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Abstract

Importance—Interventions encouraging primary care patients' engagement with their clinicians to address depression could improve outcomes but foster unnecessary treatment.

Objective—Determine whether a depression engagement video (DEV) or a tailored interactive multimedia computer program (IMCP) improves initial depression care without increasing unnecessary anti-depressant prescribing.

Design—Randomized controlled trial comparing three interventions (DEV, IMCP, and control) conducted in two patients groups (*depressed*, defined by a Patient Health Questionnaire [PHQ]-9 score 5, and *non-depressed* [PHQ-9<5]) conducted between June 2010 and March 2012.

Setting—Primary care offices at 7 sites in 2 cities.

Participants—*Depressed* (N=559) and *non-depressed* (N=308) adult patients of 135 primary care clinicians.

Intervention(s)—DEV targeted to gender and income; IMCP tailored to individual patient characteristics; a sleep hygiene video (control).

Main Outcome Measure(s)—*Depressed* patients: composite measure of antidepressant recommendation and/or mental health referral (primary outcome); 12-week mental health, measured by the PHQ-8 (secondary outcome). *Non- depressed* patients: clinician-reported prescribing and patient-reported antidepressant recommendation (primary outcomes, pre-specified 3.5% non-inferiority margins).

Results—*Depressed patients*: composite care outcome rates were 18%, 26%, and 16% respectively in the DEV, IMCP, and control groups (cluster-adjusted DEV-control difference = 1.1% [95% CI −6.7 to 8.9, P=.79]; IMCP-control = 9.9% [95% CI 1.6 to 18.2, P=.02]). Twelve-week PHQ-8 effects were not significant: DEV- control = −0.2 points (95% CI −1.2 to 0.8); IMCP – control = 0.9 (95% CI −0.1 to 1.9). *Non-depressed* patients: clinician-reported antidepressant prescribing in the DEV and IMCP groups was non-inferior to control (DEV-control = −2.2%, 90% CI −8.0 to 3.498, non-inferiority (NI) P=.0499; IMCP-control = −3.3%, 90% CI −9.1 to 2.4, NI P=.02); patient-reported antidepressant recommendation did not achieve non-inferiority: DEV-control = 0.9% (90% CI −4.9 to 6.7; NI P=.23); IMCP-control = 0.3% (90% CI −5.1 to 5.7; NI P=.16).

Conclusions and Relevance—A tailored IMCP increased antidepressant recommendation and/or mental health referral among depressed patients but had no effect on 12-week mental health. The possibility that the IMCP and DEV increased patient-reported antidepressant recommendations among non-depressed patients could not be excluded. Further research is needed on the benefits and harms of these interventions.

Despite progress, depression in primary care remains under-recognized and under-treated.[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* involves segmenting a general population into smaller, more homogeneous units based on observable factors such as age, gender, 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, respectively, could enhance patient engagement and initial care for patients with depression symptoms. We also examined the extent to which each intervention promoted prescribing or recommendation of anti-depressant 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 gender 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 groups according to whether or not they had significant depression symptoms (Patient Health Questionnaire [PHQ]-9 score ≥ 5 defined depressed patients and PHQ-9 score < 5 defined non-depressed patients). Within each of these 2 groups (depressed patients and non-depressed patients) we compared the effectiveness of each intervention with an attention control (sleep hygiene video). Among depressed patients, we hypothesized that each intervention would increase delivery of depression treatments (primary outcome), encourage patients to ask questions about depression, and lead to improved mental health 12 weeks later as compared to the control group. Among non-depressed 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 as compared to the control group.

METHODS

Design overview

The trial was designed as a randomized controlled trial comparing 3 interventions: a *targeted* depression engagement video (DEV) designed to encourage patient participation in depression-related discussion and care, a *tailored* interactive multimedia computer program (IMCP), and an attention control. We report separately on results for depressed and non-depressed patient groups, defined by PHQ-9 score ≥ 5 and <5, respectively. Study procedures and protocol have been detailed elsewhere.[20] Ethics approval was obtained from the Institutional Review Boards at all performance sites.

Sampling

Patients and clinicians were recruited from primary care clinics affiliated with the University of California, San Francisco (UCSF); the San Francisco Veterans Affairs 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 email announcements and 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 of their patients.

Patient enrollment

Eligible patients were aged 25-70 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 working aged adults because of the social and

economic burden of depression in this age group.[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 1-2 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 selected for telephoning from each clinic's appointment lists in random order 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 over-sampled. Eligible patients who provided preliminary verbal consent were invited to a research appointment 1 hour prior to the upcoming "index" visit. At the UCSF urgent care clinic only, patients were approached directly by research assistants in waiting rooms, without any prior telephone screening. Patients were offered an incentive of $20-$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 attention control intervention was a sleep hygiene video produced by HealthiNation.[25]

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 provider.[9,10,23,26] The marketing firm produced 4 DEV variants targeted to gender and household income. By employing terms and images likely to resonate with the intended audience, targeted messages are generally better attended to and more deeply processed than non-targeted 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 level of depression symptoms (e.g., 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 discuss with their clinician), visit agenda (intention to discuss depression and/or depression treatment), depression causal attributions (biological, psychosocial, situational, existential),[28,29] treatment preferences (medication, counseling, both, neither),[28,30,31] self-efficacy for communicating with healthcare providers,[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, read, and perceived as relevant and are superior to non-tailored interventions in improving various health behaviors and outcomes across a broad array of patient populations and target conditions,[35] including depression.[36,37] Screenshots of the DEVs and IMCP are included in the **electronic appendix**.

Randomization and patient flow

A study Research Assistant met patients1 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 subjects into categories defined by self-reported race/ethnicity (because of its association with socio-economic position [a target of the depression engagement video] and to enhance generalizability), gender and site. Within each category, patients were randomly allocated in equal proportions to 1 of 3 study arms, in randomly permuted blocks of 9 subjects, with the size of the blocks not disclosed to research staff during enrollment. After randomization, patients were again asked about current antidepressant use; 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 were exposed to 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, subjects completed a computer based post-visit questionnaire including questions about the encounter (i.e., whether they asked about or discussed depression and/or depression-related care; whether the physician recommended an antidepressant or made a mental health referral; and when the physician arranged for primary care follow-up). Clinicians independently completed a brief post-visit questionnaire. Agreement between patient and physician for antidepressant recommendation was 87% and for mental health referral 89%. Patients in the depressed sample (PHQ-9 5 at index visit) were telephoned 12 weeks later to assess severity of depression symptoms and health status.

Outcome measures

Measures for this study include patient post-visit reports, physician post-visit reports, and 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 non-depressed, we used both patient and clinician reports.

The primary pre-specified outcome applied to the group of participants categorized as depressed was a composite measure of initial depression care ("composite care measure") defined as receiving an antidepressant recommendation, a mental health referral, or both during the index visit. Secondary outcomes included: patient-physician communication self-efficacy using a scale modified from Maly et al.[32] (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 provider for information about depression during the visit; 12-week scores on the PHQ-8 (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 SF-12 Version 2.0 Mental Health Component Summary Scores (MCS-12) and Physical Health Component Summary Scores (PCS-12) (both scored from 0-100, with higher scores representing better health).[41,42]

The primary pre-specified outcome applied to non-depressed patients was whether the clinician recommended or prescribed an antidepressant. This was assessed by clinician report of antidepressant prescribing and by patient report of whether the clinician "recommended" a medication for depression. Secondary outcomes among non-depressed patients included: 1) whether depression or depression treatment were discussed (each classified as yes/no/uncertain); 2) whether the patient requested medication for depression during the study visit (yes/no/uncertain); 3) clinician-reported face-to-face visit time (minutes) and 4) clinician-reported visit burden, computed as the sum of 3 items rating the visit in terms of "amount of time required ... amount of effort required.... [and] degree to which you found the visit difficult", each on a 0-2 scale (0=less than average, 1=about average, 2=greater than average; Cronbach's alpha, 0.79).

Statistical analysis

Details on power calculations, model assumptions, and variable selection have been reported.[20] Briefly, we fit clustered data regression models that would allow assessment of the pairwise (intervention versus control) contrasts of interest, while accounting 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 per arm for the analyses involving depressed patients was established to provide 80% power under two-sided testing (alpha=5%) to detect standardized pairwise differences of 0.3 (e.g. 15 percentage points for a binary outcome with an expected value of 50%). For analyses of non-depressed patients, the per-group target sample of 102 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 Version 12.1.[43] Binary outcomes were assessed using logistic regression models, estimated using random effects estimation or, for low event counts, generalized estimating equations. Relative comparisons for binary outcomes were expressed as adjusted odds ratios from models that adjusted for the study design (to minimize omitted covariate bias),[44] while absolute comparisons were expressed as cluster-adjusted mean percentage point differences [DIFFs] on the original scale of measurement. Cluster-adjusted mean percentages and differences were estimated via Stata's margins post-estimation command, 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 effect linear regression models with adjustment for stratifiers. In the depressed sample all pairwise contrasts were estimated with 95% confidence intervals and tested with two-sided P-values. In the non-depressed sample, two-sided 90% confidence intervals are reported, equivalent to 1-sided testing of the

inferiority null hypothesis. The significance threshold was $P<0.05$ for all contrasts. For harms, we report non-inferiority [NI] P-values for only the antidepressant prescribing and recommendation outcomes, using pre-specified tolerance margins of 3.5 percentage points. When the NI P-value is less than 0.05, the contrast is statistically significant in favor of non-inferiority at the specified tolerance margin.

Models adjusting for strata included the following terms: patient gender, ethnicity, and practice setting [multispecialty group, faculty/resident practice, health maintenance organization, or VA clinic]), and (in analyses of depressed patients) baseline PHQ-9 category (5-9 vs. 10). The post-visit patient-physician communication self-efficacy outcome analysis also adjusted for pre-visit self-efficacy. 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 drop out, to avoid biases that could occur in complete case analysis.[45]

Although not pre-specified 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 was assessed by conducting analyses stratified by PHQ-9 level. Heterogeneity of treatment effects by baseline depression severity (5-9 versus 10) was assessed by fitting a model including the group-by-depression category interaction term (tested with the Wald Chi-square test [2 degrees of freedom]).

RESULTS

Patient Flow and Baseline Characteristics

Of 135 consenting clinicians, 124 enrolled at least 1 patient with a PHQ-9 score 5, and 106 enrolled at least 1 with a PHQ-9 score <5. **Figure 1** depicts the flow of patients from screening through 12-week follow-up. Of 6,191 patients assessed for eligibility, 3650 were invited to participate, and 925 (603 in the depressed sample and 322 in the non-depressed sample) were randomized to the DEV, IMCP, or attention control group prior to a primary care office visit. Of the 925 randomized participants, 58 were excluded post-randomization, leaving 867 analyzable subjects: 559 categorized as depressed and 308 as non-depressed sample. Of the 559, approximately 85% completed the 12-week telephone follow-up survey (**Figure 1**). Subjects were enrolled from June 16, 2010 to November 8, 2011; follow-up was complete by March 31, 2012.

Within both the depressed and non-depressed samples, participants assigned to the 3 experimental groups were similar in gender, age, race/ethnicity, family income, depression symptoms, and baseline self-efficacy for communicating with the physician about mental health issues (**Table 1**). In the depressed sample, 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 outcome (antidepressant recommendation and/or mental health referral)—Rates of receipt of the composite care measure were 18%, 26%, and 16% in the DEV, IMCP, and control groups, respectively (cluster-adjusted mean percentage point difference [DIFF] comparing DEV to control, 1.1, 95% CI −6.7 to 8.9, *P*=.79; DIFF comparing IMCP to control, 9.9, 95% CI 1.6 to 18.2, *P*=. 02, **Table 2**). Mixed effects models confirmed the superiority of the IMCP over control (adjusted odds ratio [AOR] 1.81, 95% CI 1.04 to 3.16, **Table 2**). The IMCP odds ratios were of similar magnitude (albeit not statistically significant) with respect to the two components of the primary outcome (AOR for antidepressant prescribing, 1.85, 95% CI 0.95 to 3.59, *P*=. 07; AOR 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 with at least moderate symptoms (AOR 2.42, 95% CI 1.11 to 5.30) but not in those with mild symptoms (AOR 1.10, 95% CI 0.44 to 2.75) (**Table 2**). The IMCP-by-depression severity interaction term was non-significant (*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 (DEV vs. Control DIFF 8.1 percentage points [95% CI 0.9 to 15.4; *P*=.03] and AOR 2.11 [95% CI 1.12 to 3.98, *P*=. 02]; IMCP vs. Control DIFF 9.9 [95% CI 2.8 to 17.1; *P*=.006] and AOR 2.19 [95% CI 1.19 to 4.04, *P*=.01]).

There were no significant intervention effects on self-efficacy for communicating with the physician about mental health issues (adjusted mean difference on the modified Maly scale [95% CI] for DEV vs. Control: 0.22 [−0.75 to 1.19], *P*=.66; for IMCP vs. Control: 0.01 [−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-weeks follow-up. All 3 outcomes improved significantly from baseline to follow-up regardless of group assignment (*P*-values all .01). There were no significant 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 10 (**electronic appendix**).

Results in Non-Depressed Patients

Among non-depressed participants, rates of *clinician-reported antidepressant prescribing* were 4.8%, 3.6%, and 6.7% in the DEV, IMCP, and control groups, respectively (**Table 4**). Rates of *patient-reported physician recommendations* for anti-depressant medication were 5.6%, 4.4% and 4.6%, respectively (**Table 4**). For the clinician-reported outcome, these results were consistent with non-inferiority (i.e., equivalence) of the two interventions as compared to the control group (non-inferiority *P*<.05, **Table 4**). However, using the patient reported measure, the upper confidence limit for the DEV versus control difference extended

to 6.7 percentage points (non-inferiority *P*=.23) and for the IMCP versus control difference to 5.7 percentage points (non-inferiority *P*=.16). Therefore, the two interventions were not found to be equivalent to the control group for the outcome of patient-reported recommendation for anti-depressant 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 upper 90% confidence bounds for differences ranging from 3.7 (patient requests for medication, comparing IMCP to control) to 15.7 (depression discussion, comparing DEV to control) (**Table 4**). There were no pre-specified inferiority margins for these outcomes. Neither of the two active interventions had significant impact (versus control) on clinician-reported visit burden or clinician-reported visit time (*P*>.60 for each of the 4 comparisons).

COMMENT

Among patients with clinically relevant depression symptoms (i.e., the depressed patient sample), both a depression engagement video (DEV) and a tailored interactive multimedia computer program (IMCP) delivered before a primary care clinician appointment increased patient-reported requests for information about depression, and the IMCP increased the primary composite outcome of antidepressant recommendation or mental health referral, as reported by the patient immediately after the primary care appointment. However, there were no significant improvements in mental health or quality of life at 12-week follow-up in response to either intervention. Among non-depressed patients, we observed no evidence of harm from either intervention for the outcome of physician-reported antidepressant prescribing but we could not exclude harm (that is a higher-rate of antidepressant prescriptions for non-depressed patients associated with each intervention) based on patient-reported antidepressant recommendation. There were no significant adverse intervention effects on other visit processes.

Overall in the depressed sample, 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 more (for whom current guidelines endorse prompt provision of medication or psychotherapy)[38,46] but not those with lower scores. While clinically plausible, these subgroup analyses were not pre-specified 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 non-verbally. 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

participants' receptiveness to anti-depressant 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 two-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 participants who participated in the 12-week follow-up telephone interview, depression symptom scores and mental and physical health component scores improved from baseline in all 3 treatment arms. 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 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 impact of combined interventions is warranted.

Among non-depressed patients (PHQ-9<5), we found small differences in rates of both antidepressant prescribing (as reported by clinicians) and antidepressant recommendations (as reported by patients). Using the patient-reported measure, we could not exclude the possibility that the two interventions increased rates of antidepressant prescriptions by at least 3.5 percentage points among the non-depressed. In judging the overall merits of the IMCP, clinicians 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 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 "non-depressed" categories was based on the PHQ-9, a valid measure of depression symptom burden but not a diagnostic instrument. Participants 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 given the goal of patient activation but still subject to reporting bias. Incomplete follow-up could have skewed 12-week outcomes, 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 (e.g., via the internet) could produce different results.

In summary, among patients with depression evaluated in a primary care setting, the use of a tailored IMCP immediately prior to a primary care visit resulted in increased receipt of the primary composite outcome of antidepressant prescription recommendation and/or mental

health referral during the primary care visit, compared to an attention control group. However, the tailored IMCP intervention had no effect on 12-week clinically meaningful outcomes. While there was no evidence of excess antidepressant prescribing among patients with minimal symptoms of depression as determined by the physician 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.

Acknowledgements

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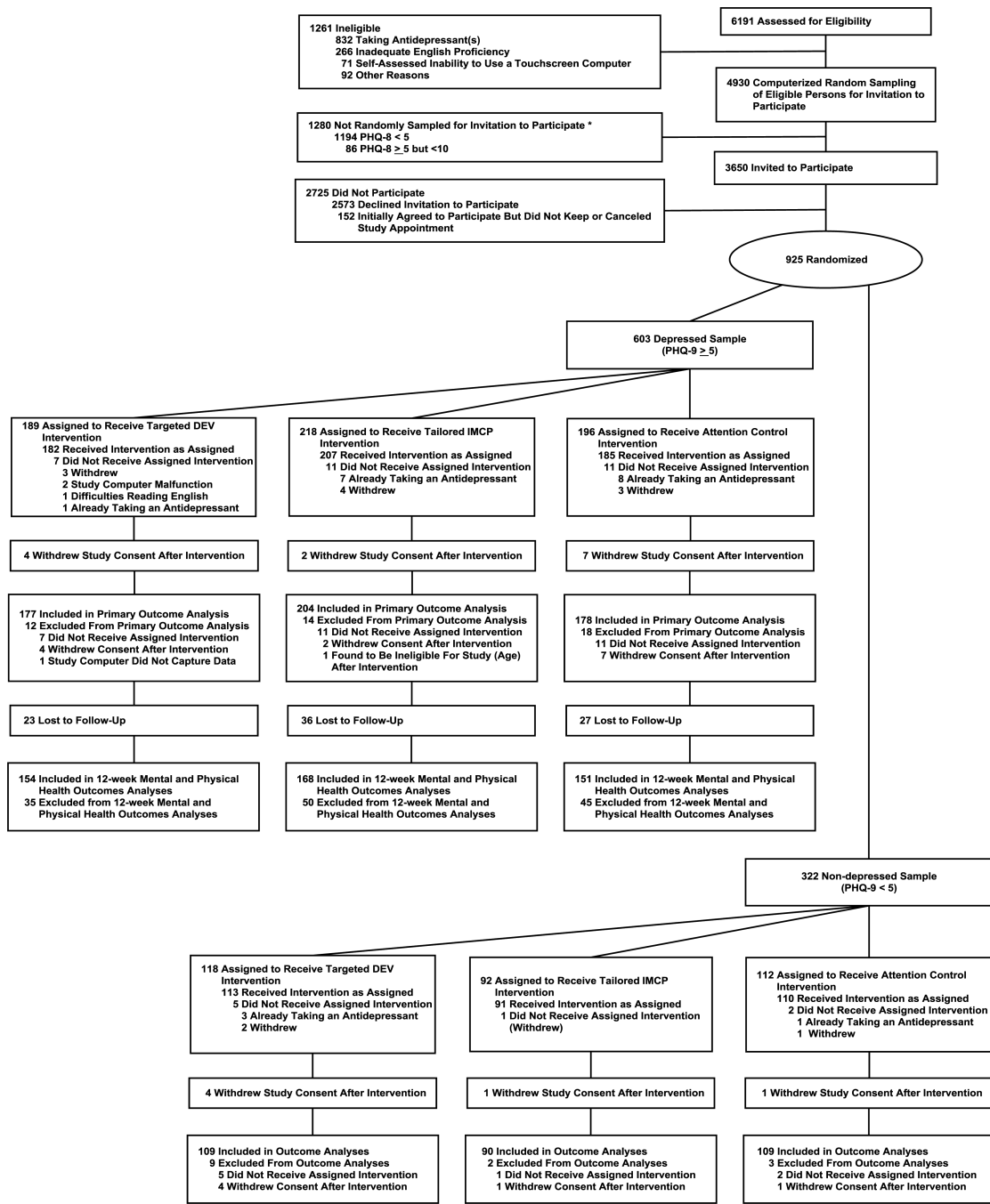
Figure 1. Flow of subjects through study

Of 6191 patients successfully contacted, 1261 were ineligible due to age, lack of English proficiency, inability to operate a computer, psychosis, or currently taking antidepressants. An additional 1280 subjects (denoted in the Figure by an asterisk) were excluded at random by an automated sampling program designed to maintain a ratio of depressed:non-depressed participants of approximately 5:3 and, within the depressed sample, to slightly over-sample patients with PHQ-8 scores 10. Of the remaining 3620 patients, 2725 declined participation or did not keep their appointments, leaving 925 (25.5%) who underwent randomization at

the index visit. A total of 58 patients (44 in the depressed sample and 14 in the non-depressed sample) were excluded post-randomization. For the effectiveness analysis, 559 patients were included in the primary analysis and 473 were available for follow-up at 12 weeks. For the harms analysis, 308 patients were included.

PHQ-9 = Patient Health Questionnaire-9

DEV = Depression engagement video

IMCP = Interactive multimedia computer program

Table 1

Baseline characteristics of participants (n=559 in depressed sample, n=308 in non-depressed sample).

	Depressed Sample[a]			Non-depressed Sample[a]		
	DEV (n = 177)	IMCP (n = 204)	Control (n = 178)	DEV (n = 109)	IMCP (n = 90)	Control (n = 109)
Female, n (%)	94 (53.1)	110 (53.9)	99 (55.6)	65 (59.6)	52 (57.8)	66 (60.6)
Age (years), mean (SD)	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, n (%)						
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, n (%)						
Less than $35,000	79 (44.6)	89 (43.6)	77 (43.3)	31 (28.4)	17 (18.9)	24 (22.0)
$35,000 or more	98 (55.4)	115 (56.4)	101 (56.7)	78 (71.6)	73 (81.1)	85 (78.0)
College or graduate degree, n/N (%)	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, n/N (%)	92/176 (52.3)	75/202 (54.0)	93/178 (52.2)	68/109 (62.4)	53/89 (59.6)	72/108 (66.7)
Practice setting[c], n (%)						
Multispecialty group practice	78 (44.1)	81 (39.7)	61 (34.3)	52 (47.7)	38 (42.2)	53 (48.6)
Faculty/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 (VA) clinic	25 (14.1)	40 (19.6)	29 (16.3)	12 (11.0)	9 (10.0)	15 (13.8)
City of care, n (%)						
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) (range 0-27, higher=more depressed)	10.0 (4.6)	10.8 (4.8)	10.6 (4.5)	1.7 (1.5)	1.9 (1.5)	1.9 (1.5)

	Depressed Sample[a]			Non-depressed Sample[a]		
	DEV (n = 177)	IMCP (n = 204)	Control (n = 178)	DEV (n = 109)	IMCP (n = 90)	Control (n = 109)
PHQ-9 category at index visit, n (%)						
0-4 (non-depressed)	--	--	--	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 (nonmissing #)	(n=172)	(n=201)	(n=178)	(n=109)	(n=88)	(n=108)
MCS-12 (range 0-100, higher=better health), mean (SD)	43.4 (11.8)[b]	40.0 (10.3)[b]	40.8 (12.3)[b]	54.5 (7.2)	55.6 (6.8)	55.5 (6.6)
PCS-12 (range 0-100, higher=better health), mean (SD)	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-physician interactions regarding mental health, mean (SD) (range 6 to 30, higher=greater self-efficacy)	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: CI, confidence interval; DEV, depression engagement video; IMCP, interactive multimedia computer program; MCS-12, SF-12 Mental Health Component Summary score; PCP, primary care provider; PHQ-9, Patient Health Questionnaire-9; PCS-12, SF-12 Physical Health Component Summary score; SD, standard deviation

Note: The depressed sample was defined by a baseline PHQ-9 score 5, the non-depressed sample by a baseline PHQ-9 score <5.

[a] Due to rounding, percentages might not sum to 100.

[b] P=.01 ANOVA for an all-way comparison (within effectiveness study group)

[c] The multispecialty group category includes the UC Davis Primary Care Network and Sutter Medical Group. The faculty/resident practice category includes UC San Francisco affiliated clinics and the UC Davis 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.

Table 2

Effects of DEV and IMCP (versus control) on receipt of composite care measure (antidepressant prescription and/or mental health referral) in depressed sample.

DEV	IMCP	Control	DEV vs. Control		IMCP vs. Control	
n/N (%)	n/N (%)	n/N (%)	Cluster-adjusted mean percentage point difference (95% CI)[a]	Adjusted odds ratio (95% CI)[b]	Cluster-adjusted mean percentage point difference (95% CI)	Adjusted odds ratio (95% CI)[b]
All subjects with PHQ-9 score 5 (N=559)						
31/177	53/204	29/178	1.1 (−6.7, 8.9)	1.16 (0.63, 2.12)	9.9 (1.6, 18.2)	1.81 (1.04, 3.16)
(17.5)	(26.0)	(16.3)	*P* value = .79	*P* value = .64	*P* value = .02	*P* value = .04
PHQ-9 score 5-9 (N=291)						
8/103	13/99	10/89	−3.4 (−11.8, 4.9)	0.61 (0.23, 1.66)	1.9 (−7.4, 11.2)	1.10 (0.44, 2.75)
(7.8)	(13.1)	(11.2)	*P* value = .42	*P* value = .34	*P* value = .69	*P* value = .83
PHQ-9 score 10 (N=268)						
23/74	40/105	19/89	12.5 (−2.8, 27.9)	1.86 (0.79, 4.38)	19.4 (5.1, 33.8)	2.42 (1.11, 5.30)
(31.1)	(38.1)	(21.3)	*P* value = .11	*P* value = .15	*P* value = .008	*P* value = .03

Abbreviations: CI, confidence interval; DEV, depression engagement video; IMCP, interactive multimedia computer program; PCP, primary care provider

Wald chi-square test (2 d.f.) for heterogeneity of treatment effects by depressive symptom level = 2.32, *P*=.31.

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

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

Table 3

PHQ-8, PCS-12, and MCS-12 scores at baseline (n=559) and 12-week follow-up (n=473)

Intervention Arm	Time	PHQ-8 (n=# nonmissing) Estimate (95% CI)	PCS-12 (n=# nonmissing) Estimate (95% CI)	MCS-12 (n=# nonmissing) Estimate (95% CI)
DEV	Baseline	(n=177) 9.7 (9.2, 10.3)	(n=172) 38.7 (36.7, 40.8)	(n=172) 43.4 (41.8, 44.9)
	12-weeks	(n=154) 6.8 (5.9, 7.7)	(n=153) 41.4 (39.4, 43.4)	(n=153) 46.7 (44.9, 48.5)
Adjusted Over-time Mean Difference		−2.9 (−3.7, −2.2)	2.3 (0.8, 3.7)	3.0 (1.1, 4.9)
DEV v. Control Adjusted difference in mean over-time differences		−0.2 (−1.2, 0.8)	0.1 (−1.9, 2.2)	−0.2 (−2.9, 2.5)
IMCP	Baseline	(n=204) 10.5 (9.8, 11.1)	(n=201) 38.5 (36.8, 40.3)	(n=201) 40.0 (38.7, 41.4)
	12-weeks	(n=168) 8.6 (7.8, 9.4)	(n=166) 40.2 (38.3, 42.1)	(n=166) 43.2 (41.4, 45.0)
Adjusted Over-time Mean Difference		−1.9 (−2.6, −1.2)	1.8 (0.4, 3.2)	3.1 (1.3, 4.9)
IMCP v. Control Adjusted difference in mean over-time differences		0.9 (−0.1, 1.9)	−0.3 (−2.3, 1.7)	−0.1 (−2.7, 2.5)
Control	Baseline	(n=178) 10.4 (9.8, 11.0)	(n=178) 38.2 (36.1, 40.2)	(n=178) 40.8 (39.0, 42.6)
	12-weeks	(n=151) 7.6 (6.8, 8.4)	(n=148) 39.9 (37.7, 42.1)	(n=148) 44.1 (41.7, 46.4)
Adjusted Over-time Mean Difference		−2.7 (−3.5, −2.0)	2.1 (0.7, 3.6)	3.2 (1.3, 5.1)

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

Note: Adjusted mean differences and 95% confidence intervals from mixed-effects linear regression models with statistical adjustments for patient gender, race, practice setting, baseline PHQ-9 category, and random effects for patients and for physician. Confidence intervals for timepoint-specific means are adjusted for clustering by physician, using clustered survey data analysis methods. Compared to non-respondents 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 0-24 (higher=more depressed); the PCS-12 and MCS-12 are scored from 0-100 (100=better health).

Table 4

Potential harms in the non-depressed sample of 308 patients (PHQ-9 score <5)

Outcome	DEV (n=109) n (%)	IMCP (n=90) n (%)	Control (n=109) n (%)	DEV vs. Control Cluster-adjusted mean percentage point difference (90% CI)[a]	IMCP vs. Control Cluster-adjusted mean percentage point difference (90% CI)[a]
Antidepressant prescribed (clinician reported; n=292 due to 16 missing values)[b]	5 (4.8)	3 (3.6)	7 (6.7)	−2.2 (−8.0, 3.49) *NI P* value = .0499	−3.3 (−9.1, 2.4) *NI P* value = .02
Antidepressant recommended (patient reported)[b]	6 (5.6)	4 (4.4)	5 (4.6)	0.9 (−4.9, 6.7) *NI P* value = .23	0.3 (−5.1, 5.7) *NI P* value = .16
Depression discussed (patient reported)[c]	51 (47)	36 (40)	48 (44)	3.3 (−9.2, 15.7)	−2.9 (−15.8, 10.0)
Depression treatment discussed (patient reported)[c]	25 (23)	14 (16)	18 (17)	5.9 (−2.7, 14.5)	−0.8 (−8.9, 7.4)
Depression medication requested (patient report)[b]	7 (6.4)	2 (2.2)	2 (1.8)	4.6 (−0.05, 9.3)	0.4 (−3.0, 3.7)

Abbreviations: CI, confidence interval; IMCP, interactive multimedia computer program; PCP, primary care provider; DEV, depression engagement video; NI, noninferiority

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

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

[c]Logistic regression model estimated with random intercepts to adjust for clustering of patients within PCPs.