Technology-facilitated depression care management among predominantly Latino diabetes patients within a public safety net care system: Comparative effectiveness trial design

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\textbf{ARTICLE INFO}

\textbf{Article history:}
Received 24 July 2013
Revised 29 October 2013
Accepted 1 November 2013
Available online xxxx

\textbf{Keywords:}
Type 2 diabetes
Hispanic/Latino
Depression
Safety net
Health technology applications
Care management model

\textbf{ABSTRACT}

Health disparities in minority populations are well recognized. Hispanics and Latinos constitute the largest ethnic minority group in the United States; a significant proportion receives their care via a safety net. The prevalence of diabetes mellitus and comorbid depression is high among this group, but the uptake of evidence-based collaborative depression care management has been suboptimal. The study design and baseline characteristics of the enrolled sample in the Diabetes–Depression Care-management Adoption Trial (DCAT) establishes a quasi-experimental comparative effectiveness research clinical trial aimed at accelerating the adoption of collaborative depression care in safety net clinics. The study was conducted in collaboration with the Los Angeles County Department of Health Services at eight county-operated clinics. DCAT has enrolled 1406 low-income, predominantly Hispanic/Latino patients with diabetes to test a translational model of depression care management. This three-group study compares usual care with a collaborative care team support model and a technology-facilitated depression care model that provides automated telephonic depression screening and monitoring tailored to patient conditions and preferences. Call results are integrated into a diabetes disease management registry that delivers provider notifications, generates tasks, and issues critical alerts. All subjects receive comprehensive assessments at baseline, 6, 12, and 18 months by independent English–Spanish bilingual interviewers. Study outcomes include depression outcomes, treatment adherence, satisfaction, acceptance of assessment and monitoring technology, social and economic stress reduction, diabetes self-care management, health care utilization, and care management model cost and cost-effectiveness comparisons. DCAT’s goal is to optimize depression screening, treatment, follow-up, outcomes, and cost savings to reduce health disparities.

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http://dx.doi.org/10.1016/j.cct.2013.11.002

Please cite this article as: Wu S, et al. Technology-facilitated depression care management among predominantly Latino diabetes patients within a public safety net care sys..., Contemp Clin Trials (2013), http://dx.doi.org/10.1016/j.cct.2013.11.002
1. Introduction

Depression is a chronic, often life-long illness [1]. Patients with diabetes are at risk for major depression that can amplify morbidity, mortality, and cost [2,3]. The high prevalence of depression with concurrent diabetes may increase patient disability and their need for social support while negatively impacting treatment efficacy, medication adherence, hospitalization risk, self-care management, patient—physician connectedness, and quality of life [4–10]. Concurrent comorbid illness and patient self-rated health can also contribute to depression [11,12]. Complex patients with diabetes are at high risk for clinically significant depression [13], and a bidirectional association between depressive symptoms and diabetes is common [11,14,15].

Low-income, culturally diverse populations with chronic illness have a two-fold higher risk of comorbid depression compared with the general population, with rates of depression among Hispanics/Latinos reaching as high as 33% [16]. Hispanics/Latinos have a higher prevalence of diabetes compared with non-Hispanic whites [17], and those with comorbid depression and diabetes are at a greater risk for functional disability, mortality, and poor health service use. Racially, ethnically, culturally, and economically driven treatment preferences and care-seeking behavior are well documented. Disparities related to receiving a diagnosis, counseling, mental health referrals, antidepressant medication (AM) prescriptions, and depression care follow-up are common [18–28]. Hispanics/Latinos are less likely to be diagnosed or receive depression care, and they experience socio-economic barriers to care; they also have lower use rates of AM, are at a greater risk of discontinuing AM, and frequently prefer psychotherapy to AM use [29].

Increasing evidence has shown that primary care depression treatment is effective among low-income, racial/ethnic minority populations [30–34]. When collaboration between primary care physicians (PCPs) and mental health professionals is supported by systematic feedback to the primary care team and enhanced with nurse or social worker care management [35], the treatment of depression becomes efficacious and cost-effective. However, the complex mix of patient, provider, and health system factors in safety net settings impedes the adoption of evidence-based collaborative depression care and results in persistent disparities in depression outcomes.

Safety net patients encounter self-care management stress because of difficulties in communicating with and communication between multiple medical providers, managing concurrent illnesses, uncoordinated treatment plans, and navigating supportive community resources [36–40]. Concurrently, safety net care providers often find that engaging patients with major depression is challenging, particularly when accompanied by a concurrent chronic illness, because it requires active depression symptom assessment and management over time on top of managing a medical condition such as diabetes. Thus, patients miss out on remission, recovery, relapse, and recurrence follow-up assessments [1].

Safety net primary care providers are responsible for synthesizing health-related information, medication reconciliation, and multi-provider communication inclusive of specialty and emergency department/inpatient providers. Furthermore, they must deal with literacy [26], language, cultural preference, and financial barriers to patient care. Providers, thus, may lack the time and skills required to effectively communicate and interact with diverse patient populations, especially those who need depression management. The Diabetes—Depression Care-management Adoption Trial (DCAT) technology-enhanced care model aims to address several of these barriers.

2. Methods

2.1. Overall design and hypotheses

The DCAT trial aims at comparing approaches to accelerating the adoption of collaborative team depression care. The study is in collaboration with Los Angeles County Department of Health Services (DHS) Ambulatory Care Network (ACN), the second-largest safety net care system in the United States. DCAT is a translational study consistent with current evidence-based clinical recommendations about depression screening and treatment. The U.S. Preventive Services Task Force recommends screening adults for depression if depression care provider support is available, whereas other guidelines encourage providers to apply an adaptive treatment approach designed to ensure patient-specific reductions in depression. DCAT intervention is built on the effective Multifaceted Depression and Diabetes Program (MDDP) randomized clinical trial [30–33] and extensive evidence from the depression collaborative team care model [35,40,41] and is responsive to known barriers to treatment among DHS patients in safety net clinics. The study population consists of low-income, predominantly Hispanic/Latino patients with diabetes who receive primary care within public safety net hospital- or community-based DHS outpatient clinics.

The DCAT clinical trial uses a comparative effectiveness research (CER) design to conduct a quasi-experimental study comparing three delivery models in three groups: usual care (UC), supported care (SC), and technology-facilitated care (TC). Every participant in the study groups is given a set of educational and community resource written materials in Spanish or English. DHS leadership selected eight primary care clinics, based on criteria that reflect geographic and diabetes care model diversity. The UC group includes two community clinics and represents the status quo of clinical practice, where the translation and adoption of depression care evidence is performed by the PCPs and their staff. The SC and TC groups each include two care teams of the DHS diabetes disease management program (DMP). These teams practiced in two community clinics and one hospital-based outpatient clinic; that is, in both SC and TC, one of the two teams practiced in both a community clinic and a hospital outpatient clinic.

The DMP’s practice model uses team staff (i.e., physicians, nurse practitioners, nurses, and social workers) acquainted with guidelines and protocols to support diabetes, congestive heart failure, and asthma care management for high-risk or high-utilization patients. The program includes a home-grown web-based chronic disease registry to support clinical assessment and decisions. SC models are efficacious and can be cost-effective for chronic disease management. However, integrating depression comorbidity care remains a substantial challenge, especially in performing proactive acute treatment follow-up and long-term monitoring and management. The...
reasons are multifactorial and include the intensive labor and time involvement required to engage in collecting, summarizing, and reviewing individual or aggregate patient data to facilitate care. The challenges also are in depression care continuation. The DMP is designed for limited-time care management (typically 6 months); then patients are transferred back to their primary medical providers. Continuous depression symptom assessment, treatment monitoring, and relapse prevention become more challenging in the busy primary care practices.

In testing a new approach for depression care management implementation, DCAT TC provides advanced health technology to facilitate automated depression assessment, support for patient self-management, optimized therapy receipt, and timely treatment follow-up. This intervention aims to apply technology applications to enable care teams to fill gaps in current depression care. The technology applications are designed to facilitate patient engagement and optimal adaptive depression management in primary care, improve health care outcomes at reduced utilization costs, reduce individual patient physical or economic burden, and be responsive to patient care preferences. The care management technology development was in part based on lessons learned from the first DHS test of an automated remote monitoring system developed by DHS for patients with heart failure.

DCAT, therefore, compares study outcomes between the following three groups:

- two non-DMP usual primary care practices,
- two DMP-supported care practices (in which patients meet with nurse diabetes care managers and social workers for 6 months and then return to usual primary care practices), and
- two DMP-supported care practices followed by primary care practices after 6 months plus the technology applications for 12 months.

All subjects received comprehensive assessments at baseline, 6, 12, and 18 months by independent English–Spanish bilingual interviewers. The different care models experienced by the SC and TC group patients provide a natural experiment to study the independent effects of DMP care management, the technology, and the combinations.

The DMP leadership assigned the care teams to the TC and SC groups based on administrative and geographic considerations rather than clinical or team-related criteria. Each study patient is in the study group located where he or she sought care during recruitment.

The primary DCAT hypotheses are as follows: (1) the care management technology implementation will ensure high-fidelity delivery of recommended depression care screening and monitoring over time; (2) depression symptom reduction, better functional status, quality of life, and patient satisfaction with care between the TC and the SC will not be statistically significantly different, but both will be greater than the UC group at 6- and 12-month assessments; (3) difference in the diabetes care process and outcomes between TC and SC will not be statistically significant, but both will be greater than the UC group at 6- and 12-month assessments; (4) less healthcare utilization will occur in TC at 6- and 12-month assessments, where the greatest level of technology is applied; and (5) of the three groups, the TC group will be the most cost-effective approach for accelerating adoption of depression screening, monitoring, and adaptive treatment. Secondary research questions will address the following: (a) medical provider satisfaction with the technology used in the TC group; (b) patient satisfaction with and acceptance of TC automated calls; (c) factors identified by medical providers and clinic administrators related to satisfaction, barriers, and sustaining the intervention post-trial; (d) patients’ reported satisfaction, facilitating factors, and barriers to receipt and acceptance of technology-facilitated depression care; and (e) the relative importance of the care management team and the care management technology.

2.2. Care management technology

A key DCAT care delivery innovation is a novel automated telephonic assessment (ATA) call system linked with the DMP’s disease management registry (DMR) for patient assessment and to facilitate timely proactive follow-up by the patient’s DMP care providers (Fig. 1). Depression assessment may seem an unlikely candidate for automation because of the highly sensitive and personal nature of the symptoms. However, protocols for screening and monitoring depression do not require professional training; and since depression diagnostics are limited to symptoms, they are easily adaptable to communication-based technology without requiring supplemental technology or devices. The Indiana Cancer Pain and Depression (INCPAD) Trial tested the first automated (by telephone or Internet) depression symptom monitoring system; INCPAD found the system to be acceptable to cancer patients and to result in improved depression outcomes when coupled with centralized telephone-based care management [42,43]. DCAT is the first trial to design and evaluate an ATA system for diabetes patients’ depression symptom assessment and treatment monitoring that serves the safety net population, includes both English and Spanish languages, and is intended to be implemented in real-world primary care settings.

We selected telephone as the communication platform because phones are the most accessible technology among the low-income population. The ATA uses “Amy,” the persona of the automated call system who speaks a natural voice, rather than a system-generated text-to-speech robotic voice, to administer the assessment questions. Patients can select their choice of language (English or Spanish) for the calls from Amy. The DCAT ATA has built in both automated speech recognition (ASR) and interactive voice response (IVR) technologies that allow call respondents to either speak their responses to Amy’s questions or punch numbers on a keypad. ASR has the advantage of eliminating number-punching errors, which are a concern for diabetes patients with sensing or vision problems. DCAT ATA uses the Patient Health Questionnaire 9 items (PHQ-9) for depression screening and symptom monitoring because it provides both a dichotomous diagnosis of probable major depression and a continuous severity score. Patients are identified as having clinically significant depression if they have a PHQ-9 score of ≥10. A PHQ-9 score of ≥10 has been found to have 77–80% sensitivity and 92–94% specificity for a diagnosis of major depressive disorder (MDD) based on structured psychiatric interviews [44–46]. Patients assessed as not depressed at baseline are screened quarterly, whereas
patients assessed as depressed at baseline – either by symptoms, diagnosis, or antidepressant treatment – are monitored monthly. The frequency of monitoring was based on the recommendations of the co-author clinicians (Guterman, Gross-Schulman, and Katon), who considered clinical quality, patient safety, and practice feasibility. Outbound automated calls are scheduled based on a dynamic protocol of type of call (screening or monitoring), calendar dates, clinical events, call history, and patient preferences (such as call time), using data and the DCAT algorithms in the DMR. Patients can opt for password-protected access to enhance privacy and can use the system to reschedule the call or request human follow-up.

The screening call collects information in four categories: (1) depressive symptoms (PHQ-2 and PHQ-9, as appropriate), (2) pain, (3) self-management activities, including regular physical and fun activities, and (4) patient request to be contacted by his or her provider. The monitoring call for depressed patients includes all of the above, as well as questions about AM adherence, side effects, and problem-solving skills for those patients who receive psychotherapy treatment. If a patient expresses an inclination toward self-harm or suicide (PHQ-9 item 9 response in more than half the days to nearly every day, i.e., a threshold 2 or more), the call system will automatically initiate contact with an emergency response physician to help the patient. If there is no response within 15 min, the call system initiates contact with the next physician on the emergency response team. This process repeats up to the fifth physician to ensure that the patient is attended to.

The ATA-collected data are assessed, and results are electronically integrated into the DMR for clinician viewing. Specific issues identified from the data will trigger insertion of a new provider task in the registry, including tasks to address patient callback requests, depressive symptoms, and AM issues. Further design details of the enhanced DMR and the ATA system performance are described elsewhere [47].

2.3. Eligibility

Patients were eligible for the study if they were 18 years old or older, had been diagnosed with type 2 diabetes, had a working phone number, spoke English or Spanish, and could read and understand the consent form. Patients with baseline possible suicidal ideation (PHQ-9, item 9 response in more than half the days to nearly every day, i.e., a threshold 2 or more), cognitive impairment (Short Portable Mental Status Questionnaire scores of <5) [48], alcohol abuse (two or more CAGE items from the quantity-frequency index, and questions about the patient’s perception of substance use) [49], or recent lithium/antipsychotic medication use were ineligible for the trial. Patients were not required to have depression to be eligible for the study because DCAT is addressing the elevated risk for depression among patients with diabetes by testing a care approach that incorporates depression screening, symptom monitoring, and treatment follow-up for diabetes patients.

2.4. Subject recruitment

Institutional review board approval was obtained from the University of Southern California, Olive View UCLA Medical Center, and the Los Angeles Biomedical Research Institute Human Subjects Review Boards. The enrollment period was from April 2011 to May 2012 in the eight study clinics. Patients with type 2 diabetes were identified from database and clinic records for recruitment. Patients provided verbal consent for study eligibility screening to bilingual research assistant study recruiters. Of the 1704 patients screened, 1066 (63%) were...
women and 638 (37%) were men. Men had a significantly lower enrollment rate (83% vs. 88%; p = 0.003), which was often associated with poor alcohol use scores (5% for men vs. 1% for women). Twelve patients did not sign the HIPAA agreement, and 57 patients were excluded from baseline completion. A total of 1,406 diabetes patients (83% of patients screened) provided written informed consent and completed a structured baseline interview that included both PHQ-9 and Hopkins Symptom Checklist (SCL)-20 depression symptom assessments (See CONSORT Fig. 2): 484 patients were in the UC group, 480 patients in the SC group, and 442 patients in the TC group. Patient and family depression educational materials (including a comic book fotonovela [50]) designed specifically for patients and family members with low health literacy were provided to all study patients in Spanish or English by bilingual study recruiters. The study clinic physicians were notified of the baseline depression screening results for those patients whose PHQ-9 score were 10 or higher, or who showed suicidal ideation (item 9 of PHQ-9 scored greater than 1).

Participants received no monetary incentive for the study enrollment and baseline assessment. However, they receive a $10 gift card for each follow-up assessment they complete. The study clinics participated in the study pro bono.

2.5. Data collection protocol

The ATA call system keeps a record of each call attempt and result, the captured assessment data, tasks triggered in DMR, and task completion status. Emergency response providers log the ATA alert-triggered patient suicidal or self-harm risk assessments.

Patient assessment is scheduled at baseline, 6-, 12-, and 18-months follow-up. Each interview takes approximately 45 min. Three English–Spanish bilingual study recruiters administered the baseline assessment with study patients in the recruitment clinics. Three independent English–Spanish bilingual interviewers administered the follow-up assessment by telephone. Measured variables are described below. The variables are measured at each wave of data collection unless otherwise indicated.

2.5.1. Primary outcome measures

Several measures are used to assess the ATA fidelity in delivery of recommended depression care screening and monitoring over time. These include the ATA call reach rate and completion rate, data capture rate and error rate, validity of PHQ assessment, patient safety assurance, and provider tasks generation and completion.

Regarding patient outcomes, depressive symptomatology is measured using the PHQ-9 and the SCL-20 depression scale, consisting of the 20 depression items from the SCL-90 [51]. Two standard questions from the structured clinical interview for Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV were used to assess dysthymia [52]. The Sheehan Disability Scale was used to rate functional impairment on a 10-point Likert scale [53]. Health-related quality of life was assessed using the Medical Outcomes Study Short-Form Health Survey (MOS SF-12) [54] and the Physical and Mental Component summaries (PCS and MCS) norm-based scores standardized to the general U.S. population with a mean of 50 (SD = 10). Chronic pain was defined as pain present most of the time for 6 months or longer during the past year. The SF-12 also includes...
one measure of pain impact that asks respondents to rate the level of pain interference with normal work on a scale of 5 (1 = none and 5 = extremely). The Brief Symptom Inventory (BSI) assessed anxiety [55]. Patient satisfaction with diabetes care and emotional care are assessed on a 5-point Likert scale from very dissatisfied to very satisfied.

Also included in the assessment are the summary of Diabetes Self-Care Activities Questionnaire to assess self-reported adherence [56], the Whitty 9-item questionnaire to assess diabetes symptoms [57], and the brief two-item Diabetes Distress Scale to screen for distress [58]. Moreover, we assessed self-reported weight and height (from which we calculated the body mass index [BMI]), diabetes treatment and complications, comorbid medical illness, employment, and socioeconomic stress (work, unemployment, financial problems, marital/family conflict, legal and care-giving problems, and community violence concerns). Social demographics (age, sex, marital status, racial/ethnic group, birthplace, time living in the United States, language, and education) were assessed at baseline.

From electronic medical records, DCAT obtained medical history and utilization data from 6 months pre-trial to the end of the trial. These data include hospitalization, clinic and emergency department visits, pharmacy pick-up, and International Statistical Classification of Diseases and Related Health Problems (ICD)-9 codes for diagnostic diseases, as well as the lab results of glycated hemoglobin (A1C), micro-albumin, and a lipid panel during the same period of time.

At each scheduled assessment, patients are also asked to respond to questions about their previous outpatient (medical and mental health), inpatient, and emergency room service utilization, including use outside of the United States. Questions also address travel time to clinic, length of time for average visit, and time off work due to outpatient visits. Patients are asked to have all their medication bottles available during the assessment so they can read the prescription to the interviewer; that information enables us to convert pill, dosage, and number of pills to a price.

DCAT obtains administrative cost data as follows: The Chronic Disease Score (CDS), a standardized measure of chronic medical illness [59], will be computed for each patient using clinic pharmacy records to measure chronic medical comorbidity based on prescription drug use [60]. If patients use other pharmacies, the self-report medications will be used as well. Service utilization and health care costs are determined using data from DHS outpatient and pharmacy billing records, electronic emergency room and hospitalization billing cost, and mental health care use data from medical records.

2.5.2. Secondary outcome measures

At each follow-up interview, TC patients are asked to rate their overall satisfaction with the ATA calls and their level of acceptance of using technology for depression assessment and monitoring during follow-up interviews. The project assistant keeps a log of the calls she makes to patients to assist the study team in understanding reasons for incomplete or missing calls.

2Provider perceptions of satisfaction with and sustainability of the studied care approaches and technology applications will be assessed post-trial via a semi-structured interview with the four DMP practice teams and the two primary care practices. In addition, a supplemental survey questionnaire will be used; it includes the perceived self-efficacy in diagnosing and treating depression, intention to change care of depressed patients, patient and financial barriers \( (\alpha \text{ coefficients } 0.74–0.86) \) [61], a measure of satisfaction with the studied care approaches, and an assessment of organizational barriers to care as well as helpful strategies to address these barriers.

2.6. Study intervention

Before study implementation, DCAT offered online depression management training in both antidepressant treatment (W. Katon) and problem-solving therapy (PST), an evidenced-based treatment for depression [62] that was chosen as the clinical counseling method based on patient preference and satisfaction in our previous MDDP trial [30,31] (A. Nezu). Training was open to all study clinics relevant staff. Thirty-eight clinicians viewed three webinars that were made available through online streaming or via a CD; the webinars covered depression treatment guidance and an introduction of the depression collaborative care model. Twenty-eight physicians, nurse practitioners, nurse care managers, social workers, and other clinical staff participated in the PST workshop. In addition, S. Wu and K. Ell met via telephone or in clinics with nurse managers and social workers to address questions about the training focus and to discuss staff concerns.

Patients in the UC group received traditional clinic depression and diabetes care. SC DMP clinics provided structured diabetes care management assisted by a nurse practitioner, a registered nurse, plus a clinic social worker to assist patients with mental health problems. Patients in the TC group were provided DMP care plus the aforementioned health technology applications, i.e., the ATA depression screening or monitoring calls that were integrated into the DCAT-enhanced DMR to notify providers. In addition, patients received automated telephonic appointment reminders for their DMP in-person visits.

The ATA depression screening and monitoring calls were scheduled monthly for patients meeting major depression criteria at baseline and every 3 months for patients not meeting major depression criteria at baseline. The DCAT project assistant contacted any patient who did not complete the scheduled assessment in order to complete the PHQ-9 measures. Patients could also request to be switched from the ATA to human calls, which were made by the project assistant. The TC providers received the assessment data in the DMR. If the assessment found PHQ-9 score greater than 8 or patients having AM issues (such as no medication, poor adherence, or side effects), the DMR would generate tasks to prompt the patient’s designated care managers or social worker to follow up with the patient. DMR also generates a task when a patient requests to be contacted. Suicidal or self-harm alerts were also implemented; initially in the study, three psychiatrists were on call by the ATA, with one more physician as the back-up. Eventually, co-author Guterman also assumed the responsibility and is the fifth physician in the emergency response team.

DMP depression care is based on the Depression Care Protocol (DCP; Fig. 3), which ACN Research and Innovation (R&I) developed during the study for use in the SC and TC intervention groups. These materials were readily accessible to the care team. Weeks 1–8 of the DCP include (a) first-line
treatment with AM prescribed according to the protocol by the treating physician or nurse practitioner or (b) referral to the DMP social worker for six to eight PST sessions for patients refusing medication. During Weeks 9–12, the care manager refers patients with a partial response (reduction in PHQ-9 scores) or nonresponse back to the treating physician or nurse practitioner for consideration of AM drug or dosage adjustment and the addition of PST. Patients with a full response (PHQ-9 score less than 8) receive monthly treatment maintenance and relapse-prevention behavioral activation. All patients in the SC and TC groups receive support from a nurse care manager by telephone or in the clinic; in the TC group, patients also receive the ongoing follow-up ATA calls in English or Spanish. Consistent with the DCP, patients with persistent PHQ-9 scores of 10 or higher are offered additional PST booster sessions, augmentation with low-dose trazodone, an AM that also help treat anxiety and insomnia, or referrals to specialty mental health care.

2.7. Sample size and data analysis plans

2.7.1. Sample size estimates

The target sample size was based on power analysis for two primary outcomes, reduction of prevalence of major

Fig. 3. Depression treatment protocol.
depression (PHQ-9 score ≥ 10) and depression remission (PHQ-9 score reduction ≥ 50% and less than 8 for patients with MDD at baseline). Power analyses were conducted using nQuery [63] to estimate effect sizes of the treatment with pre- and post-intervention comparisons and with longitudinal statistical approaches for repeated measures comparing the trend depression related outcomes in the DCAT study. The calculations assumed α of 0.05 and power of 0.80. With the assumptions that attrition rates will be less than 20% for patients at each 6-month follow-up assessment up to 18 months for pre- and post-intervention comparisons, a sample size of 51 depressed patients in each study group allows the study to detect a small effect size of less than 0.01 [64]. Given 25% to 30% of depression prevalence among diabetes patients from our previous MDDP trial and a 25% cushion for baseline characteristics differences due to

<table>
<thead>
<tr>
<th>Antidepressant Medications Available on DHS Formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class-SSRI</strong></td>
</tr>
<tr>
<td>Sertraline [ZOLOFT]†</td>
</tr>
<tr>
<td>Starting/Titration Dose (mg)</td>
</tr>
<tr>
<td>25 Daily</td>
</tr>
<tr>
<td>Target Dose (mg)</td>
</tr>
<tr>
<td>100-200 Daily</td>
</tr>
<tr>
<td>Key Info</td>
</tr>
<tr>
<td>Take with food</td>
</tr>
<tr>
<td>Side Effects</td>
</tr>
<tr>
<td>Common: Initial activation/agitation (if anxious start with paroxetine [PAXIL]) Sexual side effects: decreased libido, anorgasmia, delayed ejaculation GI distress: nausea, vomiting, diarrhea Dizziness, tremors Drug-drug interactions (such as serotonin syndrome seen with tramadol [ULTRAM]) Sedation (have patient take ZH0) Frequent: Headache, insomnia (have patient take QAM)</td>
</tr>
<tr>
<td><strong>Class-SNRI</strong></td>
</tr>
<tr>
<td>Venlafaxine XR® [EFFEXOR XR]†</td>
</tr>
<tr>
<td>37.5 Daily</td>
</tr>
<tr>
<td>Follow BF; purely SSRI at less than 150 daily; discontinuation syndrome if stopped abruptly; if switching to Effexor XR, start taper of first antidepressant medication; can be used as first line agent for patients with diabetic neuropathy</td>
</tr>
<tr>
<td><strong>Class - Bupropion</strong></td>
</tr>
<tr>
<td>Bupropion SR [WELBUTRIN SR]</td>
</tr>
<tr>
<td>100 Daily x 4 days, then BID</td>
</tr>
<tr>
<td>100-200 Daily</td>
</tr>
<tr>
<td><strong>Class - Tetracyclines</strong></td>
</tr>
<tr>
<td>Mirtazapine [REMERON / SOLU-TAB]</td>
</tr>
<tr>
<td>15 Nightly</td>
</tr>
<tr>
<td>Sedation at doses below 45 mg; no sexual side effects; helpful for anxiety (but no specific indication)</td>
</tr>
<tr>
<td><strong>Augmentation Medications Available on DHS Formulary</strong></td>
</tr>
<tr>
<td><strong>Augmentation and Other Strategies</strong></td>
</tr>
<tr>
<td>Add augmentation medication to current regimen. For insomnia, trazodone [DESYREL] is preferred (25 mg Nightly start/titration dose; 50 mg target dose). For antidepressant medication non-adherence, review side effects and consider referral to CSW for de-stigmatization of depression and use of antidepressant medication.</td>
</tr>
<tr>
<td><strong>Problem Solving Therapy (PST)</strong></td>
</tr>
<tr>
<td>CSW to provide focused education about PST; conduct initial PST (up to 4 sessions), then assess. If needed, may provide up to an additional 4 sessions (8 total sessions maximum).</td>
</tr>
</tbody>
</table>

Sections of this protocol were adapted from IMPACT (Improving Mood—Promoting Access to Collaborative Treatment).

Fig. 3 (continued).
quasi-experimental trial design, DCAT requires a sample size of approximately 500 type 2 diabetes patients in each study group.

2.7.2. Technology analysis
To address the fidelity and effects of the TC technology implementation, the study team will use descriptive and statistical analyses to examine several measures, including feasibility of ATA assessment response, reliability of data capturing, validity of assessment accuracy, and safety of alerting suicidal ideations. We will also analyze changes in patient satisfaction with the ATA over time (using data from the patient interview), the reasons for not responding to the ATA calls (using data from the project assistant log), and patient risk level of suicidal ideations (using data from the provider completed assessment form).

2.7.3. Outcome analysis plan
Prior to statistical analyses, the data properties will be carefully inspected through descriptive statistics, and any unusual features that may be influential will be systematically identified for all the variables. All analyses will be carried out according to the intention-to-treat rule consistent with standard practice in most clinical trials. To examine the baseline differences, the study team will also perform preliminary analyses to compare across three treatment conditions on descriptive and clinical characteristics at baseline. When the study team identifies variables that differentiate treatment groups, it will be necessary to include the variables as covariates in the analytical models or to use statistical adjustment models such as the propensity score method [65,66] to remove effects of potential confounding. It will also be statistically useful to include covariates that explain outcome variance and do not differentiate between groups, since such variables increase statistical power.

We will perform separate univariate and repeated measures analyses at each assessment to carefully examine relationships within the cross-sectional data. We will then conduct repeated measures analyses of profiles across time. Comparison of group means on continuous scales will be done using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test). The CER study design, performed at each major assessment point, will be a 3 (study groups) × 2 (care practices) factorial analysis of covariates. Longitudinal (repeated measures) analyses of continuous scales will be done using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test). The CER study design, performed at each major assessment point, will be a 3 (study groups) × 2 (care practices) factorial analysis of covariates. Longitudinal (repeated measures) analyses of continuous scales will be done using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test). The CER study design, performed at each major assessment point, will be a 3 (study groups) × 2 (care practices) factorial analysis of covariates. Longitudinal (repeated measures) analyses of continuous scales will be done using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test). The CER study design, performed at each major assessment point, will be a 3 (study groups) × 2 (care practices) factorial analysis of covariates. Longitudinal (repeated measures) analyses of continuous scales will be done using the family of statistical techniques based on the generalized linear model (e.g., ANOVA/ANCOVA, regression analysis, t-test).

2.7.4. Cost-effectiveness analysis
In moving to CER-based assessment of medical interventions, cost-effectiveness evaluations become increasingly relevant [67]. We will examine the net effect of the intervention on health care costs, including patient time costs. Costs to health care services and pharmaceuticals will be valued using average prices for allowed claims paid by Medicare. Patient time will be valued at the average wage for workers matched for ethnicity, gender, age, and educational level from the Current Population Survey. We will use alternative measures of effectiveness, not quality-adjusted life years due to small sample, in conducting our economic evaluation of the intervention. We will assess patients' employment status at each follow-up interview, to assess the effects of the intervention on this important outcome. We will use patient survey data regarding depression symptoms to calculate “depression-free days” during the study period, and gauge the cost per depression-free day. However, this measure may not be likely to fully capture all the effects of the intervention on patients' health, particularly given our focus on diabetes. For this reason, and for broader conceptual reasons, we will also combine several of the patient-reported scales into a measure of health-related quality of life (HRQOL) using structural equations models with unobservable HRQOL as a latent variable in a Multiple-Indicators Multiple Causes framework [68]. In this approach, all structural measures of patient health status including functional status and quality of life measures will be used as health status indicators, while patient clinical environmental, and background characteristics will serve as causal factors in explaining health status changes. We will compute confidence intervals for the cost-effectiveness ratios using bootstrapping and develop Cost Effectiveness Acceptance Curves [69]. As an alternative, we will also examine the net health benefit approach suggested by Stinnett and Mullahy [70].

2.7.5. Qualitative data analysis
A trained, bilingual transcriber will transcribe qualitative provider interviews after all identifiers have been removed. The study team will analyze interview transcripts using a methodology of “Coding Consensus, Co-occurrence, and Comparison” [71] (which is rooted in grounded theory) and assisted by a web-based qualitative analysis software. Disagreements in assignment or description of codes will be resolved through discussion between investigators and enhanced definition of codes. The final list of codes, constructed through consensus, will consist of a numbered list of themes, issues, accounts of behaviors, and opinions that relate to socio-cultural, organizational, and system characteristics that influence service delivery to clients. Through the process of coding interview transcripts and comparing assigned categories with each other, the different categories will be further condensed into broad themes using a format that places technology and adoption of depression evidence within the framework of the clinic's organizational and systems characteristics.

2.8. Study limitations
A possible limitation of this study is that the trial is conducted across eight DHS clinics, which may vary with respect to provider training participation, patient access, provider care modeling, and clinic neighborhood community. A second potential limitation is the focus on a predominantly Hispanic population. A third limitation is the observational study nature of the quasi-experimental trial design that may be biased by unequal patient covariates between study groups.
3. Results

Study participants are predominantly Hispanic/Latino (89%), married (55%), female (63%), and foreign born (87%) (Table 1). Most of the patients are from Mexico (840; 60%), El Salvador (172; 12%), and Guatemala (104; 7%); have been in the United States for 10 years or longer (94% of immigrants)’speak Spanish as their preferred language (83%); did not complete high school (70%); and are an average age of 53 years (SD = 9). Age at onset of diabetes ranged from 11 to 76 years (mode = 40, M = 43, SD = 10). At baseline, 50% of participants were on insulin, and 70% of patients self-reported having ≥1 diabetes complications. Nearly 60% reported a BMI ≥ 30 kg/m², and 77% self-reported ≥1 comorbid medical conditions. Study participants reported significant financial stress at baseline: two-thirds were unemployed, nearly all (92%) had no money left over at the end of the month, and 70% had difficulty paying bills.

At 6 months before the trial, 165 (12%) study participants were listed in the DHS registry with the standard ICD-9 code MDD = 311, with 90 (55%) of these patients having purchased AM at a study clinic pharmacy. In contrast, at study baseline assessment, more than 28% of the 1406 study patients had a PHQ-9 score equal to 10 or more, and 112 (8%) had PHQ-9 scores of 8 or 9. For these patients, pharmacy pick-up records identified that 77 (19%) baseline depressed patients and 79 (8%) baseline nondepressed patients had AM dispensed at 6 months pre-baseline. At the baseline interview, 84 (21%) of the depressed and 45 (4%) of the nondepressed patients reported taking AM. More than 90% of the study patients had at minimum one A1C lab test done during the 6 months before baseline (lipid panel test, 81%; micro-albumin test, 60%). However, only 14% had met the A1C goal of less than 7%, and 70% of patients had poorly controlled diabetes with A1C ≥ 8% (A1C average for the study participants is 9.25%).

Table 2 presents baseline data among the three study groups. There were no significant differences in PHQ-9 depression or BSI anxiety symptoms, self-rated health, or Sheehan Disability Scale ratings across the three study groups. Other demographic and diabetes variables varied significantly across study groups. This was anticipated given that in the quasi-experimental DCAT design, pre-treatment differences are more common than those expected from randomized experimental design. To control for pre-treatment differences in study outcome analyses, the study team will use propensity scores to evaluate post-treatment outcomes. Propensity score is the conditional probability for a participant to be in a specific treatment condition given pre-treatment characteristics. Propensity scoring has been frequently applied in observational studies to adjust for bias on pre-treatment variables [65,66].

4. Discussion

DCAT has successfully recruited over 1400 patients with diabetes who have high rates of poorly controlled diabetes, clinically significant depression, or both. The study has also engaged eight DHS clinics, provided online depression care management training for study physicians, nurses, and social workers, facilitated the development of a depression care protocol, and developed ATA patient monitoring telephone calls (in Spanish and English) and patient–provider/provider communication technology applications. In addition, DCAT facilitates – via an automated call every 3 months to TC group patients who were not depressed at baseline – routine depression symptom identification and care activation (when indicated) for multiple provider teams. The automated system simplifies depression screening by activating provider treatment when indicated and enhancing understanding of depression onset-related factors over time. Cost analyses will be conducted at completion of the study.

The importance of the DCAT study is two-fold: it focuses on an underserved population in the second largest U.S. safety net health system, and it aims to reduce disparities in depression care. DHS serves more than 800,000 low-income, predominately Hispanic/Latino patients. DHS has begun implementing a provider-empaneled Patient-Centered Medical Home (PCMH) model [72] in which each patient has a designated primary care team composed of physician or nurse practitioner, nurses, medical assistant, and, in some clinics, social workers. Movement toward the PCMH model is consistent with a recently released Institute of Medicine [73] report that underscores the need for a PCMH path toward health equity by providing care that does not vary in quality based on patient sex, race/ethnicity, socioeconomic status, or geographic location.

The DCAT study design is consistent with the need to increase collaborative academic and community-stakeholder care system research teams to improve safety net care primary care, reduce disparities and barriers to patient engagement, and address cost concerns. DCAT simultaneously aims to address patient self-management need, health literacy limitations, care preferences, and uptake, while simultaneously improving patient–provider care management relationships
and communication. For example, the automated calls invite patients to request a provider call back, and the system informs the requested provider of the patient request. DCAT also manages outcome data collected electronically from the calls and provided via the shared multi-provider registry, particularly with respect to patient-expressed self-harm.

DCAT is consistent with the Chronic Care Model [74] in which patient-centered need, health care provider delivery, and patient outcomes are a product of patient–provider interaction and six health care process components (delivery system design, patient self-management support, community resource linkages, provider team and decision support, shared clinical information system, and health system organization). DCAT facilitates collaborative, equitable involvement of its partners in all study phases: DHS ACN R&I and academic team members meet regularly with clinic care team staff to focus on the decision-making process at each stage of the study, including problem definition and issue selection, research design, study implementation, results interpretation, and determining how the results should be used for action. Members of the research team also interact with clinic medical directors, nurses, and social workers to address provider concerns and questions. In light of high patient loads and increasing time constraints, this interaction has led to increased provider interest in and support of the DCAT study aims. The collaborative team designed, implemented, and provided ongoing follow-up during the course of the study and has begun conducting provider studies.

The DCAT study strives to ensure that its processes are both scalable and sustainable. During the course of the study, lessons have been learned from ongoing solicited feedback from stakeholder patients and providers. These lessons are reflected in updates to and changes in both the intervention and the technology to maximize potential uptake in Los Angeles County’s large safety net care system. The study also uses a cyclical and iterative process. An example is the development of the cascade of alerts to providers who are responsible for responding to patient self-harm or suicidal ideation warnings. The suicide alert function and designated emergency response team were developed in response to primary care providers’ requests because of their concerns of patient safety and their own capacity to respond to the alerts. Moreover, this technology is responsive to tenets of the patient-centric care model and is adaptable in that patients can specify convenient times to receive the automated calls and reschedule the calls if they arrive at inconvenient times. DCAT contributes important insights about patient-centered technology-assisted approaches to improve patient–provider and cross-provider care management.

In conclusion, the DCAT automated care management technology addresses major barriers to adoption of evidence-based depression care with low-income minority patients in safety net primary care settings. The system is designed to use automated, periodic telephonic assessments and behavioral prompting to incorporate depression management into the care of patients with diabetes. The technology is customizable and flexible in its configuration to meet individual patient needs, preferences, and treatment history. The patient assessment system is fully integrated with the DHS DMR to facilitate team-care workflow. The technology-facilitated depression care management approach has the potential to be a cost-effective alternative to meet the needs of underserved populations. Using a CER design, DCAT will shed light on the acceptance and effectiveness of using automated care

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Table 2
Baseline data comparisons between study groups.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>UC</th>
<th>SC</th>
<th>TC</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N*</td>
<td>Statistics</td>
<td>N*</td>
<td>Statistics</td>
</tr>
<tr>
<td>Female</td>
<td>484</td>
<td>334 (69%)</td>
<td>480</td>
<td>285 (59%)</td>
</tr>
<tr>
<td>Age</td>
<td>484</td>
<td>55.05 (9.27)</td>
<td>480</td>
<td>52.09 (9.25)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>482</td>
<td>454 (94%)</td>
<td>480</td>
<td>400 (83%)</td>
</tr>
<tr>
<td>Diabetes characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1C value</td>
<td>383</td>
<td>8.37 (1.91)</td>
<td>473</td>
<td>9.59 (2.21)</td>
</tr>
<tr>
<td>On insulin treatment</td>
<td>484</td>
<td>132 (27%)</td>
<td>480</td>
<td>322 (67%)</td>
</tr>
<tr>
<td>BMI (body mass index)</td>
<td>476</td>
<td>32.40 (7.00)</td>
<td>470</td>
<td>32.66 (7.63)</td>
</tr>
<tr>
<td>Whitty-9 diabetes symptoms (range 1–5; 1 = none, 5 = every day)</td>
<td>484</td>
<td>1.67 (0.62)</td>
<td>480</td>
<td>1.72 (0.65)</td>
</tr>
<tr>
<td>Toolberg diabetes self-care in the past 7 days (range 0–7)</td>
<td>484</td>
<td>4.00 (1.34)</td>
<td>480</td>
<td>4.75 (1.24)</td>
</tr>
<tr>
<td>Depression and anxiety</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9 score 10 or greater</td>
<td>484</td>
<td>137 (28%)</td>
<td>480</td>
<td>146 (30%)</td>
</tr>
<tr>
<td>PHQ-9 total score (possible range 0–27)</td>
<td>484</td>
<td>6.67 (5.50)</td>
<td>480</td>
<td>6.93 (6.49)</td>
</tr>
<tr>
<td>SCL-20 mean score (possible range 0–4)</td>
<td>484</td>
<td>0.56 (0.56)</td>
<td>480</td>
<td>0.64 (0.75)</td>
</tr>
<tr>
<td>BSI anxiety score (possible score 0–24)</td>
<td>484</td>
<td>1.35 (2.97)</td>
<td>480</td>
<td>1.30 (3.25)</td>
</tr>
<tr>
<td>SF-12 emotional (general population = 50, higher = better health)</td>
<td>484</td>
<td>50.05 (12.17)</td>
<td>479</td>
<td>49.03 (14.39)</td>
</tr>
<tr>
<td>Physical conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-rated health (range 1–5; 1 = poor, 5 = excellent)</td>
<td>484</td>
<td>2.30 (0.81)</td>
<td>480</td>
<td>2.33 (0.85)</td>
</tr>
<tr>
<td>Sheehan disability scale (range 0–10; 0 = none, 10 = extremely)</td>
<td>483</td>
<td>2.24 (2.83)</td>
<td>480</td>
<td>2.13 (3.02)</td>
</tr>
</tbody>
</table>

Abbreviation: UC = usual care, SC = supported care; TC = technology-facilitated care; PHQ-9 = Patient Health Questionnaire-9; SCL-20 = 20-item Symptom Checklist; BSI = Brief Symptom Inventory; SF-12 = Short-Form Health Survey.

* Number of respondents.

b Values are numbers (percentages) for categorical variables; mean (SD) for continuous variables.

c Chi-square test for categorical variables; ANOVA F-test for continuous variables.
management technology as a vehicle to facilitating collaborative depression care and improving outcomes for safety net patients.

Disclosure

Only one author, Jeffrey Guterman, reports a proprietary or commercial interest in the automated telephonic assessment system discussed in this article.

Acknowledgments

The study is supported by a grant from the Assistant Secretary of Planning and Evaluation of the U.S. Department of Health and Human Services to Dr. Shinyi Wu (grant number 1R18AE000054-01). Trial Registration: NCT01781013, clinical trials.gov/ct/gui. We acknowledge the LAC-DHS clinics, providers, and patients who participated in the DCAT study. We also acknowledge the research team and the technology team for their contribution to the study.

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