	109	88	108
MCS-12, mean (SD)[d]	43.4 (11.8)[e]	40.0 (10.3)[e]	40.8 (12.3)[e]	54.5 (7.2)	55.6 (6.8)	55.5 (6.6)
PCS-12, mean (SD)[d]	38.7 (14.1)	38.5 (13.5)	38.2 (13.0)	46.7 (11.6)	48.1 (10.9)	46.3 (11.8)
Self-efficacy for patient-clinician interactions regarding mental health, mean (SD)[f]	20.9 (6.0)	21.3 (6.2)	20.8 (6.2)	22.9 (4.8)	23.4 (4.7)	23.5 (5.1)

Abbreviations: DEV, depression engagement video; IMCP, interactive multimedia computer program; MCS-12, Mental Health Component Summary score; PHQ-9, Patient Health Questionnaire-9; PCS-12, Physical Health Component Summary score; SF-12, 12-Item Short Form Health Survey.

[a] Due to rounding, percentages might not sum to 100. The depressed cohort was defined by a baseline PHQ-9 score of 5 or greater, the nondepressed cohort by a baseline PHQ-9 score less than 5.

[b] The multispecialty group category includes the University of California, Davis (UCD), Primary Care Network and Sutter Medical Group. The faculty or resident practice category includes University of California, San Francisco, affiliated clinics and the UCD Ambulatory Care Center. The health maintenance organization category includes participating clinics from Kaiser Permanente. The Veterans Affairs category includes the Veterans Affairs Medical Center in San Francisco, California, and the Northern California VA Health System.

[c] Range 0-27, higher is more depressed.

[d] Range 0-100, higher is better health.

[e] For an all-way comparison, the analysis for the variance within the depressed cohort is $P = .01$.

[f] Range 6-30, higher is greater self-efficacy.

with at least moderate symptoms (adjusted OR, 2.42 [95% CI, 1.11 to 5.30]) but not in those with mild symptoms (adjusted OR, 1.10 [95% CI, 0.44 to 2.75]) (Table 2). The IMCP depression severity interaction term was nonsignificant ($P = .31$).

Intervention Effects on Patient Engagement

The percentage of patients requesting information about depression during the visit was 17.7% (95% CI, 11.4% to 23.9%) in the DEV group, 19.5% (95% CI, 13.3% to 25.6%) in the IMCP group, and 9.5% (95% CI, 4.9% to 14.1%) in the control group. Patients assigned to the DEV and IMCP groups were significantly more likely than control patients to request information about depression (cluster-adjusted, mean PPD: DEV vs control, 8.1 [95% CI, 0.9 to 15.4], $P = .03$; IMCP vs control, 9.9 [95% CI, 2.8 to 17.1], $P < .001$]; and adjusted OR: DEV vs control, 2.11 [95% CI, 1.12 to 3.98], $P = .02$; IMCP vs control, 2.19 [95% CI, 1.19 to 4.04], $P = .01$).

There were no significant intervention effects on self-efficacy for communicating with the clinician about mental health issues (adjusted mean difference on the modified Maly scale: DEV vs control, 0.22 [95% CI, −0.75 to 1.19], $P = .66$; IMCP vs control, 0.01 [95% CI, −0.88 to 0.90], $P = .98$).

Intervention Effects on 12-Week Outcomes

Table 3 shows scores on the PHQ-8 (depression), MCS-12 (mental health), and PCS-12 (physical health) by intervention group at baseline and at 12-week follow-up. All 3 outcomes improved significantly from baseline to follow-up regardless of group assignment (*P* values all ≤ .01). There were no signifi-

Table 2. Effects of DEV and IMCP vs Control on Receipt of Composite Care Measure (Antidepressant Prescription and/or Mental Health Referral) in Depressed Cohort

	No./Total (%)			DEV vs Control		IMCP vs Control	
	DEV	IMCP	Control	Cluster-Adjusted, Mean PPD (95% CI)[a]	Adjusted OR (95% CI)[b]	Cluster-Adjusted, Mean PPD (95% CI)	Adjusted OR (95% CI)[b]
Total group[c]	31/177 (17.5)	53/204 (26.0)	29/178 (16.3)	1.1 (−6.7 to 8.9)	1.16 (0.63 to 2.12)	9.9 (1.6 to 18.2)	1.81 (1.04 to 3.16)
P value				.79	.64	.02	.04
PHQ-9 score of 5-9 (n = 291)[d]	8/103 (7.8)	13/99 (13.1)	10/89 (11.2)	−3.5 (−11.8 to 4.9)	0.61 (0.23 to 1.66)	1.9 (−7.4 to 11.2)	1.10 (0.44 to 2.75)
P value				.42	.34	.69	.83
PHQ-9 score of ≥10 (n = 268)[d]	23/74 (31.1)	40/105 (38.1)	19/89 (21.3)	12.5 (−2.8 to 27.9)	1.86 (0.79 to 4.38)	19.4 (5.1 to 33.8)	2.42 (1.11 to 5.30)
P value				.11	.15	.01	.03

Abbreviations: DEV, depression engagement video; IMCP, interactive multimedia computer program; OR, odds ratio; PPD, percentage point difference.

[a] Cluster-adjusted, mean percentage point differences estimated via Stata's postestimation command margins following a simple (unadjusted) mixed-effects logistic regression model that included fixed effects for study group and random effects for clinicians to adjust inferences for nesting of multiple patient observations within 124 clinicians. Margins were estimated with the random effect for each observation set to 0 (the mean value). The *P* values are for the Wald χ^2 test of the null hypothesis that the contrast is 0.

[b] Adjusted ORs estimated in the mixed-effects logistic regression model with fixed effects to adjust for patient sex, race/ethnicity and baseline PHQ-9 category and practice setting and with random effects to adjust for nesting of patients within 124 clinician practices (residual intracluster correlation coefficient = 0.096).

[c] All patients with a PHQ-9 score of 5 or greater (n=559).

[d] Wald χ^2 test (2 *df*) for heterogeneity of treatment effects by depressive symptom level = 2.32, *P* = .31.

Table 3. PHQ-8, PCS-12, and MCS-12 Scores at Baseline (n=559) and 12-Week Follow-up (n=473)[a]

	PHQ-8		PCS-12		MCS-12	
Intervention Group	Patients, No.	Estimate, Mean (95% CI)	Patients, No.	Estimate, Mean (95% CI)	Patients, No.	Estimate, Mean (95% CI)
DEV						
Baseline	177	9.7 (9.2 to 10.3)	172	38.7 (36.7 to 40.8)	172	43.4 (41.8 to 44.9)
Follow-up at 12 wk	154	6.7 (5.8 to 7.6)	153	41.4 (39.4 to 43.4)	153	46.7 (44.9 to 48.5)
Adjusted over-time mean difference		−2.9 (−3.7 to −2.2)		2.3 (0.8 to 3.7)		3.0 (1.1 to 4.9)
DEV vs control, adjusted difference in mean over-time differences		−0.2 (−1.2 to 0.8)		0.1 (−1.9 to 2.2)		−0.2 (−2.9 to 2.5)
IMCP						
Baseline	204	10.5 (9.8 to 11.1)	201	38.5 (36.8 to 40.3)	201	40.0 (38.7 to 41.4)
Follow-up at 12 wk	168	8.7 (7.8 to 9.5)	166	40.2 (38.3 to 42.1)	166	43.2 (41.4 to 45.0)
Adjusted over-time mean difference		−1.9 (−2.6 to −1.2)		1.8 (0.4 to 3.2)		3.1 (1.3 to 4.9)
IMCP vs control, adjusted difference in mean over-time differences		0.9 (−0.1 to 1.9)		−0.3 (−2.3 to 1.7)		−0.1 (−2.7 to 2.5)
Control						
Baseline	178	10.4 (9.8 to 11.0)	178	38.2 (36.1 to 40.2)	178	40.8 (39.0 to 42.6)
Follow-up at 12 wk	151	7.6 (6.8 to 8.4)	148	39.9 (37.7 to 42.1)	148	44.1 (41.7 to 46.4)
Adjusted over-time mean difference		−2.7 (−3.5 to −2.0)		2.1 (0.7 to 3.6)		3.2 (1.3 to 5.1)

Abbreviations: DEV, depression engagement video; IMCP, interactive multimedia computer program; MCS-12, Mental Health Component Summary score; PHQ-8, Patient Health Questionnaire-8; PCS-12, Physical Health Component Summary score.

[a] Adjusted mean differences and 95% CIs from mixed-effects linear regression models with statistical adjustments for patient sex, race/ethnicity, practice setting, baseline PHQ-9 category, and random effects for patients and for clinicians. The CIs for time point–specific means are adjusted for clustering by clinician, using clustered survey data analysis methods. Compared to nonrespondents at 12 weeks, those who completed the 12-week survey were older, more likely to be partnered, to have higher incomes, to have been recruited from the Sacramento area, and to have better mental health status. However, attrition was not associated with treatment assignment. The PHQ-8 is scored from 0 to 24 (higher scores indicate more depressed); the PCS-12 and MCS-12 are scored from 0 to 100 (100 indicates better health).

Table 4. Potential Harms in the Nondepressed Cohort of 308 Patients (PHQ-9 Score <5)

Outcome	No. (%) of Patients			Cluster-Adjusted, Mean PPD (90% CI)[a]	
	DEV (n = 109)	IMCP (n = 90)	Control (n = 109)	DEV vs Control	IMCP vs Control
Clinician reported					
Antidepressant prescribed[b,c]	5 (4.8)	3 (3.6)	7 (6.7)	−2.2 (−8.0 to 3.5)	−3.3 (−9.1 to 2.4)
P value for noninferiority				.05	.02
Patient reported					
Antidepressant recommended[c]	6 (5.5)	4 (4.4)	5 (4.6)	0.9 (−4.9 to 6.7)	0.3 (−5.1 to 5.7)
P value for noninferiority				.23	.16
Depression discussed[d]	51 (47)	36 (40)	48 (44)	3.3 (−9.2 to 15.7)	−2.9 (−15.8 to 10.0)
Depression treatment discussed[d]	25 (23)	14 (16)	18 (17)	5.9 (−2.7 to 14.5)	−0.8 (−8.9 to 7.4)
Depression medication requested[c]	7 (6.4)	2 (2.2)	2 (1.8)	4.6 (−0.05 to 9.3)	0.4 (−3.0 to 3.7)

Abbreviations: DEV, depression engagement video; IMCP, interactive multimedia computer program; PPD, percentage point difference.

[a] Cluster-adjusted, mean percentage point differences estimated via Stata's postestimation command margins following simple logistic regression models for clustered data, with study group as the sole fixed-effects term in the model, to adjust inferences for the nesting of multiple patient observations within 106 clinicians. Clustered data models estimated either via generalized estimating equations or mixed-effects logistic regression. For mixed-effects models, margins were estimated with the clinician random effect for each observation set to 0 (the mean value). Noninferiority *P* values are for Wald χ^2 test of the 1-sided inferiority null hypothesis that the contrast is 3.5 percentage points or greater.

[b] N = 292, due to 16 missing values.

[c] Logistic regression model estimated using generalized estimation equations (due to small number of outcomes) to adjust for clustering of patients within clinicians.

[d] Logistic regression model estimated with random intercepts to adjust for clustering of patients within primary care clinicians.

cant differences between IMCP and control or between DEV and control at 12-week follow-up (*P* values all ≥.05, Table 3). Similar results were obtained when the sample was restricted to patients with baseline PHQ-9 scores of 10 or greater (eTable 1 in the Supplement).

Results in Nondepressed Patients

Among nondepressed patients, rates of clinician-reported antidepressant prescribing were 4.8% in the DEV group, 3.6% in the IMCP group, and 6.7% in the control group (**Table 4**). Rates of patient-reported clinician recommendations for antidepressant medication were 5.6% in the DEV group, 4.4% in the IMCP group, and 4.6% in the control group (Table 4). For the clinician-reported outcome, these results were consistent with noninferiority (ie, equivalence) of the 2 interventions compared with the control group (*P* < .05 for noninferiority, Table 4). However, using the patient-reported measure, the upper confidence limit for the DEV vs control difference extended to 6.7 percentage points (*P* = .23 for noninferiority) and for the IMCP vs control difference to 5.7 percentage points (*P* = .16 for noninferiority). Therefore, the 2 interventions were not found to be equivalent to the control group for the outcome of patient-reported recommendation for antidepressant medication. For discussion of depression (in general), discussion of depression treatment (specifically), and patient requests for depression medication, cluster-adjusted mean differences between each of the active interventions and control were consistently less than 6 percentage points, with 90% CIs for differences invariably crossing zero (Table 4). Similar results were obtained in more fully adjusted models (eTable 2 in the Supplement). There were no prespecified inferiority margins for these outcomes. Neither of the 2 active interventions had a significant effect (vs control) on clinician-reported visit burden or clinician-reported visit time (*P* > .60 for each of the 4 comparisons).

Discussion

Among patients with clinically relevant depression symptoms (ie, the depressed patient cohort), a tailored IMCP, but not a targeted DEV, delivered before a primary care clinician appointment increased the primary composite outcome of antidepressant recommendation or mental health referral, as reported by the patient immediately after the visit. Both the DEV and the IMCP increased patient-reported requests for information about depression. However, there were no significant improvements in mental health at the 12-week follow-up in response to either intervention. Among nondepressed patients, we observed no evidence of harm from either intervention for the outcome of clinician-reported antidepressant prescribing, but we could not exclude harm (defined as a higher rate of antidepressant prescriptions for nondepressed patients associated with each intervention) based on patient-reported antidepressant recommendation. There were no statistically significant adverse intervention effects on other visit processes, although the patients in the DEV group made approximately 3-fold more requests for antidepressants than IMCP or control group patients.

Overall in the depressed cohort, assignment to the IMCP, but not the DEV, was associated with a statistically significant 10-percentage point increase in the likelihood of receiving the primary composite outcome of antidepressant recommendation, mental health referral, or both. The estimated intervention effect was statistically significant in the subgroup of patients with PHQ-9 scores of 10 or higher (for whom current guidelines endorse prompt provision of medication or psychotherapy),[38,46] but not those with lower scores. Although clinically plausible, these subgroup analyses were not prespecified and should be viewed as exploratory, especially

since there was no statistically significant interaction between intervention group and PHQ-9 score category.

In considering the mechanism by which the IMCP improved clinical processes of care, we speculate that individualized information about depression and its manifestations may have helped some depressed individuals to identify their personal symptoms and distress as depression and to communicate these insights to providers verbally or nonverbally. In turn, clinicians may have been less deterred by perceptions of depression-related stigma on the part of patients and consequently more disposed to offer treatment. In addition, individualized information about depression treatment may have increased some patients' receptiveness to antidepressant medication or psychotherapy. These tentative explanations should be tested in future studies.

Among patients who were depressed, assignment to the DEV or IMCP was associated with a 2-fold increased likelihood of asking the treating clinician about depression. However, regardless of intervention group, most patients never broached the topic. The dearth of depression-related discussion could reflect more pressing clinical issues, competing demands,[47] or reluctance to raise the issue of depression.

Among depressed patients who participated in the 12-week follow-up telephone interview, depression symptom scores and MCS-12 and PCS-12 scores improved from baseline in all 3 treatment groups. However, neither the DEV nor the IMCP was associated with improved mental or physical health outcomes compared with control. Thus, our interventions did not demonstrate benefit at the 12-week follow-up. Translating improvements in initial depression process of care into better clinical outcomes may require reinforcement, clinician support, or systems improvement and additional research examining the effect of combined interventions is warranted.

Among nondepressed patients (PHQ-9 score < 5), we found small differences (0-3 percentage points) in rates of both antidepressant prescribing (reported by clinicians) and antidepressant recommendations (reported by patients). Using the patient-reported measure, we could not exclude the possibility that the 2 interventions increased rates of antidepressant prescriptions by at least 3.5 percentage points among the nondepressed. There was, however, no substantive evidence of adverse intervention effects as measured by clinician-reported visit burden or duration. In judging the overall merits of the IMCP, physicians and care managers will have to weigh the benefits (improved process of care) against potential risks of overtreatment.

The brevity of both interventions makes them potentially suitable, when further validated, for widespread implementation in health care settings. Patients could complete depression screening questionnaires on touchscreen machines and, if warranted, receive prompts to select an appropriate multimedia program.

There were study limitations. Eligibility and classification into depressed and nondepressed categories was based on the PHQ-9 score, a valid measure of depression symptom burden but not a diagnostic instrument. Patients were volunteers recruited from 2 metropolitan regions in northern California; the generalizability of our findings to other settings and types of patients is unknown. Randomization by patient rather than by clinician or clinic had advantages, but may have diluted intervention effects. Although allocation concealment was achieved, full blinding was infeasible. The primary outcome among depressed patients was based on patient report—arguably the most appropriate choice for the goal of patient activation, but still subject to reporting bias. Incomplete follow-up could have skewed 12-week outcomes, even though the direction of this bias is unpredictable. Finally, this study examined the effectiveness of the interventions in office settings. Administration in a different context (eg, via the Internet) could produce different results.

Conclusions

Among depressed patients evaluated in a primary care setting, the use of a tailored IMCP immediately prior to a primary care visit resulted in the increased receipt of the primary composite outcome of antidepressant prescription recommendation, mental health referral, or both during the primary care visit compared with a control group. However, the tailored IMCP intervention had no effect on 12-week, clinically meaningful outcomes. Although there was no evidence of excess antidepressant prescribing among patients with minimal symptoms of depression as determined by the clinician-reported outcome, potential overtreatment cannot be excluded based on the patient-reported outcome. Further research is needed to determine effects on clinical outcomes and whether the benefits outweigh possible harms.

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