COMRADE: Collaborative Care Management for Distress and Depression in Rural Diabetes

NCT02863523

December 11, 2017

PROTOCOL AND DATA ANALYSIS

1. Introduction

Type 2 diabetes (T2D), a significant public health burden, is more prevalent in the southeastern US which includes most of the CDC defined “Diabetes Belt” [1]. It is estimated that 9.3% of Americans have diabetes and in the counties included in the Diabetes Belt; the percent affected ranges from 11 to 11.7%. Those with T2D are twice as likely to have symptoms of depression and this relationship may be bi-directional [2]. Depressive symptoms may also interfere with glycemic control and adherence to the prescribed treatment regimen [3]. Diabetes related distress, originally investigated by Polonsky et al. [4], can be associated with depressive symptoms but appears to be a distinct condition [5]. Diabetes related distress reflects the emotional distress, defined as “patient concerns about disease management, support, emotional burden, and access to care”. High levels of regimen related distress have been associated with poor medication adherence, lower self-efficacy, and higher levels of HbA1c [6]. Early evidence suggests that improvement in depressive symptoms and/or distress have been associated with improvement in glycemic control and quality of life [7–9]. Katon et al. [7] described a shared or integrated approach to both T2D and depression using a care manager specifically trained in both diseases, with psychiatrist back-up. However, Katon et al.'s work was done in the northwestern US with a predominantly Caucasian population with diabetes and depression only (distress not targeted) with good access to medical care services and the availability of back-up psychiatrists. Bogner et al. [8] implemented an integrated care management strategy for patients with T2D and co-morbid depression who were likely to have medication adherence challenges. This study also provided excellent evidence for the present study; however, it was conducted in an urban setting in the northeastern US, targeted depressive symptoms only, and outcomes were only measured at 12 weeks so that the long-term effect of their model is unknown. Hessler et al. [9] used an electronic intervention model and showed that reductions in regimen-related distress were associated with improvements in medication adherence and glycemic control. However, this study was conducted in an urban location on the west coast. Despite the limitations of available data, the American Diabetes Association in its latest guidelines [10] now recommends both regular screening for psychosocial issues as well as evaluation and treatment including a collaborative patient-centered approach involving behavioral health professionals when indicated. However, the extent to which this collaborative behavioral and medical care model can be effectively implemented in busy primary care practices in the southeastern US diabetes belt or other areas of high prevalence, where many patients with poorly controlled T2D and behavioral co-morbidities are managed, remains poorly defined. The investigators undertook the present study to investigate the pragmatic implementation of an integrated care delivery model in the diabetes belt in the rural southeastern United States with a much larger African American population.

In this protocol, the authors describe the design, rationale, and methods from a prospective randomized pragmatic trial of an innovative model involving a culturally-relevant integrated medical and behavioral intervention for uncontrolled T2D, tailored to the unique needs of patients in the southeastern US diabetes belt. The objective of this clinical trial was to determine

the feasibility for delivering and evaluating coordinated and integrated behavioral and medical care for adult patients with uncontrolled T2D who have comorbid diabetes-related distress and/or depressive symptoms, in the context of a busy primary care practice and surrounding rural communities. The intervention included a carefully defined protocol for face-to-face and telephone delivered cognitive behavioral health interventions, tailored to the presence and severity of co-morbid distress and/or depression, in addition to routine medical care for T2D.

2.2. Intervention design

The study was designed as a prospective, randomized, non-blinded pragmatic trial with randomization at the patient level to the intervention arm or to usual care. For the intervention arm, a collaborative or integrated care model involving tailored cognitive-behavioral therapies plus American Diabetes Association guideline [10]-informed standard medical care was considered to represent the most practical approach to treating the established co-morbid illness in busy primary care settings in the southeastern US. The intervention was designed to utilize modified versions of evidence-based collaborative care management strategies – particularly those described by Katon et al. [7] and Banger et al. [8]. Further, the intervention model was built on the authors' prior work [11], and was designed to:

1. Involve an integrated and collaborative care delivery system that extends the capacity of busy primary care providers to be able to screen and manage the psychological and behavioral needs of complex co-morbid patients with T2D

2. Focus on specific behavioral problems such as depressive and diabetes-related distress symptoms that prior literature suggests limits optimal care outcomes

3. Utilize a unique stepped care approach that quickly moves the patient to the right level of care and increases or decreases the degree of intervention based on patient response

4. Be culturally tailored to be relevant in the southeastern US and to African Americans

5. Use a trained care manager linked to primary care clinicians and health psychologists so that it might be readily deployed even in communities without access to a psychiatrist

6. Employ a community health worker to provide specific social support and navigation

7. Use a combined face-to-face and telephone visit structure to improve care and cost efficiency and to facilitate generalizability in underserved and rural communities

2.3. Study population and setting

The study was specifically targeted at patients with uncontrolled T2D who also reported either depressive symptoms and/or symptoms of diabetes-related distress, as measured by previously validated instruments (see below). In our prior pilot work in this same region using the same instruments [11], 40% of patients screened positive for diabetes related distress and 21.5% reported elevated depressive symptoms. The study took place in an academic Family Medicine clinic setting that included a residency program located in the southeastern U.S.

2.3.1. Screening

The population screened for this study included: adult patients (18 to 75 years of age) who had established care at the academic primary care practice (at least one visit in the last 12 months) and who had an electronic medical record established diagnosis of T2D and a recent (< 12 mo.) HbA1c that reflected inadequate glycemic control (HbA1c≥7.0). Exclusion criteria for screening included a medical record established diagnosis of advanced disease (e.g., end stage renal disease, advanced heart failure, blindness, metastatic cancer) or the presence of alcoholism, cognitive impairment, or major psychiatric disease that would preclude active participation. Individuals who met preliminary eligibility were contacted by the study coordinator and invited to be seen for a study-specific visit or was screened following a regular provider visit. At the time of placement into an examination room for the study visit, a statement of informed consent and HIPPA consent was carefully reviewed with each potential participant. A two-item version of the Diabetes Distress Scale (DDS-2) and the two-item version of the Patient Health Questionnaire (PHQ-2) was then administered as a screening instrument by office staff. These 2-item versions have excellent sensitivity (95% and 97%, respectively), and are defined in greater detail below in the outcome measures section. Study staff collected the completed measures and scored them. If the score on either measure was considered positive (mean score > 3 on DDS-2; total score > 3 on PHQ-2), the individual was assessed regarding glycemic control. A screening fingerstick HbA1c test was obtained while the patient was in the examination room and evaluated using a Siemens analyzer [DCA Vantage portable analyzer, Siemens Medical Solutions, Malvern, PA] as described below. If the patient met all the screening criteria described above, had a HbA1c value that day that was>7.0, and also had positive co-morbid behavioral symptoms (depressive and/or diabetes-related distress symptoms on one or more of the 2 item screening instruments), then he/she was scheduled for an enrollment visit into the study. Once enrolled, the patient completed the full DDS-17 and PHQ-9 plus additional baseline instruments that are defined below and was then scheduled for a study orientation visit.

2.4. Sample size and randomization procedures

Sample size was estimated as follows. The primary outcome measure was determined to be the change in mean HbA1c from baseline to 12-months follow-up. In the intervention arm, mean HbA1c was hypothesized to decrease by −0.7 compared to no change in the usual care arm (based on values reported by Bogner et al. [8]). Using an $\alpha = 0.05$ and a power estimate of 0.80, the crude sample size needed in each group was approximately n=50 for a total sample size of N=100 patients. The investigators chose to recruit and randomize approximately 70 patients into each arm anticipating the possibility of dropouts and incomplete follow-up data in some patients. Randomization was designed as a blocked randomization process, controlled by one of the investigators, using a computer-generated allocation sequence with allocation concealment from treating providers, with eligible patients randomized in blocks of four to the intervention or control group. Patients were randomized at the beginning of the orientation visit, held one week after the screening visit) and were provided group specific orientation to the study as detailed below.

2.5. Implementation

At the outset of the study, project faculty met weekly and hired a project coordinator who managed logistics and facilitated patient recruitment as well as all data collection and data entry.

2.5.1. Intervention staff selection and training

The primary intervention was delivered by a team of behavioral providers working together including a nurse care manager who provided small-changes lifestyle coaching [11], a doctoral student in clinical psychology or psychologist who provided cognitive behavioral treatment sessions including elements of problem-solving therapy where indicated, and a community health worker who provided navigation and social support. The nurse care manager was an African American registered nurse from the local area with>10 years' experience in care management for patients with diabetes. A local African American adult female community health worker with>10 years' experience in chronic disease care, was hired to provide social support and navigation in the community to acquire needed diabetes resources. All staff hired had strong interpersonal skills including a demonstrated ability to establish rapport quickly with a wide range of people. The nurse manager and other intervention staff received extensive (≥80 h) training by the investigators in all aspects of the intervention including diabetes-specific evaluation and management, depression and distress specific evaluation and management, cognitive-behavioral/problem solving therapy intervention components, disease and severity stratification, response evaluation and stepped-care transitions, psychological and medical treatment intensification, working with providers and community partners, and project-specific evaluation. One of the investigators provided regular supervision of the care manager from a behavioral intervention perspective.

2.5.2. Orientation session

Patients who completed the screening visit and signed informed consent completed a study orientation visit one week later during which height, weight, and sitting blood pressure (BP) were measured using standardized procedures. All patients in both study arms were provided with educational materials about T2D (Living with Diabetes, American College of Physicians, Product #: 11033420E). Patients randomized at the orientation visit into the Usual Care Arm were provided with general information about the COMRADE study and with a brief orientation to future study assessment visits. Patients randomized to the intervention group were provided with general information about the COMRADE study, a weight scale, and were assigned to one of two levels of behavioral treatment based on the level of baseline scores (see below). Intervention group patients also received an innovative, patient-friendly Tracking for Success Calendar developed for daily monitoring of six possible diabetes and mood self-management behaviors including fasting blood glucose, weight, medication administration, food intake, step count, and mood. Each intervention arm patient was instructed to use this for the duration of the study and these records were reviewed at the start of every study-related session by the assigned behavioral interventionist. Following explanation of study materials and orientation to the COMRADE program, patients were scheduled to attend their first behavioral treatment session.

2.5.3. Initial assessment of co-morbid behavioral symptoms and severity stratification

Once randomized at the orientation visit, patients in both groups completed a full battery of measures which are detailed below. The full psychological measures [Patient Health Questionnaire-9 (PHQ-9) for depressive symptoms and the Diabetes-related Distress-17 (DDS-17) scales for diabetes-related distress symptoms], were promptly scored by study staff and used to triage or stratify patients into one of two appropriate evidence-based behavioral interventions based on the severity of symptoms of depression or distress [(Small Changes Lifestyle Coaching if PHQ-9 < 10 and/or mean DDS-17 < 3) or Cognitive Behavioral Therapy (CBT; PHQ-9≥10 and/or mean DDS-17 – ≥3.0)]. Based on these two measures, it was possible to have patients with only depressive symptoms, only diabetes-related distress symptoms, or a combination of both distress and depressive symptoms. This complex design was specifically chosen for pragmatic reasons related to: 1) insuring generalizability in primary care where patients with uncontrolled diabetes frequently have either or both of these co-morbidities, and 2) to explore whether evidence-based but tailored treatments would relieve varying levels of symptoms of diabetes-related distress and/or depression and facilitate diabetes control when delivered in this integrated care fashion in the context of a busy primary care practice. The proposed stratification design may also have the potential to be more efficient and cost-effective than providing a potentially suboptimal level of intervention for a period of time before intensifying treatment as might occur in a standard stepped care model. Therefore, the behavioral intervention was designed to pilot test a severity-stratified behavioral treatment model with patients being triaged at baseline to one of three levels of behavioral intervention (small changes lifestyle coaching, or one of two levels of cognitive behavioral therapy), each paired with guideline informed standard medical care delivered by the patient's primary care provider with available consultative support from the study's diabetologist to assist with medication selection and monitoring. All three levels of behavioral health intervention had the overarching goal of improving the patient's glycemic control (i.e., HbA1c) as well as improving depressive and/or distress symptoms. 2.5.4. Behavioral health intervention structure and content In the first 6 months of behavioral treatment all patients in the intervention arm received one individual orientation session and 12 individually tailored behavioral treatment sessions that included the content described below, delivered by the study staff (trained nurse or health psychologist/doctoral clinical health psychology student) described above. Patients completed the orientation session and the first intervention session for each level of behavioral intervention in-person and then had the choice of completing the subsequent sessions either in-person or by telephone. Session duration ranged from 30 to 60 min depending on treatment content and individual patient needs; patients were not charged for the behavioral intervention. All study interventionists met bi-weekly as a group with the principal investigators for supervision and consultation. The registered nurse met one-on-one weekly for supervision with the licensed clinical psychologist principal investigator. The diabetologist (i.e., primary care physician with advanced training in diabetes care) was also on-site and available for consultation and referral of patients who developed severe diabetes signs or symptoms (e.g., hypoglycemia, hyperglycemia).

2.5.5. Small changes lifestyle intervention

The Small Changes treatment sub-group included intervention arm patients with low levels of diabetes-related distress and/or depressive symptoms and the intervention focused on lifestyle modifications to improve diabetes and mood based on the Small Changes health behavior change model [12] as we have previously described [11], as well as American Diabetes Association (ADA) [10] recommended diabetes education topics of healthy eating, being active, monitoring, taking medication regularly, healthy coping, and decreasing risks. The Small Changes model encourages health behavior change and maintenance through the use of incremental goals over time that are self-selected by patients and relative to their baseline. The Small Changes approach has been shown to be more effective for weight loss than traditional treatment in a health care setting with Veterans [13]. Small Changes lifestyle intervention sessions were delivered by a nurse trained in behavior change and focused on the development of self-management strategies and the setting of SMALL (specific, measurable, action-oriented, linked-to-your-life, and long-term) goals. Patients were instructed to self-monitor and record daily fasting finger stick blood sugar (FSBS), weight, mood, medication taking, and selected nutritional intake (using only check marks) using the provided calendar and scale as well as their daily steps with pedometers provided by the study. Nutritional monitoring and goal setting was based on a Stop Light Guide [14] which was adapted for diabetic populations. In this modified system, food and beverage items were categorized as “Green” (high nutrient value, little effect on glycemic control), “Yellow” (high nutrient value, moderate effect on glycemic control), and “Red” (low nutrient value, large effect on glycemic control). While patients were introduced to the full modified Stop Light Guide, patients were instructed only to monitor how many red foods they were eating daily and make relative nutritional changes to their daily baseline consumption of “Red Foods”. Specifically, patients checked-off daily servings of Red Foods in five categories (breakfast, lunch, dinner, snacks, and beverages) in order to get a daily total of Red Food servings (sum from these five categories) and then set goals to reduce their daily total throughout the course of treatment. Monitoring and goal setting was designed in this manner to reduce monitoring burden and to increase the patient's focus on food and beverage items with potential for substantial adverse impact on weight and glycemic control.

2.5.6. Cognitive behavioral therapy

The Cognitive Behavioral Therapy (CBT) subgroup focused on the reduction of depressive and/or diabetes-related distress symptoms through modification of negative thoughts and problematic behaviors as well as improvement of diabetes self-management strategies. CBT combines cognitive therapy, which targets maladaptive thinking that impacts emotions and behavior with behavioral therapy which directly targets the behaviors which impact mood. CBT intervention components were guided by two evidence-based treatment manuals [15,16] as well as an evidence-based manual [17] for behavioral activation. Session content utilized cognitive techniques to identify and challenge general and diabetes-specific cognitive distortions that result in maladaptive behavior; and behavioral techniques including behavioral activation and specific behavior change related to diabetes and/or mood (self-monitoring, sleep hygiene, eating habits etc.). Patients were taught behavioral strategies to become re-engaged in pleasant activities (behavioral activation) as well as cognitive techniques to identify and then challenge cognitive distortions that result in negative automatic thoughts and subsequent maladaptive

behavior. These sessions occurred in 50 min face-to-face (in private therapy rooms in the primary care clinic) or via telephonic visits with the health psychologist/student. Problem-solving strategies were utilized as needed to assist with behavioral goals related to mood and diabetes management.

CBT Therapy was also tailored to individual patient needs. For patients who met criteria for this subgroup but who had more intermediate levels of depressive or distress symptoms, the health psychologist utilized Problem Solving Therapy (PST), a variant of CBT which focuses on facilitation of effective coping and adaptive problem-solving skills [18]. Problem Solving Therapy has been shown to be an effective intervention strategy for improvement in both diabetes specific outcomes and depression [19,20], particularly in patients with lower socioeconomic status and diabetes [21]. Problem Solving Therapy has also been adapted for delivery in primary care settings (PST-PC) as a brief form of evidence-based psychotherapy [22] and is supported by randomized controlled studies in primary care settings [23]. Patients receiving CBT involving PST began treatment by compiling a personalized on-going list of "problems" or areas for potential improvement based on ADA recommended [10] diabetes topics. In each session, the patient chose a problem from his or her list to address and used the following steps: 1) problem definition, 2) establishment of realistic goals for problem resolution, 3) generation of multiple solution alternatives, 4) determination of the pros and cons of solution alternatives 5) evaluation and solution choice, 6) implementation of the preferred solution, and 7) evaluation of the outcome. Additionally, patients were provided education about behavioral activation for mood improvement and were assisted with setting goals to increase engagement in pleasurable activities for improved mood. Primary care providers for patients in the intervention arm were offered consultation with the diabetologist and, when needed, consultation with a clinical pharmacist to optimize medical management. Primary care providers were instructed to titrate medication dosages to appropriate therapeutic dosages based on finger-stick blood sugar response and subsequent HbA1c values. Patient response, adherence, and potential for side effects were monitored regularly by the nurse care manager during face-to-face and telephone follow-up, with particular attention to the potential for hypoglycemia associated with insulin and sulfonylurea drugs.

2.5.7. Community based support of the intervention

All intervention patients had access to a trained Community Health Worker (CHW) who had extensive experience promoting healthy behaviors for chronic disease management in the targeted region. This CHW component of the intervention was designed as culturally relevant peer support and as a navigator to community resources that helped patients address logistical challenges to implementing healthy behaviors, problem solving, and accessing healthy food/activity in the target community. The CHW contacted each intervention patient by phone approximately quarterly and offered logistical and navigational support as well as encouragement for behavioral change.

2.5.8. Usual care group (control)

Patients in the control group received the educational materials described above (i.e., Living with Diabetes book) and continued to receive usual care at their primary care provider's office.

2.5.9. Overall study evaluation

The authors evaluated the effectiveness of this stratified integrated behavioral health model on diabetes related distress, depressive symptoms, and diabetes outcomes (see measures below) at 6- and 12-month follow-up visits. It was hypothesized that the collaborative behavioral health intervention would produce greater improvement in diabetes related distress, depressive symptoms, as well as HbA1c at 6 and 12 months vs. usual care. A priori analyses were also designed to evaluate mediators of the relationship between improvement in psychological measures (distress/depression) and improvement in HbA1c with the hypothesis that the intervention-associated improvements in diabetes-related distress, regimen related distress, and depressive symptoms would be associated with improvements in A1c in part via association with improvements in self-care behaviors.

2.5.10. Mid-study Re-assessment and maintenance treatment

At the 6-month mid-study assessment, all patients were re-evaluated using the same measures described below, and either continued to receive twice monthly behavioral sessions (for those with no improvement in distress and depressive symptom scores) as originally assigned at the initial orientation visits, or were transferred to once per month telephonic maintenance follow-up care (for those whose distress and depressive symptom scores improved). Maintenance treatment reinforced prior intervention strategies that produced benefit and provided lifestyle behavioral counseling using elements of the small changes model described above) by the nurse care manager.

2.6. Biological and psychosocial measures

Patients in both intervention and control groups completed a demographic questionnaire [age, gender, race (African American, Caucasian, other), highest education level completed (high school or less, some college, college degree, any graduate education), marital status (single, married, separated, divorced, widowed), annual household income ($ < 40,000/yr. vs.≥ $40,000/yr.) duration of diabetes (yrs.; self-reported), number of doctor visits in the last 12 months] at baseline; biological and psychosocial assessments were completed at baseline, 6, and 12 months. Weight was obtained using an Eatsmart Precision Plus Bathroom Scale model ESBS-05. Height was measured using a wall stadiometer. Blood pressure was obtained using an Omron Intellisense Automatic BP Monitor model BP760 (Omron, Inc., Chicago, IL) using a standardized protocol. All patients were seated for five minutes with both feet on the floor, and with their arm supported. Blood pressure was measured twice and averaged. HbA1c was measured by fingerstick using the Siemens Medline DCA Vantage 2000 HbA1c Reagent Kit. The study utilized previously validated psychosocial measures including the Patient Health Questionnaire (PHQ-9), Diabetes Distress Scale (DDS-17), and the Satisfaction with Life Scale with data collected at baseline, 6-months, and 12-months. The PHQ-9 is a nine-item self-report measure [24] intended for use in primary care settings to assess symptoms of depression. Scores can be summed to indicate, minimal, mild, moderate, or severe depressive symptoms. The

DDS-17 is a 17-item self-reported measure [4] which is designed to indicate a respondent's level of current emotional distress related to diabetes management. Scores are summed and divided by 17 (i.e., mean score) to categorize distress as low, moderate, or high. The DDS-17 also has four subscales, including the Regimen Related Distress sub-score which is an average from five items that assess distress associated with specific treatment and monitoring activities, and which has been correlated with diabetes outcome measures [6,9]. The Satisfaction with Life Scale [25] is a 5-item self-report measure designed to assess satisfaction with a respondent's life as a whole. The study also utilized several previously validated health behavior measures including the Diabetes Empowerment Scale, The Summary of Diabetes Self-Care Activities Measure (SDSCA), the Rapid Eating Assessment for Participants – Shortened Version (REAP-S), and the Duke Activity Status Index, with data collected at baseline, 6-months, and 12-months. The Diabetes Empowerment Scale-Short Form [26] is an abbreviated self-report measure of diabetes-related psychosocial self-efficacy. Dietary habits were assessed using the REAP-S, a 16-item self-report survey [27] designed for use in primary care to directly assess dietary habits for patients with diabetes. Physical activity was assessed by the Duke Activity Status Index, a 12-item self-report measure [28] to assess functional capacity.

2.6.1. Data analysis plan

All data was collected by project staff via in-person interviews/assessments at all time points and entered into a REDCap database. Demographic and baseline data will be compared between treatment groups; co-variates will be used for any significant differences on subsequent analyses. The principal outcome measure, change in HbA1c, and secondary outcome measures (e.g., change in DDS-17 score, PHQ-9 score, etc.) from baseline to 12 months of follow-up, will be compared (intervention group vs. usual care group) using Students t-test or analysis of variance (ANOVA) as appropriate. The correlation between change in HbA1c and changes in other factors such as DDS-17 score, PHQ-9 score, Diabetes Empowerment Scale Score, etc. will be examined using Pearson Correlation Coefficient. Where appropriate, multivariate analyses including general linear models will be used to further examine the relationship between changes in psychosocial variables and change in HbA1c, (e.g., change in depression or distress and relationship to change in HbA1c) while controlling for demographic characteristics and baseline values. In addition, based on our previous work [11], analyses examining treatment outcomes based on insulin use between the treatment and control groups will be conducted using Students t-test or repeated measures ANOVA. Furthermore, exploratory analyses, including multiple linear regressions, will be examined in the treatment intervention group to examine potential mechanisms for change across time. Missing data at follow-up associated with patients missing assessments will be addressed by using multiple imputations to replace missing values. All variables with<20% of randomly missing data will be kept and imputed. Multiple imputation is preferred because it is superior to other missing data approaches (i.e. mean replacement, last observation) and removing patients with missing data from the study (i.e. list-wise) which would result in a significant loss of the study sample. All analyses will be conducted using SPSS vs. 24 (IBM, Armonk, New York).

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