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Integrating Type 2 Diabetes Mellitus and Depression Treatment among African-Americans: A Randomized Controlled Pilot Trial

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Abstract

Purpose—The purpose of this study was to examine whether integrating depression treatment into care for Type 2 diabetes mellitus among older African-Americans improved medication adherence, glycemic control, and depression outcomes.

Methods—Older African-Americans prescribed pharmacotherapy for Type 2 diabetes mellitus and depression from physicians at a large primary care practice in West Philadelphia were randomly assigned to an integrated care intervention or usual care. Adherence was assessed at baseline, 2, 4, and 6 weeks using the Medication Event Monitoring System (MEMS) to assess adherence. Outcomes assessed at baseline and 12 weeks included standard laboratory tests to measure glycemic control and the Center Epidemiologic Studies Depression Scale (CES-D) to assess depression.

Results—In all, 58 participants aged 50 to 80 years participated. The proportion of participants who had 80% or greater adherence to an oral hypoglycemic (intervention 62.1% vs. usual care 24.1%) and an antidepressant (intervention 62.1% vs. usual care 10.3%) was greater in the intervention group in comparison with the usual care group at 6 weeks. Participants in the integrated care intervention had lower levels of glycosylated hemoglobin (intervention 6.7% vs. usual care 7.9%) and fewer depressive symptoms (CES-D mean scores, intervention 9.6 vs. usual care 16.6) compared with participants in the usual care group at 12 weeks.

Conclusion—A pilot randomized controlled trial integrating Type 2 diabetes mellitus treatment and depression was successful in improving outcomes among older African-Americans. Integrated interventions may be more feasible and effective in real world practices with competing demands for limited resources.

Introduction

Older African-Americans are twice as likely as to be diagnosed with diabetes and are over two times as likely to die from diabetes in comparison with non-Hispanic whites.¹ By 2050 it is estimated that the number of older adults in developed countries with diabetes will increase by 220%² yet the proportion of adults whose diabetes is controlled is decreasing over time³ and is particularly low among older African-Americans.⁴ Depression is common among African-Americans with diabetes.⁵ Depression is a risk factor for diabetes⁶ and risk of depression is increased by a factor of two in older patients with diabetes.⁷ Depression has been specifically linked to prognostic variables in diabetes such as micro- and

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macrovascular complications⁸ and is associated with poor adherence to medications for diabetes.⁹

The 2002 Institute of Medicine (IOM) Report commissioned by the United States Congress, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* reported significant health disparities in the treatment of illness and delivery of care across ethnic groups, with diabetes and mental health being no exception.¹⁰ African-American patients with diabetes have been found to receive lower quality care, have more visits to the emergency department and fewer physician visits per year.^{11, 12} With regard to depression, while the United States seen an overall increase in antidepressant use, the increase has occurred mostly among white patients.¹³ African-American patients have been found to be less adherent to diabetes and depression treatment regimens, even though no ethnicity-related treatment response difference has been identified.^{14, 15}

The primary health care setting is pivotal for the identification and treatment of diabetes and co-morbid mental disorders for elderly minorities. Despite startling ethnic disparities in diabetes outcomes,¹⁶ African-Americans are just as likely as whites to be seen in primary care for the management of diabetes.^{17, 18} In addition, African-American patients are more likely to seek mental health care from a primary care physician rather than a mental health specialist.^{19, 20} However, behavioral interventions in primary care to improve compliance to Type 2 diabetes mellitus (DM) treatment have been more effective for whites than African-Americans which may be due to a failure to incorporate factors that have been found to increase engagement and adherence among African-Americans, namely integrated designs^{21, 22} and cultural tailoring.²²⁻²⁷

No known trials in primary care have integrated management of Type 2 DM and depression among older African-Americans. Improving the ability of primary care settings to integrate the management of Type 2 DM and depression among older African-Americans will have an important public health impact. There is an urgent need for research that can bring potentially life-extending strategies²⁸ to the management of both diabetes and depression. The aim of this intervention was to focus on improving medication adherence to both Type 2 DM and depression treatment among older African-Americans. Adherence remains a significant impediment to improving care^{29, 30} and is an important predictor of glycemic control.^{31, 32} The conceptual framework, adapted from Cooper and colleagues,³³ is practical in its approach and provides a framework that allows for flexible, tailored interventions (Figure 1). The intervention addresses each factor resulting in nonadherence in the conceptual model through a multifaceted, culturally tailored individualized approach in which participants work with the integrated care manager to develop strategies to overcome barriers to medication adherence. The purpose of the study was to examine whether integrating depression treatment into care for Type 2 diabetes mellitus among older African-Americans improved medication adherence, glycemic control, and depression outcomes.

Hypothesis

The hypothesis was that in a sample of older African-American primary care patients with Type 2 DM and depression, patients who were randomized to receive the intervention compared with usual care would demonstrate the following adherence outcomes at 6 weeks: (1) a greater proportion of participants who had 80% or greater adherence to an oral hypoglycemic agent and (2) a greater proportion of participants who had 80% or greater adherence to an antidepressant medication, and the following clinical outcomes at 12 weeks: (1) lower amounts of glycosylated hemoglobin in their blood and (2) fewer depressive symptoms.

Methods

Recruitment Procedures

Patients were recruited from a community-based primary care practice in West Philadelphia with 12 family physicians. Over 30,000 patient visits occur per year at the practice. The research protocols were approved by the University of Pennsylvania Institutional Review Board and all participants gave written informed consent. From April 2007 to June 2008, depressed older adults with Type 2 diabetes mellitus with upcoming appointments were recruited. Patients were initially identified through an electronic medical record with the following inclusion criteria: (1) aged 50 and older; (2) a $Hb_{a1c} \geq 7$ at their last primary care office visit or a prescription for an oral hypoglycemic agent within the past year; and (3) a diagnosis of depression or a prescription for an antidepressant within the past year.

In all, 90 patients were identified by electronic medical records as potentially eligible and were approached for further screening. Of those approached, 63 (70.0%) provided oral consent for screening. Fifty-eight (92.1%) of the 63 who consented for screening were deemed eligible for participation. In order to include as many older persons who were willing and able to participate as possible participants with a range of depressive symptoms were included in this study, reflecting the concept of the relapsing, remitting nature of depression in primary care.³⁴ In all, 58 eligible African-American patients completed enrollment procedures and were randomly assigned to an integrated care intervention (n=29) or to usual care (n=29).

Intervention

Integrated care can be defined as a set of techniques and organizational models to create connectivity, alignment, and collaboration within and between the cure and care sectors at the funding, administrative, and/or provider levels.³⁵ The goals of integrated care generally are to enhance quality of care and quality of life, consumer satisfaction, system efficiency for patients with complex problems cutting across multiple sectors and providers.^{36, 37} Relying on this framework, an integrated care intervention was carried out in which an integrated care manager collaborated with physicians to help participants recognize depression in the context of Type 2 DM, offered guideline-based treatment recommendations, monitored adherence and clinical status, and provided appropriate follow-up. This study differed from other studies by focusing on the integrated care manager's unique role as an intermediary or liaison between the elderly depressed patient with Type 2 DM and the physician in promoting adherence to an oral hypoglycemic agent and antidepressant. The key components of the Integrated Care Intervention were: (1) provision of an individualized program to improve adherence to oral hypoglycemic agents and antidepressants that recognizes patients' social and cultural context; and (2) integration of Type 2 DM treatment with depression management.

The integrated care manager worked individually with patients to address the factors involved in adherence presented in the conceptual model (Figure 1). Through in-person sessions and telephone conversations the integrated care manager provided education about depression and Type 2 DM emphasizing the importance of controlling depression in order to manage Type 2 DM; encouragement and relief from stigma; help to identify target symptoms for both conditions; explanations for the rationale for oral hypoglycemic agent and antidepressant usage; assessment for the presence of side-effects and assistance in their management; assessment for progress (e.g. improvement in finger-stick glucose measurements and reduction in depressive symptoms); assistance with referrals and; monitoring and response to life-threatening symptoms (e.g. chest pain, suicidality). The Integrated Care Manager conducted cultural interviewing to assist participants in devising

culturally acceptable solutions to nonadherence. Diabetes information for participants was tailored to the cultural context of participants.³⁸ The intervention was presented to patients as a supplement to, rather than a replacement for, existing primary care treatment. A multi-faceted approach was employed because education alone has not been found to be effective for improving adherence.³⁹

The intervention consisted of three 30 minute in-person sessions and two 15-minute telephone monitoring contacts over a four-week period. A Master's level research coordinator was trained as an integrated care manager and administered all study activities. Prior to trial initiation, the integrated care manager received training on pharmacotherapy for Type 2 diabetes mellitus and depression management, cultural interviewing and sensitivity, and culturally competent evidence-based practices for quickly building rapport in the primary care settings⁴⁰⁻⁴⁵ during weekly clinical sessions with the principal investigator (PI). Under the supervision of the PI the integrated care manager conducted mock study activities with two participants and thereafter received ongoing weekly supervision for all study activities monitoring 25% of weekly sessions to ensure that the integrated care manager was adherent to study protocols.

Usual Care

At baseline, 2, 4, 6, and 12 weeks participants underwent the same assessments as participants in the integrated care intervention. Assessments were conducted in-person (as were assessments in the integrated care intervention). The PI randomly monitored 25% of sessions conducted weekly to ensure that there was no carry-over of the intervention into the usual care group.

Measurement Strategy

To screen potential participants the Mini International Neuropsychiatric Interview (MINI) assessed for the presence of mania or hypomania, psychotic syndrome, alcohol abuse or dependence, acutely suicidal or psychotic thoughts.⁴⁶ The Mini-Mental State Examination (MMSE), a short standardized mental status examination widely employed for clinical and research purposes,⁴⁷ was used to evaluate cognitive impairment (defined as MMSE < 21).⁴⁸ Patients were asked whether patients resided in a care facility that provided their medications on schedule and whether they were unwilling or unable to use Medication Event Monitoring System (MEMS).

At baseline sociodemographic characteristics were assessed using standard questions. Functional status was measured using the Medical Outcomes Study Short Form (SF-36).^{49, 50} Adherence to an oral hypoglycemic agent and an antidepressant medication was measured at baseline, 2, 4, and 6 weeks. Adherence to oral hypoglycemic agents and antidepressants was measured using electronic monitoring data obtained from MEMS Caps. MEMS Caps are medication bottle caps containing microelectronics that record the date and time the bottle is opened. MEMS caps are an informative technique allowing identification of the precise time of container opening when medications are taken. At baseline and 12 weeks blood glycemic control was assessed in accordance with American Diabetes Association Guidelines.⁵¹ Hb_{a1c} assays were performed at a single, accredited laboratory using a standard liquid chromatographic method to measure Hb_{a1c}.⁵² The assay methodology did not change during the study period. At baseline and 12 weeks the Center for Epidemiologic Studies Depression Scale (CES-D) was employed to measure depression. The Centers for Epidemiologic Studies Depression (CES-D) scale was developed by the Center for Epidemiologic Studies at the National Institute of Mental Health for use in studies of depression in community samples.⁵³⁻⁵⁵ The CES-D contains 20 items. The CES-D has been employed in studies of older adults.^{56, 57}

Analytic strategy

Characteristics of participants at baseline in the integrated care intervention or usual care were compared using the Mann-Whitney U and Fisher's exact test (for continuous or categorical variables as appropriate). In addition, characteristics of participants who refused and did not refuse participation in the study were compared using the Mann-Whitney U and Fisher's exact tests. Blood glyceemic control and depressive symptoms were compared in the intervention group and usual care groups using the Mann-Whitney U test at 12 weeks. Adherence was defined as the percent of prescribed doses taken and was calculated as the number of doses taken divided by the number of doses prescribed over the observation period *100%. Adherence was dichotomized at a threshold of 80% because the proportion of pills taken was highly skewed and failed normality assumptions. The 80% cut-point has been used as a threshold to assess adherence to medication regimens.⁵⁸ Fisher's exact test was employed to compare the proportion of participants who were adherent to oral hypoglycemic agents and antidepressants in the intervention group with the usual care group at 6 weeks. Analysis was conducted using SPSS version 12.0 (SPSS, Chicago, IL). A level of statistical significance set at $\alpha = 0.05$ was employed, recognizing that tests of statistical significance are approximations that serve as aids to interpretation and inference.

Results

Sample characteristics

Participants ranged from 50 to 80 years old, with an average age of 60.2 years (SD=7.4 years). Forty-nine (84.5%) of the 58 participants were women. Characteristics of participants in the integrated care intervention did not differ significantly from participants in the usual care group (Table 1). There were no statistically significant differences in characteristics of patients who provided oral consent for screening and those who did not. All participants attended the required sessions at baseline, 2, 4 and 6 weeks as well as the final follow-up at 12 weeks and continued to receive regular care from their primary care physician and other medical specialists.

Outcomes

The proportion of participants who had 80% or greater adherence to an oral hypoglycemic agent was greater in the intervention group in comparison with the usual care group at 6 weeks (intervention 62.1% vs. usual care 24.1%; $p<.01$). The proportion of participants who had 80% or greater adherence to an antidepressant was greater in the intervention group in comparison with the usual care group at 6 weeks (intervention 62.1% vs. usual care 10.3%; $p<.001$). Participants who received the intervention had lower amounts of glycosylated hemoglobin in their blood (intervention 6.7% vs. usual care 7.9%; $p<.05$) in comparison with participants in the usual care group at 12 weeks. Participants randomized to the intervention group had fewer depressive symptoms in comparison with participants in the usual care group at 12 weeks (CES-D mean scores, intervention 6.9 vs. usual care 16.6; $p=.04$) (Table 2).

Conclusion

This preliminary pilot study supports the usefulness of a brief primary care based integrated care intervention to improve adherence to oral hypoglycemic agents and antidepressants, blood glyceemic control, and depression symptoms among older African-Americans. Primary care older African-American patients randomized to an integrated care intervention in comparison with older African-American patients randomized to usual care showed higher rates of adherence to oral hypoglycemic agents and antidepressants at 6 weeks and lower

amounts of glycosylated hemoglobin in their blood and fewer depressive symptoms at 12 weeks.

Before discussing the implications of the findings, the limitations of this study require discussion. First, the results were obtained from patients who received care at one primary care site that might not be representative of most primary care practices. However, this practice was probably similar to other primary care practices in the region. Second, this preliminary investigation was limited to 58 participants and the follow-up period was short, but the participants were randomized to the intervention or usual care. Third, the intervention would require additional resources in primary care settings. However, the intervention has a simple design and future implementation will explore whether ancillary health personnel could be trained to carry out the intervention. Fourth, MEMS Caps were used to measure adherence. All methods for assessing adherence have limitations. MEMS caps were used as the primary measure of adherence because MEMS caps have a low failure rate⁵⁸ and may be more sensitive than other adherence measures.⁵⁹ In addition, prior studies have shown that MEMS caps do not significantly influence adherence.^{58, 60} Also, any effect of MEMS caps on medication adherence would be experienced equally in both groups and therefore would not influence a comparative assessment by randomization assignment. The adherence threshold of was 80% in this analysis. While this threshold has been assessed in some clinical research,⁵⁸ the clinical relevance of this threshold has not been tested for many medications. Lastly, psychological variables, such as depression, cannot be observed directly and the measures employed may not reflect the construct being measuring.

Despite the limitations of this study, findings from this study deserve attention because previous intervention trials to reduce the burden of Type 2 DM in primary care targeting older African-Americans have not addressed depression.⁶¹⁻⁶⁶ Integrated interventions may be more feasible and effective in real world practices with competing demands for limited resources and have been found to be more engaging and acceptable to African-Americans.^{21, 22, 67} In this intervention, depression treatment was integrated into care for Type 2 DM so a single program could assist older African-Americans with Type 2 DM and depression. Consistent with the hypothesis patients randomized to the integrated intervention had a greater proportion of participants with 80% or greater adherence to an oral hypoglycemic agent and an antidepressant at 6 weeks as well as lower amounts of glycosylated hemoglobin and fewer depressive symptoms in their blood at 12 weeks.

A recent review of diabetes self-management interventions noted that an assessment of the feasibility of many interventions is limited by failure to report overall contact time with study participants.⁶⁸ The total contact time for this study was 2 hours (three 30 minute in-person meetings and two 15 minute telephone contacts). The minimal time involved in the study implementation supports prior findings that integrated interventions may provide a feasible and effective solution in real world practices with competing demands for limited resources.⁶⁹ Another distinguishing factor of this intervention was the high retention rate of study participants (100%). The high retention rate is aligned with findings indicating that older primary care patients are more likely to be engaged in integrated care than other forms of care provision⁷⁰ and integrated care models are particularly effective in improving access to and participation in mental health services among African American primary care patients.²¹

Interventions to narrow ethnic disparities have addressed patient-level, health care system-level, and community-level factors. This study sought to modify the health behaviors of individual patients and evaluated the effectiveness of a relatively brief pilot randomized controlled trial with a focus on adherence for the management of Type 2 DM as well as depression in older African-American primary care patients. Further research is needed to

evaluate this intervention in a larger, more representative sample, with longer periods of follow-up. Although statistically significant clinical outcomes were found at 12 weeks, the pilot results did not provide information on how long the improvement might continue or the maximal improvement. Finding similar results in a larger sample over a longer follow-up period would provide information for primary health care practices and providers on possible approaches to the care of depressed older African-Americans with Type 2 DM.

Implications for Practice

Depressed older African-Americans with Type 2 DM randomized to an integrated care intervention in comparison with depressed older African-Americans with Type 2 DM randomized to usual care demonstrated improved medication adherence and clinical outcomes. Because the sample was derived from primary health care, the public health significance is high. Further research supporting the extent of the clinical benefit of this intervention in primary care is the first step in implementing this type of program. Future investigations could explore enhancing and sustaining the effect of the intervention for example through the training of ancillary health personnel, such as Licensed Practical Nurses, who are already working in primary care practices to carry out the intervention. These findings should propel the development and dissemination of models of care that better integrate depression management for African-Americans with diabetes and other chronic conditions.

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Table 1

Sample characteristics at baseline (n=58). P-values represent comparisons according to Fisher's exact and Mann Whitney U tests for categorical or continuous data, respectively

	Intervention (n=29)	Usual Care (n=29)	P value
Sociodemographic characteristics			
Age, years (s.d.)	61.6 (8.3)	58.3 (6.3)	.26
Gender, women n (%)	24 (82.8%)	25 (86.2%)	.50
Less than HS education, n (%)	8 (27.6%)	5 (17.2%)	.27
Lives alone, n (%)	16 (55.2%)	11 (37.9%)	.15
SF-36 scores			
Physical function score, mean (s.d.)	43.8 (30.3)	55.3 (38.2)	.33
Social function score, mean (s.d.)	80.0 (29.8)	77.9 (39.8)	.46
Role physical score, mean (s.d.)	44.0 (39.9)	65.5 (42.5)	.05
Role emotional score, mean (s.d.)	66.7 (43.6)	79.3 (39.3)	.21
Bodily pain score, mean (s.d.)	46.2 (32.6)	55.2 (36.5)	.29
Other covariates			
MMSE, mean (s.d.)	27.2 (2.8)	28.3 (1.9)	.10
Number of medications, n (s.d.)	10.2 (3.3)	7.7 (3.2)	.03
Outcome measures			
Hb _{alc} , mean (s.d.)	7.3 (2.3)	7.3 (2.0)	.70
CES-D, mean (s.d.)	15.6 (11.7)	19.7 (16.7)	.47
≥ 80% adherent to oral hypoglycemic, n (%)	10 (34.5%)	6 (20.7%)	.19
≥ 80% adherent to antidepressant, n (%)	8 (27.6%)	4 (13.8%)	.17

Abbreviations: HS, high school; s.d., standard deviation; MMSE, Mini-Mental State Examination; Hb, Hemoglobin; CES-D, Center for Epidemiologic Studies Depression Scale.

Table 2

Adherence to oral hypoglycemic agents and antidepressants of older African-American participants in usual care and in the integrated intervention at 6 weeks. Glycemic control and depression symptoms of older African-American participants in usual care and in the integrated intervention at 12 weeks (n=58). P-values represent statistical tests employing Mann Whitney U tests for continuous measures and the Fisher's exact test for categorical variables

	Intervention (n=29)	Usual Care (n=29)	P value
Hb_{a1c} , mean (s.d.)	6.7 (2.3)	7.9 (2.6)	.019
CES-D , mean (s.d.)	9.6 (9.4)	16.6 (14.5)	.035
≥ 80% adherent to oral hypoglycemic , n (%)	18 (62.1%)	7 (24.1%)	.004
≥ 80% adherent to antidepressant , n (%)	18 (62.1%)	3 (10.3%)	<.001

Abbreviations: Hb, hemoglobin; CES-D, Center for Epidemiologic Studies Depression Scale; s.d., standard deviation.