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Study protocol: The Technology-Enhanced Coaching (TEC) program to improve diabetes outcomes – A randomized controlled trial

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ABSTRACT

Background: Racial and ethnic minority adults with diabetes living in under-resourced communities face multiple barriers to sustaining self-management behaviors necessary to improve diabetes outcomes. Peer support and decision support tools each have been associated with improved diabetes outcomes.
Methods: 290 primarily African American adults with poor glycemic control were recruited from the Detroit Veteran's Administration Hospital and randomized to Technology-Enhanced Coaching (TEC) or Peer Coaching alone. Participants in both arms were assigned a peer coach trained in autonomy-supportive approaches. Coaches are diabetes patients with prior poor glycemic control who now have good control. Participants met face-to-face initially with their coach to review diabetes education materials and develop an action plan. Educational materials in the TEC arm are delivered via a web-based, educational tool tailored with each participant's personalized health data (iDecide). Over six months, coaches call their assigned participants once a week to provide support for weekly action steps. Data are also collected on an Observational Control group with no contact with study staff. Changes in A1c, blood pressure, other patient-centered outcomes and mediators and moderators of intervention effects will be assessed.
Results: 290 participants were enrolled.
Discussion: Tailored e-Health tools with educational content may enhance the effectiveness of peer coaching programs to better prepare patients to set self-management goals, identify action plans, and discuss treatment options with their health care providers. The study will provide insights for scalable self-management support programs for diabetes and chronic illnesses that require high levels of sustained patient self-management.
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1. Introduction

Like in many other US health systems, in spite of improvements from Veteran's Administration (VA) health care quality initiatives, from 15 to 30% of VA diabetes patients still have A1c's of 9.0% or greater [1]. Providers face barriers to initiating and intensifying medication regimens, and many patients face barriers to effective diabetes self-management. These barriers include lack of sufficient understanding of diabetes and its treatments; lack of self-confidence and/or motivation to manage diabetes well; and passivity in office visits with providers without posing their questions or articulating their concerns. In addition, many adults with diabetes lack effective social support to help them overcome structural and other barriers to effective diabetes self-management [2]. Moreover, low-income African Americans with diabetes experience a 50–100% higher burden of illness and mortality from diabetes, have worse glycemic control, and experience more barriers to diabetes self-management than non-Latino white adults [3]. Although these disparities are less severe in VA than in other health systems, they are still marked [4,5]. Low-income racial and ethnic minority adults report high levels of diabetes-specific emotional distress [6], and, even among Veterans, have high rates of low health literacy and numeracy [7–9]. Patients who are actively involved in treatment decision-making tend to be more satisfied with their health care [10], more adherent to treatment, and have a better quality of life [11]. Yet, African-American patients report receiving less information and participating less in health care clinic visits [12–14]. This contributes to worse information exchange, less optimal medical decisions, and lower patient satisfaction, leading to poor medication adherence and outcomes [15,16].

Higher levels of social support—especially illness-specific support—are associated with better diabetes and other illness self-management [17]. Telephone based peer support helps reduce problematic health behaviors, depression, and, in both VA and non-VA randomized controlled trials of peer health coaches or mentors, has contributed to

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improved diabetes outcomes [18–22]. A recent VA Randomized Control Trial (RCT) led by co-investigator Judith Long found that telephone-based peer mentoring led to greater improvements in glycemic control among African American diabetic Veterans than financial incentives or usual care [5].

Along with peer support, decision and educational aids 'tailored' based on characteristics unique to that person have been found to improve health outcomes [23,24]. In three recent RCTs, diabetes medication decision support tools increased knowledge, blood sugar management, patient involvement in treatment decision-making, and decreased diabetes-related distress [25,26]. Yet, many of these tools have targeted patients who have a high level of computer and health literacy. While a recent AHRQ review of 150 consumer health informatics (CHI) applications concluded that these programs engage consumers, enhance traditional clinical interventions, and improve health outcomes [27], the report identified significant knowledge gaps, including the need to evaluate CHI applications among racial and ethnic minority populations and low-literate populations. The report also emphasized the lack of CHI applications engaging nontraditional health care supporters such as peer mentors. To address these gaps in knowledge, the aim of this study is to evaluate the addition of Tailored Interactive Diabetes Medication and Self-Management Decision Support Tools into a Telephone Based Peer Coaching Program.

2. Research design and methods

2.1. Overview

We are conducting a parallel, two-armed randomized controlled trial including diabetes patients who have poor glycemic control. The trial will compare a six-month telephone-based peer mentor program in which the peer mentors do not have access to a tailored interactive computer-based tool (iDecide) versus a 6-month telephone-based peer coaching intervention with an initial face-to-face session facilitated by iDecide followed by weekly telephone contacts. We will compare changes in A1cs between these two arms, and with an observed, usual care group (Aim 1). This will enable us to examine the efficacy of peer support in this population, which differs from the populations and sites of our prior peer support interventions, and if significant differences are found to compare the effect size with those of our earlier RCTs comparing peer support with usual care comparison groups. Between the two randomized peer support and peer support + iDecide arms, we will also compare changes in blood pressure control and medication adherence as well as the key patient-centered outcomes of patients' satisfaction and involvement with care, perceived social support, and diabetes-specific quality of life (Aim 2). Point-of-service A1cs and blood pressure will be assessed at baseline, 6 months, and 12 months. To assist in VA efforts to create a menu of options for patients, we will examine patient characteristics associated with willingness to participate and engage in the proposed intervention, as well as key mediators and moderators of intervention effects (Aim 3). The study duration will be 4 years, to allow for peer coach and patient recruitment, completion of the 6-month program, and assessment of outcomes at 6 months and at 12 months.

Many prior health services studies focus on intervention efficacy as the exclusive measure of success rather than a program's potential for successful implementation and dissemination in 'real-world' clinics [28]. To increase the usefulness of this study's findings to VA and other health systems, we will use the RE-AIM framework to evaluate intervention elements of interest to clinical managers [29]. The goal of RE-AIM is to broaden the focus of interventional research to include dimensions critical to an intervention's implementation in usual care after a trial is completed. We will use mixed methods research methods [30] to investigate elements important for implementation and dissemination. This approach involves the collection, analysis, and mixing of both quantitative and qualitative data. The specific design will be an "embedded" mixed methods design involving collecting qualitative data during the intervention to better understand the mechanisms influencing implementation and the outcomes. A chief characteristic of an embedded design is that the qualitative data provides a supportive role and is embedded at different phases of the trial [31]. Using mixed methods, we will gather data on how peer coaches, primary care clinic staff, and patients experience the intervention and how the experiences of participants together with the results of the trial help us modify the intervention for future use. Using this approach, we hope to ensure that the intervention has the greatest possible likelihood of adoption in VA and other health systems should we find it has positive effects on processes and outcomes of care.

2.2. Study sample and setting

2.2.1. Description of site

The John D. Dingell VAMC in Detroit serves 44,453 Veterans. In FY11, this site provided 447,409 outpatient visits and 5055 inpatient hospitalizations. Approximately 62% of Veterans who receive their care at the Detroit VA are African American, with a large number living within Detroit. Although 19 MDs, 26 RNs, 10 LPNs and 9 MAs serve these patients in the outpatient setting, the number of diabetes patients with poor risk factor control far exceeds their capacity to provide regular, sustained care management. As of FY11, 28% or 1909 of the 8263 Veterans with diabetes who received care at the Detroit VA had A1cs > 8% over the prior year.

2.3. Patient selection, recruitment and randomization

A rolling pool of potential recruits was identified on a monthly basis. Patients were identified who met one of the following criteria within the past 12 months: (1) one hospitalization with a diabetes-related ICD-9 code; (2) two outpatient visits with a diabetes-related ICD-9 code; or (3) at least one prescription for a glucose control medication (insulin or oral agents) or monitoring supplies [33]. Eligible participants also had anA1c of at least 8.0% if age < 70 or at least 8.5% if age 70 + within the 6 months prior to enrollment. Using ICD-9 diagnostic codes, we excluded patients who had an active substance abuse disorder or serious psychiatric illness (PTSD, bipolar disorder, dementia, schizophrenia, or personality disorders). We then sent names of the patients to their primary care providers to identify any patients who they did not recommend inviting to participate in the program. An invitation letter was then sent to eligible patients, with a follow up call by a research associate to provide more information about the study. Patients who agreed to participate were scheduled to complete written informed consent and the baseline assessments, with coded baseline survey data entered directly onto the iPad so information for tailoring will be in the program. Randomization was being stratified to the extent possible by gender and whether the patient was on insulin, as gender and insulin use may moderate treatment effects. Variable block sizes were programmed into the computer randomization precluding prediction of treatment assignments by study staff.

2.3.1. Peer support alone arm

Participants randomized to receive peer support alone (without the iDecide tool) after they complete their baseline assessments were matched with a peer coach of the same gender, race, approximate age (±7 years) and whether they also use insulin to the extent possible. Matching as closely as possible on shared characteristics and self-management challenges has been found to lead to better peer relationships in prior studies. Participants in this arm were given copies of the AHRQ consumer-focused guides, "Pills for Type 2 Diabetes" and "Insulin for Type 2 Diabetes" and encouraged to review them. The information in these two guides was used in the iDecide tool, so this group received the same diabetes anti-hyperglycemic medication information provided in the iDecide tool. All received copies of the printed guides. The