Contemporary Clinical Trials 37 (2014) 342–354

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

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

Shinyi Wu [a,h,*], Kathleen Ell [b], Sandra G. Gross-Schulman [c], Laura Myerchin Sklaroff [c], Wayne J. Katon [d], Art M. Nezu [e], Pey-Jiuan Lee [b], Irene Vidyanti [a], Chih-Ping Chou [f], Jeffrey J. Guterman [c,g]

[a] Daniel J. Epstein Department of Industrial and Systems Engineering, University of Southern California, United States
[b] School of Social Work, University of Southern California, United States
[c] Los Angeles County Department of Health Services, United States
[d] Department of Psychiatry and Behavioral Sciences, University of Washington, United States
[e] Drexel University College of Arts and Sciences, United States
[f] Keck School of Medicine, Department of Preventive Medicine, University of Southern California, United States
[g] David Geffen School of Medicine at UCLA, United States
[h] RAND Corporation, United States

ARTICLE INFO

Article history:
Received 24 July 2013
Revised 29 October 2013
Accepted 1 November 2013
Available online 8 November 2013

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

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.

* Corresponding author at: Daniel J. Epstein Department of Industrial and Systems Engineering, University of Southern California, Los Angeles, CA 90089-0411, United States. Tel.: +1 213 740 5073.

E-mail addresses: shinyiwu@usc.edu (S. Wu), ell@usc.edu (K. Ell), sschulman@dhs.lacounty.gov (S.G. Gross-Schulman), lsklaroff@dhs.lacounty.gov (L.M. Sklaroff), wkaton@u.washington.edu (W.J. Katon), Arthur.M.Nezu@drexel.edu (A.M. Nezu), peylee@usc.edu (P.-J. Lee), irenevidyanti@gmail.com (I. Vidyanti), cchou@usc.edu (C.-P. Chou), jguterman@dhs.lacounty.gov (J.J. Guterman).

1551-7144/$ – see front matter © 2013 Elsevier Inc. All rights reserved.
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