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Psychosocial Factors Affecting Diabetes Self-Management

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ABSTRACT

As type 2 diabetes requires complex self-management behaviors to avoid long-term complications, it is crucial that practitioners understand the psychosocial factors that may affect diabetic patients' chronic disease self-management. Previous literature has identified depression and sleep disturbance as salient psychosocial factors that may impede self-management behaviors and lead to less favorable clinical biomarkers of diabetes self-management. We investigated the effects of undiagnosed depression, self-reported anxiety symptoms, diabetes distress, and obstructive sleep apnea on indicators of diabetes self-management through secondary analysis of a dataset including psychosocial, behavioral, and clinical measures from a sample of 667 diabetic patients at federally qualified health centers. It was found that depressive symptoms, regardless of diagnostic status, were associated with worse diabetes self-management, as were self-reported anxiety symptoms and diabetes distress. These relationships were not fully mediated by diabetes self-efficacy or diabetes knowledge. Obstructive sleep apnea was associated with worse medication adherence, even when controlling for measures of psychological distress. These findings suggest that primary care practitioners should routinely screen for depressive symptoms and obstructive sleep apnea risk factors and that further research is needed to determine the causal pathways linking these psychosocial risk factors to health-related outcomes for patients with type 2 diabetes.

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BACKGROUND AND SIGNIFICANCE

Type 2 diabetes is an increasingly urgent public health concern in the US and worldwide. It has been estimated that 9.3% of the US population carries a diagnosis of diabetes, which is considered to be the sixth leading cause of death for women and the fifth leading cause of death for men (CDC, 2014). In 2012, approximately 371 million people worldwide had received a diagnosis of diabetes, a number projected to increase to 552 million by the year 2030 (International Diabetes Federation, 2012; Maiorino, Bellastella, & Esposito, 2014; Wild, Roglic, Green, Sicree, & King, 2004). It is predicted that diabetes will continue to increase in prevalence, particularly among low-income populations, due to population growth, aging, urbanization, and higher rates of obesity and physical inactivity (Giraldi & Kristensen, 2010). Type 2 diabetes disproportionately affects low-income people and people of certain ethnic groups, including Native Americans, African Americans, Latinos, and Asian Americans (CDC, 2014). Therefore, better management and prevention of this chronic disease is not only a public health concern but a matter of social justice.

Type 2 diabetes accounts for 90-95% of all diabetes cases and is characterized by insulin resistance, a disorder in which muscle, liver, and fat cells do not effectively utilize insulin, resulting in a gradual loss of the ability of the pancreas to produce sufficient quantities of that hormone (CDC, 2014). Diabetes affects many different organ systems and may lead to severe complications when blood glucose levels are not well-controlled; potential complications of diabetes include heart disease, stroke, hypertension, blindness, kidney disease, and peripheral neuropathy necessitating lower-limb amputation (Campos, 2012; CDC, 2014). In many cases, these complications are highly preventable with proper adherence to medication, sufficient physical activity, a healthy diet, and routine self-monitoring of blood sugar. Thus, proper chronic

disease self-management is vital among patients with type 2 diabetes but is also cognitively demanding and behaviorally complex.

Previous research has attempted to elucidate the effects of a variety of psychosocial factors on diabetes self-management and clinical outcomes in an effort to identify points of potential intervention to optimize quality of life and minimize diabetes-related complications. From this body of research, depression and sleep disturbance (especially obstructive sleep apnea) have emerged as apparent risk factors for less favorable medical outcomes among patients with type 2 diabetes (Ali et al., 2010; Semenkovich, Brown, Svrakic, & Lustman, 2015; Souza et al., 2017). However, it is unclear based on the current body of research whether these relationships are mediated by biological pathways, behavioral pathways, or both. At present, the effectiveness of primary care providers in screening for these diabetes risk factors is unclear. Moreover, it is unclear how best to intervene in order to optimize diabetes self-management behaviors and medical outcomes.

The following three studies seek to add to the literature concerning psychosocial and behavioral factors affecting diabetes self-management. In developing the hypotheses to be tested, we considered two parallel conceptual frameworks: one conceptual framework modeling psychosocial determinants of health and health-related behaviors among individuals, and another at the systems-level addressing factors affecting healthcare delivery. Hypotheses across all three studies were derived from the Theory of Planned Behavior, which posits that behavioral intention tends to predict behavior, and that behavioral intention is determined by one's attitude, subjective norms, and perceived behavioral control (Ajzen, 1985). The Chronic Care Model was the conceptual framework employed to inform practice implications of our findings. The Chronic Care Model states that improved healthcare outcomes for patients with chronic diseases result

from productive interactions between informed, activated patients and prepared, proactive practice teams, which are determined by organizations of healthcare embedded within communities and subject to community-wide policies and resources (Wagner et al., 2001).

All of these studies are based on secondary analysis of data collected between August 2008 and January 2010 as part of a quasi-experimental, clinic-randomized comparison of two approaches to a diabetes self-management intervention. The dataset includes sociodemographic, psychological, behavioral, and clinical measures collected from over 600 patients with type 2 diabetes at six federally qualified health centers in Missouri.

In the first study, we sought to estimate the frequency of undiagnosed but clinically significant depressive symptoms among this sample of primary care patients with type 2 diabetes and to describe the sociodemographic characteristics of patients with clinically significant but undiagnosed depressive symptoms. Furthermore, we sought to investigate whether medication adherence, physical activity, and clinical biomarkers of health status appeared less favorable for those with undiagnosed but clinically significant depressive symptoms compared to other participants. The long-term goal of this research is to reduce the number of cases of undiagnosed but clinically significant depressive symptoms among patients with type 2 diabetes, allowing these patients to access appropriate mental health treatment to improve both their quality of life and their diabetes self-management.

The second study sought to explore the role of anxiety and diabetes distress as two additional mental health risk factors that may influence diabetes self-management, and to investigate whether diabetes self-efficacy and/or diabetes knowledge might mediate the relationships between mental health risk factors and diabetes self-management. The long-term

goal of this study is to inform future interventions designed to mitigate the effects of mental health symptoms on diabetes self-management outcomes.

Finally, the purpose of the third study was to estimate the frequency of obstructive sleep apnea in our sample of socioeconomically disadvantaged patients with type 2 diabetes and to clarify the relationship between obstructive sleep apnea, mental health risk factors, and behavioral self-management of diabetes. This research may assist in justifying more routine screening for obstructive sleep apnea within primary care settings and shaping behavioral interventions to reduce the impact of obstructive sleep apnea on diabetes self-management and clinical outcomes.

The following three studies are innovative because they may provide a more nuanced understanding of known risk factors for poor diabetes-related outcomes (depression and obstructive sleep apnea) as well as exploring less well-understood risk factors (including anxiety symptoms and diabetes-related distress). An additional strength of these studies is that they examine the effects of psychosocial and demographic factors on both behavioral outcomes (i.e. medication adherence and physical activity) and clinical biomarkers of health status (i.e. glycemic control, body mass index, cholesterol level, and blood pressure). These studies hold promise for informing future primary care interventions aimed at improving quality of life and health prognosis for people living with type 2 diabetes.

PART I:

Frequency and Associations of Undiagnosed but Clinically Significant Depressive Symptoms among Patients with Type 2 Diabetes

Introduction

Patients with chronic medical conditions and comorbid depressive disorders tend to experience their medical and psychiatric diagnoses as inter-related (DeJean, Giacomini, Vanstone, & Brundisini, 2013). Thus, it is not surprising that type 2 diabetes leads to psychological distress, because it carries the threat of potentially devastating complications and requires significant lifestyle modifications. Previous research has estimated that the prevalence of major depressive disorder as defined by the DSM-V is two to three times higher among patients with type 2 diabetes compared to non-diabetic patients, and that clinically significant depression results in a 65% increased risk of developing type 2 diabetes (American Psychiatric Association, 2013; Campayo et al., 2010; Roy & Lloyd, 2012; Roy, Lloyd, Pouwer, Holt, & Sartorius 2012). For patients with type 2 diabetes, clinically significant depressive symptoms may lead to worse medical outcomes, including worse glycemic control and higher incidence of diabetes-related complications (Ali et al., 2010; Lin et al., 2010).

A number of biological and behavioral pathways have been proposed to explain the relationship between depressive symptoms and glycemic control. Autonomic and neurohormonal dysregulation, weight gain, inflammation, and hippocampal structural alterations have been investigated as potential components of a shared biological etiology between type 2 diabetes and depressive disorders (Semenkovich et al., 2015). Clinically significant depressive symptoms have been found to be a risk factor for treatment nonadherence among patients with type 2 diabetes, suggesting that behavioral factors may also explain the relationship between depression and diabetes self-management outcomes (Gonzalez et al., 2008). Considering the multifaceted and bidirectional relationship between depression and type 2 diabetes, the International Diabetes Federation and American Diabetes Association have recommended that depressive symptoms

should be routinely assessed in primary care treatment of patients with type 2 diabetes (American Diabetes Association, 2016; International Diabetes Federation, 2012).

Despite the abundance of research linking diabetes and depression, it is unclear at present how effectively primary care providers may be screening for clinically significant depressive symptoms, particularly among low-income populations. In their literature review, Hermanns et al. (2013) concluded that current screening practices fail to detect mood symptoms among approximately half of diabetic patients with comorbid depression. Another literature review described current depression screening practices in primary care settings as unstructured, informal, "sporadic," and "opportunistic" (Holt & van der Feltz-Cornelis, 2012, pp. 72, 77). A recent secondary analysis of data collected from over 33,000 physician-patient encounters found that the overall rate of depression screening among general primary care populations was only 4.2% but was significantly higher for patients with chronic conditions (Akincigil & Matthews, 2017).

The present investigation sought to estimate the frequency of undiagnosed but clinically significant depression symptoms in a low-income sample of primary care patients with type 2 diabetes and to describe sociodemographic and health-related characteristics associated with undiagnosed but clinically significant depressive symptoms. In addition, associations between multiple indicators of depression (diagnostic status and endorsement of clinically significant depressive symptoms) and multiple indicators of diabetes self-management, including behavioral factors (medication adherence and physical activity) and clinical biomarkers (glycemic control, body mass index, low-density lipoprotein cholesterol, and blood pressure) were investigated.

In light of the socioeconomically disadvantaged, safety-net population from which the dataset was collected, it was expected that many patients without any documentation of a

depressive diagnosis would endorse clinically significant depressive symptoms. It was hypothesized that participants endorsing undiagnosed but clinically significant depressive symptoms would in general exhibit worse medication adherence and glycemic control, would be less physically active, and would have higher BMI, LDL cholesterol, and blood pressure when compared to other participants.

Methods

This study utilized baseline data collected as part of a randomized controlled trial of a Diabetes Guide educational intervention funded by the Missouri Foundation for Health. Participants in this randomized controlled trial were recruited from six federally-qualified outpatient health centers across three different sites in Missouri. More detailed information about the development and application of the Diabetes Guide intervention has been published elsewhere (Wolf et al., 2014).

Participants

Eligibility: Participation in the study was limited to English-speaking patients 30 years of age or older. All participants had received a prior diagnosis of type 2 diabetes as indicated by their electronic medical record. All participants had at least three prior visits to the clinic from which they were recruited. Visual impairment, hearing impairment, and moderate to severe cognitive deficits were considered exclusionary criteria for participation in this study.

Recruitment and informed consent procedures: Recruitment occurred between August 2008 and January 2010. During that time, staff at each of the six federally qualified clinics worked with research assistants to initiate contact with potential participants and obtain informed consent. Patients whose medical charts included a documented diagnosis of type 2 diabetes were mailed a letter describing the study and instructions for how to opt-out of participation. Those

who did not opt-out were contacted by research assistants and asked for their consent. A total of 671 patients were enrolled in the trial, with 661 patients having complete data for this study's analysis. The remaining 10 patients dropped out of the study before baseline interviews were conducted. The Northwestern University Institutional Review Board, University of Missouri-Columbia, and an independent review board (Copernicus, Raleigh, NC) approved study procedures.

Assessment Procedures and Measures

All measures were administered by phone and in person at baseline, using existing, validated instruments and self-report questionnaires. Sociodemographic characteristics of participants were assessed by self-report, as participants were asked to self-identify age, sex, race, income, and highest education level completed.

The dependent variables of the analysis were clinical biomarkers of health status, self-reported medication adherence, and self-reported physical activity level. Clinical biomarkers of health status (including HbA1c, BMI, LDL cholesterol, and systolic blood pressure) were extracted from medical records at the closest possible date to the administration of baseline questionnaires (within 6 months prior or 2 weeks afterwards). BMI, HbA1c, LDL cholesterol, and blood pressure were measured both as continuous variables and as dichotomous categorical variables. Cutoff points for determining categorical variables represented the range of values considered healthy or well-controlled according to the current standards when data was collected. (American Diabetes Association, 2010; National High Blood Pressure Education Program, 2004). Due to the unique variability of systolic blood pressure compared to the other indicators of health status, the three blood pressure readings closest to the date of baseline

measures (within 6 months prior or 2 weeks afterwards) were extracted from patients' electronic medical records and the mean of these three readings was the value used in analysis.

Self-reported medication adherence was assessed using the Morisky Medication Adherence Scale, a 4-item measure intended to capture both intentional and unintentional nonadherence to medication regimen in order to classify patients as having either low or high medication adherence (Morisky, Green, & Levine, 1986). Scores with three or more positive item responses are considered to indicate high medication adherence. The Morisky Medication Adherence Scale has been found to be a reliable instrument (Cronbach's $\alpha = 0.61$) with predictive and concurrent validity of 0.75 and 0.60, respectively (Morisky, Green, & Levine, 1986).

Participants' level of physical activity was assessed using a scale from the Behavioral Risk Factor Surveillance System (BRFSS) and categorized as either meeting US recommendations or not (with the recommended/sufficient amount defined as at least 30 minutes per day, 5 days per week). A systematic review of publications assessing reliability and validity of the BRFSS found the physical activity scale to be reliable ($\kappa = 0.60$) and valid (Pierannunzi, Hu & Balluz, 2013).

For each patient, a manual medical chart review was conducted to screen for any documented diagnosis of a depressive disorder in the past year. Current depressive symptoms were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) for Depression, an 8-item questionnaire for measuring the severity of depressive symptoms over the past week. This questionnaire was developed using Item Response Theory and demonstrates favorable psychometric properties (Cronbach's $\alpha = 0.96$, $r = 0.72$-0.83). The PROMIS Depression assesses the following domains of depression: low mood (dysphoria), poor

self-image (self-criticism, feelings of worthlessness), and social factors (loneliness, interpersonal alienation), as well as decreased positive affect and engagement (anhedonia). Somatic symptoms of depression (i.e. sleep disturbance and changes in appetite) are not included in the PROMIS Depression, thus eliminating confounding effects of these symptoms when assessing patients with comorbid medical conditions (Cella et al., 2010; Pilkonis et al., 2014).

Patients considered to meet criteria for "clinically significant" depressive symptoms were those who received a T-score of 60 or above on the PROMIS Depression. Although the PROMIS Depression was not developed as a diagnostic tool, previous studies have suggested that a T-score of 60 represents a reasonable cutoff point for symptoms of clinical significance (Cella et al., 2014; Choi, Chalet, Cook, & Cella, 2014; Pilkonis, et al., 2014). This cutoff point represents one standard deviation higher than the mean of the norming sample. Using this cutoff point, participants were divided into two groups based on their PROMIS Depression scores: those with clinically significant depressive symptoms and those without clinically significant depressive symptoms. These two groups were divided further based on whether "problem lists" in participants' medical charts included a diagnosis of a depressive disorder in the past year. Thus, the resulting four "depression groups" (the primary independent variable of the investigation) were as follows:

Group 1 (No symptoms/No diagnosis): Participants reporting no depressive symptoms or non-clinically-significant depressive symptoms (as indicated by PROMIS Depression $T < 60$) and for whom no documented depression diagnosis was found in medical records from the past year.

Group 2 (Symptoms/No diagnosis): Participants reporting significant depressive symptoms (as indicated by PROMIS Depression T ≥ 60) but for whom no documented depression diagnosis was found in the past year. This group may be understood as potentially reflecting those with undiagnosed but clinically significant depressive symptoms.

Group 3 (No symptoms/Diagnosis): Participants reporting no depressive symptoms or non-clinically-significant depressive symptoms (as indicated by PROMIS Depression T < 60) but for whom a documented depressive diagnosis was found in the past year. This group may be understood as potentially reflecting those with well-treated or well-controlled depressive conditions, or those with histories of incorrectly diagnosed depressive disorders (i.e. "false positives").

Group 4 (Symptoms/Diagnosis): Patients reporting depressive symptoms of clinical significance (as indicated by PROMIS Depression T ≥ 60) and for whom a documented depression diagnosis was found in the past year. This group may be understood as potentially reflecting those for whom receiving a prior diagnosis of a depressive condition did not result in adequate treatment for symptoms to remit to a non-significant level.

Statistical Analysis

The four "depression groups" outlined above were compared with respect to demographic characteristics (age, sex, race, education, and income), as well as indicators of diabetes self-management and health status (medication adherence, physical activity, BMI, HbA1c, LDL cholesterol, and blood pressure) using Pearson's chi-square and ANOVA. Bivariate associations that were found to be significant would then be used to build multivariable

models statistically controlling for demographic factors found to differ significantly across the four depression groups using logistic and linear regression.

Although the primary independent variable of interest was membership to the four depression groups, exploratory analyses were also conducted using presence of clinically significant depressive symptoms, presence of a documented depressive diagnosis, and severity of depressive symptoms as independent variables and each of the indicators of diabetes self-management and health status (medication adherence, physical activity, BMI, HbA1c, LDL cholesterol, and blood pressure) as dependent variables.

All statistical analyses were conducted using STATA software version 14.1 (StataCorp, College Station, TX).

Results

See Table 1.1 for demographic characteristics of the overall sample. The average age of participants was 56.0 years (SD=11.4). Most participants were female (63%), and the sample was predominantly White (66%). The majority of participants reported an annual household income lower than $15,000 (57%). College graduates represented a minority of the sample (14%).

Distribution of Depression Groups

Of the entire sample, 21% endorsed clinically significant depressive symptoms (as evidenced by a PROMIS Depression T-score of 60 or higher), and 34% were found to have a documented diagnosis of a depressive disorder. The majority of participants (60%) had neither clinically significant depressive symptoms nor a documented depressive diagnosis (Group 1, No symptoms/No diagnosis). Among the participants who endorsed clinically significant depressive symptoms, 39% had no documented diagnosis of a depressive disorder. Thus, 8% of the total

sample fell into the group potentially representing participants with undiagnosed but clinically significant depressive symptoms (Group 2, Symptoms/No diagnosis). Participants who endorsed few or no depressive symptoms but were found to have a documented depressive diagnosis represented 19% of the sample (Group 3, No symptoms/Diagnosis). Finally, 13% of participants exhibited both clinically significant depressive symptoms and a documented depressive diagnosis (Group 4, Symptoms/Diagnosis).

Mean depression scores (PROMIS) were found to differ significantly across the four depression groups ($F = 297.55$, $\eta^2 = 0.58$, $p < 0.0001$). Post hoc tests using a Bonferroni correction showed all pairwise comparisons to be significant ($p < 0.001$) except between Groups 2 and 4 ($p = 0.160$). Therefore, among those who endorsed clinically significant depressive symptoms, there was no significant difference in severity of symptoms between those who had received a diagnosis (Group 4) and those who had not (Group 2). See Table 1.2 for means and standard deviations of PROMIS Depression scores for each of the four depression groups.

Demographic Characteristics of Depression Groups

Age ($F = 7.4$, $p < 0.001$), sex ($\chi^2 = 22.3$, $p < 0.001$), and income ($\chi^2 = 37.9$, $p < 0.001$) were found to differ significantly across the four depression groups (see Table 1.1). Post hoc tests using a Bonferroni correction showed that individuals in Group 1 (No symptoms/No diagnosis) were significantly older than those in the other three groups ($p < 0.01$). Males were disproportionately represented in Group 2 (Symptoms/No diagnosis) compared to the other three groups ($p < 0.001$). Females ($p < 0.001$) were disproportionately represented in Group 4 (Symptoms/Diagnosis) compared to Group 1 (No Symptoms/No Diagnosis) and Group 2 (Symptoms/No diagnosis). Group 1 (No symptoms/No diagnosis) was significantly higher-earning than all other groups ($p < 0.01$).

Indicators of Diabetes Self-Management and Health Status among Depression Groups

The majority of the overall sample evidenced poor diabetes self-management behaviors and less than optimal clinical biomarkers of health status (see Table 1.3). Approximately two thirds of participants (66%) were classified as reporting low medication adherence. Likewise, approximately two thirds of participants (66%) reported insufficient levels of physical activity. Only 6% of participants were found to be in the healthy BMI range. Participants with well-controlled HbA1c (28%) and blood pressure (29%) represented a minority of the sample.

None of the self-management indicators or clinical outcomes investigated (medication adherence, physical activity, BMI, glycemic control, LDL cholesterol, and blood pressure), were found to differ significantly across the four depression groups (see Table 1.3).

Exploratory Analyses

Although no meaningful differences were identified across depression groups with respect to diabetes self-management behaviors or health status indicators, we went on to explore the main effects of each of the variables used to construct the four depression groups. We repeated the above bivariate analyses using the following independent variables: presence of a depressive diagnosis (as indicated by chart review), endorsement of clinically significant depressive symptoms (as indicated by PROMIS Depression T ≥ 60), and severity of current depressive symptoms (as indicated by PROMIS Depression T-score analyzed as a continuous variable). The presence of a depressive diagnosis was not found to be associated with any self-management indicators or clinical outcomes. Endorsement of clinically significant depressive symptoms was associated with low medication adherence (χ^2=6.66, OR = 1.75, $p < 0.01$) but was not associated with any other self-management indicators or clinical outcomes.

Participants classified as having low medication adherence received higher depression scores on average (t = 3.55, Cohen's $d = 0.29$, $p < 0.001$) as did those with insufficient physical activity (t = 2.31, Cohen's $d = 0.19$, $p < 0.05$). Logistic regression clustered by clinic showed that severity of depressive symptoms was significantly associated with low medication adherence and insufficient physical activity when age, sex, race, education, income, number of years with diabetes, and diagnostic status were included in the models (medication adherence: OR = 0.97, 95% CI = 0.96-0.99, $p < 0.01$; physical activity: OR = 0.97, 95% CI = 0.97-0.98, $p < 0.001$). The effect sizes were small for each of these findings despite statistically significant *p*-values.

Higher depression scores were weakly but significantly associated with higher BMI (Pearson's $r = 0.09$, $p < 0.05$). Linear regression clustered by clinic showed that the association between severity of depressive symptoms and BMI was attenuated to a non-significant level when age, sex, race, education, income, number of years with diabetes, and diagnostic status were included in the model as covariates (B = 0.05, 95% CI = -0.067-0.167, $p = 0.370$).

Discussion

This study sought to estimate the frequency of undiagnosed but clinically significant depressive symptoms among a safety-net sample of primary care patients with type 2 diabetes, to describe the demographic characteristics of patients with undiagnosed but clinically significant depressive symptoms, and to investigate whether these patients exhibited worse diabetes self-management behaviors and health-related outcomes than others in the sample.

We found that among community-based primary care practices serving vulnerable patient populations, nearly 1 in 4 patients reported current depressive symptoms of clinically significant severity. Yet, approximately 40% of patients with clinically significant depressive symptoms in our sample were not recognized as having received a diagnosis of a depressive condition,

suggesting inadequate depression screening practices within primary care settings. Patients with clinically significant but undiagnosed depressive symptoms represented approximately 8% of the total sample in this investigation.

From the results of this study, it appears that being female is a risk factor for having more severe depressive symptoms, but that being male is a risk factor for having clinically significant yet undiagnosed depressive symptoms. Considering the paucity of participants in this sample self-identifying as Hispanic/Latino, Asian, or "other race," the study was underpowered to detect statistically significant relationships between race and the presence of undiagnosed but clinically significant depressive symptoms.

Regardless of whether undocumented depression predicted worse diabetes-related outcomes, the results of this study show that a substantial number of patients are potentially missing out on the opportunity to receive treatment for their depressive symptoms. Identifying these patients and appropriately documenting their depressive diagnoses is an important step towards connecting them to appropriate mental health services, thus improving their functioning and quality of life, if not their diabetes self-management.

While the results of our investigation did not show that patients with undiagnosed but clinically significant depressive symptoms exhibited significantly worse diabetes self-management behaviors or less favorable clinical biomarkers of health status than other groups, our findings supported previous research linking depression to worse diabetes outcomes. Severity of depressive symptoms (regardless of diagnostic status or threshold of clinical significance) was found to be associated with insufficient physical activity, low medication adherence, and higher BMI in our sample. This finding suggests that symptom management may be an appropriate goal of treatment of depression in primary care settings.

Future research seeking to replicate the four depression groups used in this study may consider reviewing medical charts in full for any mention of depression, rather than relying solely on diagnostic codes appearing in patients' problem lists. Future studies in this domain might also compare depressive symptoms occurring in the context of different diagnostic categories in affecting diabetes-self management. For example, it would be useful to know whether depressive symptoms occurring in the context of a bipolar disorder, an adjustment disorder, postpartum depression, or major depressive disorder might affect diabetes self-management differently compared to depressive symptoms occurring in the context of a persistent depressive disorder.

In general, there were few patients in our sample exhibiting high medication adherence, sufficient physical activity, healthy BMI, and well-controlled HbA1c, LDL cholesterol, and blood pressure. This finding underscores the vulnerable and underserved nature of populations seeking care at federally qualified health centers and the ways in which socioeconomic disadvantage may translate to worse health outcomes and ultimately worse medical prognosis. Systemic barriers to accessing adequate healthcare must be addressed in order to improve clinical outcomes among socioeconomically disadvantaged populations. Future studies may consider using positive deviance methodologies to explore the factors contributing to successful diabetes self-management among the few patients who exhibited favorable indicators of health status (Bradly, Curry, & Ramanadhan, 2009). Considering the limited number of patients in our sample exhibiting favorable diabetes self-management behaviors and indicators of health status, our study may have been underpowered to uncover associations between undiagnosed depression and worse clinical outcomes.

A number of additional limitations must be considered in interpreting the results of this study. First, the cross-sectional design of the analysis limits our ability to make causal inferences about the relationship between depressive symptoms, diabetes self-management behaviors, and clinical biomarkers. It is possible that depressive symptoms could limit patients' ability and motivation to adhere to a diabetes self-management regimen. However, it is also possible that depressive symptoms could arise as a result of the challenges and frustrations of living with a poorly-managed chronic disease. Other factors, such as obesity, could predispose patients to both depressive symptoms and worse health-related outcomes. Previous researchers have already commented on the bidirectional relationship between diabetes and depression (e.g. Golden et al., 2008; Penckofer, Doyle, Byrn, & Lustman, 2014).

Another notable limitation of this study was the potential lack of validity in constructing the four depression groups and labeling them as such. It is possible that participants could have been diagnosed with depression by a provider outside of their primary care clinic without communicating that information to their primary care clinic. It is also possible that those labeled as having clinically significant but undiagnosed depressive symptoms had not yet had the opportunity to be diagnosed if their depressive symptoms were new in the past week. Likewise, the medical chart extraction from which depressive diagnoses were determined only included diagnostic codes from the previous year. Therefore, it is possible that someone who had received a depressive diagnosis more than a year ago might be considered "undiagnosed" in this study. Notably, among those who endorsed clinically significant depressive symptoms, there was no statistically significant difference found in severity of depressive symptoms between those who had received a diagnosis of depression and those who had not. This finding addresses the

potential limitation that participants in Group 2 (Symptoms/No diagnosis) might be rightfully undiagnosed because their symptoms were not severe enough to merit a depressive diagnosis.

Further research, ideally in the form of longitudinal studies including both psychosocial measures and clinical biomarkers, would be needed to definitively elucidate causal pathways linking depression to diabetes self-management and medical outcomes. Likewise, randomized controlled interventional studies would be needed to demonstrate whether treatment of depression results in more favorable medical outcomes for patients with type 2 diabetes. Considering that our study found depression symptom severity (as opposed to having met a clinical threshold) to be associated with diabetes self-management, it would also be interesting to test whether an evidence-based depression treatment (such as manualized CBT) might improve diabetes outcomes even for patients who do not experience clinically significant distress or impairment from mood symptoms.

Despite the limitations of this investigation, its key findings may inform best practices for routine depression screening in primary care settings serving patients with type 2 diabetes. Primary care settings, particularly those serving socioeconomically disadvantaged patients, could benefit from more effective and standardized routine screenings for depressive symptoms.

Conclusions

This study revealed a high frequency of cases of undiagnosed but clinically significant depressive symptoms among a low-income sample of patients with type 2 diabetes. In screening for depressive symptoms among populations with type 2 diabetes, medical providers should be especially thorough in assessing depressive symptoms among men and among patients who are low-income and less educated. Depressive symptoms, regardless of whether or not they are diagnosed, may contribute to worse diabetes self-management.

PART II:

Diabetes Self-Efficacy as a Potential Mediator of the Relationship between Mental Health Risk Factors and Diabetes Self-Management

Introduction

Successful management of type 2 diabetes often requires patients to modify longstanding aspects of their lifestyle, including physical activity, diet, weight management, and adherence to medication and self-monitoring schedules. As management of type 2 diabetes is behaviorally complex, it is perhaps unsurprising that recent and longstanding research findings have demonstrated associations between a variety of mental health risk factors and poor diabetes self-management.

Previous research has identified depression, anxiety, and diabetes-related distress as three mental health risk factors in particular that may impede diabetic patients' ability to perform diabetes self-management behaviors and thus to enjoy better health-related outcomes (Fisher et al., 2008). Both depressive symptoms and anxiety symptoms have been found to be independently associated with treatment nonadherence and poor glycemic control among patients with type 2 diabetes (Gonzalez et al., 2008; Kendzor et al., 2014). Previous research has also suggested that patients experiencing these mental health risk factors tend to be less physically active than non-depressed controls (Schuch et al., 2017). Moderate and high levels of diabetes distress, a construct measuring the emotional distress associated with various aspects of living with diabetes, have been found to be associated with poor medication adherence, poor glycemic control, high blood pressure and high LDL cholesterol (Pandit et al., 2014).

By contrast, diabetes self-efficacy and diabetes knowledge have been shown to be associated with improved behavioral self-management, glycemic control, and clinical biomarkers of health among patients with diabetes (Al-Qazaz et al., 2011; Lee et al., 2016). Diabetes self-efficacy refers to the degree to which patients feel confident in their ability to manage their diabetes (Grinslade, Paper, Jing, & Quinn, 2015). Diabetes knowledge, which is often the

primary goal of diabetes education interventions, refers to patients' understanding of the biological underpinnings of diabetes and how to manage diabetes as a chronic condition (Eigenmann, Skinner, & Colagiuri, 2011).

The purpose of this study was to investigate the role of diabetes self-efficacy as an explanatory factor that may potentially mediate the relationship between mental health risk factors (depressive symptoms, anxiety symptoms, and diabetes distress) and successful self-management of type 2 diabetes (as evidenced by medication adherence, physical activity, and glycemic control and other clinical biomarkers). This finding would be consistent with the Theory of Planned Behavior, Social Cognitive Theory, and the Trans-Theoretical Model, all of which suggest that self-efficacy is a key determinant of health-related behavior and behavior change (Ajzen, 1985; Bandura, 1986; Prochaska & Velicer, 1997). By contrast, it is hypothesized that diabetes knowledge will be associated with better self-management (consistent with the Theory of Planned Behavior) but will not attenuate the relationships between mental health risk factors and diabetes self-management. The results of this study may inform interventions to reduce the impact of depression, anxiety, and diabetes distress on self-management and health outcomes among patients with type 2 diabetes.

Methods

This study utilized baseline data collected as part of a randomized controlled trial of a Diabetes Guide educational intervention funded by the Missouri Foundation for Health. Participants in this randomized controlled trial were recruited from six federally-qualified outpatient health centers across three different sites in Missouri. More detailed information about

the development and application of the Diabetes Guide intervention has been published elsewhere (Wolf et al., 2014).

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All measures were administered by phone and in person at baseline, using existing, validated instruments and self-report questionnaires. Sociodemographic characteristics of

participants were assessed by self-report, as participants were asked to self-identify age, sex, race, income, and highest education level completed.

The dependent variables in this study were medication adherence, physical activity level, BMI, HbA1c, LDL cholesterol, and systolic blood pressure.

Self-reported medication adherence was assessed using the Morisky Medication Adherence Scale, a 4-item measure intended to capture both intentional and unintentional nonadherence to medication regimen (Morisky, Green, & Levine, 1986) in order to classify patients as having either low or high medication adherence. Scores with three or more positive item responses are considered to indicate high medication adherence. The Morisky Medication Adherence Scale has been found to be a reliable instrument (Cronbach's $\alpha = 0.61$) with predictive and concurrent validity of 0.75 and 0.60, respectively (Morisky, Green, & Levine, 1986). Participants' level of physical activity was assessed using scales from the Behavioral Risk Factor Surveillance System (BRFSS) and categorized as either meeting US recommendations or not (with the recommended/sufficient amount defined as at least 30 minutes per day, 5 days per week). A systematic review of publications assessing reliability and validity of the BRFSS found the physical activity scale to be reliable ($\kappa = 0.60$) and valid (Pierannunzi, Hu & Balluz, 2013).

Clinical biomarkers of health status, including hemoglobin A1c (HbA1c), body mass index (BMI), low-density lipoprotein (LDL) cholesterol, and systolic blood pressure were extracted from medical records at the closest possible date to the administration of baseline questionnaires (within 6 months prior or 2 weeks afterwards). Due to the unique variability of blood pressure compared to the other indicators of health status, the three blood pressure readings closest to the date of baseline measures (within 6 months prior or 2 weeks afterwards)

were extracted from patients' electronic medical records and the mean of these three readings was the value used in analysis.

Depressive symptoms, anxiety symptoms, and diabetes distress were the mental health risk factors analyzed as independent variables in our analysis. Current depressive and anxiety symptoms were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS). The PROMIS Depression is a reliable and valid (Cronbach's $\alpha = 0.96$, $r = 0.72\text{-}0.83$) 8-item questionnaire for measuring the severity of depressive symptoms over the past week (Cella et al., 2010). The PROMIS Anxiety (Cronbach's $\alpha = 0.96$, $r = 0.80$) is a reliable and valid 7-item questionnaire for measuring the severity of anxiety symptoms such as fearfulness, worry, and tension during the past week (Cella et al., 2010).

Diabetes distress was assessed using the Diabetes Distress Scale, a 17-item tool administered during an in-person interview assessing emotional burden of diabetes, physician-related distress, interpersonal distress, and regimen-related distress. Patients were asked to rate the extent to which various aspects of living with diabetes have been problematic for them over the past month (Polonsky et al., 2005). The Diabetes Distress Scale has demonstrated strong reliability and validity (Cronbach's $\alpha = 0.87$, $r = 0.82$) in psychometric testing (Polonsky et al., 2005).

Diabetes self-efficacy and diabetes knowledge were analyzed as potential mediators of the relationships between each of the independent and dependent variables of the study. Diabetes self-efficacy was evaluated using the Diabetes Self-Efficacy Scale, a reliable and valid 8-item questionnaire in which participants were asked to rate their level of confidence in performing a variety of self-care activities related to diabetes management (Sarkar, Fisher, & Schillinger, 2006). Diabetes knowledge was assessed using the Diabetes Knowledge Questionnaire, a 24-

item instrument in which respondents were asked open-ended questions about parts of the body affected by diabetes, nutritional information, and blood sugar, resulting in a score from 0-9 (Garcia, Villagomez, Brown, Kouzekanani, & Hanis, 2001). The Diabetes Knowledge Questionnaire has demonstrated strong reliability and validity (Cronbach's $\alpha = 0.78$, $r = 0.70$) in psychometric testing (Garcia et al., 2001).

Statistical Analysis

Bivariate analyses were conducted to determine the direction, magnitude, and significance level of associations between each of the mental health risk factors and each of the self-management indicators. The variables considered to be mental health risk factors were depressive symptoms (as indicated by PROMIS Depression T-score), anxiety symptoms (as indicated by PROMIS Anxiety T-score), and diabetes distress (as indicated by Diabetes Distress Scale score). The variables considered to be self-management indicators were medication adherence (low or high), physical activity level (recommended amount or less than recommended amount), BMI, HbA1c, LDL cholesterol, and systolic blood pressure.

Further bivariate analyses revealed the direction, magnitude, and significance level of associations between each of the mental health risk factors (depressive symptoms, anxiety symptoms, and diabetes distress) and each of the potential mediating factors (diabetes self-efficacy and diabetes knowledge). Additional bivariate analyses were then conducted to determine the direction, magnitude, and significance level of associations between each of the potential mediating factors (diabetes self-efficacy and diabetes knowledge) and each of the above-listed self-management indicators. Bivariate associations not found to be significant at the 0.05 level were excluded from further analyses.

Finally, linear and logistic regression models were constructed based on significant bivariate associations to determine whether relationships between each of the mental health risk factors (depressive symptoms, anxiety symptoms, and diabetes distress) and each of the self-management indicators (medication adherence, physical activity level, BMI, HbA1c, LDL cholesterol, and blood pressure) remained significant when each of the potential mediating factors (diabetes self-efficacy and diabetes knowledge) was added to the model as a covariate. We compared beta coefficients (for continuous outcomes) or odds ratios (for binary outcomes) to determine if, and to what extent, attenuation occurred when each of the potential mediating factors was included in the model as a covariate.

Results

See Table 2.1 for results of bivariate analyses of the relationships between each of the presumed mental health risk factors (depressive symptoms, anxiety symptoms, and diabetes distress) and each of the indicators of self-management (medication adherence, physical activity, BMI, HbA1c, LDL cholesterol, and systolic blood pressure). Depressive symptoms were found to be significantly associated with low medication adherence ($t = 3.55$, $p < 0.001$), insufficient physical activity ($t = 2.31$, $p < 0.05$), and higher BMI (Pearson's $r = 0.09$, $p < 0.05$). Depressive symptoms were not found to have a statistically significant relationship with HbA1c, LDL cholesterol, or blood pressure.

Anxiety symptoms were found to be associated with medication adherence, such that those in the low medication adherence group had significantly higher anxiety scores on average ($t = 4.31$, $p < 0.001$). Anxiety symptoms were not found to be associated with any other self-management indicators.

Diabetes distress, like depressive and anxiety symptoms, was associated with low medication adherence ($t = 4.35$, $p < 0.001$). Diabetes distress was also significantly associated with insufficient physical activity ($t = 2.17$, $p < 0.05$), higher BMI (Pearson's $r = 0.13$, $p < 0.01$), and higher HbA1c (Pearson's $r = 0.27$, $p < 0.001$). As with the other mental health risk factors, diabetes distress was not found to have a statistically significant relationship with either LDL cholesterol or blood pressure.

Table 2.1 also shows the results of bivariate analyses of the relationships between diabetes self-efficacy and diabetes knowledge and each of the self-management indicators. Diabetes self-efficacy was found to be significantly associated with high medication adherence ($t = -4.03$, $p < 0.001$), sufficient physical activity ($t = -3.07$, $p < 0.01$), lower HbA1c (Pearson's $r = -0.14$, $p < 0.001$), and higher systolic blood pressure (Pearson's $r = 0.08$, $p < 0.05$). Diabetes self-efficacy was not found to be significantly correlated with BMI or LDL cholesterol. Diabetes knowledge was not found to be significantly associated with any of the self-management indicators (medication adherence, physical activity, BMI, HbA1c, LDL cholesterol, or systolic blood pressure).

Diabetes self-efficacy was found to be significantly and negatively correlated with each of the three mental health risk factors ($p < 0.001$ for depressive symptoms, anxiety symptoms, and diabetes distress, see Table 2.2 for correlation coefficients). Diabetes knowledge was found to have no significant relationship with either depressive symptoms or anxiety symptoms, but was found to be significantly and positively correlated with diabetes distress ($p < 0.05$).

Bivariate relationships that were not found to be significant were not included in multivariable analyses. Because diabetes knowledge was not found to be associated with any of the self-management indicators in bivariate analyses, only diabetes self-efficacy was included in

multivariable models to test if it would attenuate relationships between mental health risk factors and self-management outcomes (see Table 2.3). All multivariable analyses statistically controlled for age, sex, race, income, education level, number of years with diabetes, and clustering effects by clinic.

Both depressive symptoms and anxiety symptoms were significantly associated with medication adherence in logistic regression models, such that a single unit increase in either score was associated with 3% lower odds of falling into the high medication adherence group (depressive symptoms: OR = 0.97, 95% CI = 0.96-0.99, $p < 0.01$; anxiety symptoms: OR = 0.97, 95% CI = 0.95-0.98, $p < 0.01$). Both of these relationships remained significant when diabetes self-efficacy was introduced into the models (depressive symptoms: OR = 0.98, 95% CI = 0.96-1.00, $p = 0.05$; anxiety symptoms: OR = 0.98, 95% CI = 0.95-0.99, $p < 0.05$). Likewise, diabetes distress was significantly associated with medication adherence, such that a single unit increase in diabetes distress score corresponded to 39% lower odds of high medication adherence (OR = 0.61, 95% CI = 0.50-0.74, $p < 0.001$). The association between diabetes distress and medication adherence was attenuated but remained statistically significant when diabetes self-efficacy was included in the model (OR = 0.70, 95% CI = 0.54-0.91, $p < 0.05$).

It was found that depressive symptoms were significantly associated with physical activity level in logistic regression models, as a single unit increase in PROMIS Depression score reduced the odds of falling into the sufficient physical activity group by 2% (OR = 0.98, 95% CI = 0.97-0.99, $p < 0.001$). Inclusion of diabetes self-efficacy into the model did not attenuate this relationship (OR = 0.98, 95% CI = 0.97-0.99, $p < 0.001$). Diabetes distress was also significantly associated with physical activity level. A single unit increase in diabetes distress corresponded to 26% lower odds of achieving the recommended level of physical

activity (OR = 0.74, 95% CI = 0.63-0.87, $p < 0.001$). The relationship between diabetes distress and physical activity was attenuated when diabetes self-efficacy was included in the model but remained statistically significant (OR = 0.84, 95% CI = 0.72-0.98, $p < 0.05$).

Diabetes distress was significantly associated with glycemic control in a linear regression model. A single unit increase in diabetes distress score was associated with an increase of 0.55 in HbA1c (B = 0.55, 95% CI = 0.36-0.73, $p < 0.001$). This relationship was not significantly attenuated when diabetes self-efficacy was introduced into the model (B = 0.49, 95% CI = 0.26-0.72, $p < 0.001$).

Discussion

Consistent with previous research, we found that severity of mental health symptoms was linked to poor diabetes self-management as indicated by low medication adherence, insufficient physical activity, higher BMI, and worse glycemic control. The findings of this study suggest that diabetes self-efficacy may be one of many pathways through which mental health symptoms affect self-management behaviors. Thus, self-efficacy can be a target for interventions aimed at reducing the impact of mental health symptoms on self-care for people with type 2 diabetes.

Perhaps surprisingly, it was found that diabetes knowledge did not correlate with any of the indicators of diabetes self-management. In other words, there was no association found between participants' understanding of facts about diabetes and participants' medication adherence, physical activity level, BMI, glycemic control, LDL cholesterol, or blood pressure. This result may seem surprising in light of copious amounts of literature demonstrating improved adherence and health outcomes resulting from diabetes education interventions (Loveman, Frampton, & Clegg, 2008). On the other hand, the finding that diabetes knowledge was not

associated with successful self-management in this study underscores previous research demonstrating that mere knowledge of medical recommendations is not enough to ensure healthy behaviors; this aspect of human behavior has been demonstrated in numerous contexts including among patients with diabetes (Tseng, Liao, & Chuang, 2017). Training patients with type 2 diabetes to have the skills necessary to manage their condition may help build their confidence, thus partially mitigating the deleterious effects of mental health symptoms on self-management behaviors and health-related outcomes. Our findings suggest that diabetes self-management interventions should be aimed at both teaching the skills necessary to manage diabetes and improving patients' confidence in their ability to use those skills. Diabetes self-management interventions that are exclusively educational may be less effective in improving adherence and health related outcomes than interventions that are both educational and motivational.

A number of limitations must be considered in interpreting the results of the present study. The observational nature of this data limits the ability to draw causal inferences about the associations between variables. As a result, it was not possible to state that mental health risk factors *predicted* poor diabetes self-management in this study; rather, it could only be stated that mental health risk factors were *associated* or *correlated* with poor diabetes self-management.

Although statistically significant bivariate associations were found between mental health risk factors and indicators of diabetes self-management, the strength of these correlations was considered either "weak" or "very weak" using traditional cutoffs for such descriptions of magnitude (Glasser & Winter, 1961). Although these bivariate relationships garnered statistically significant *p*-values, the effect sizes were small and of questionable clinical significance. Furthermore, considering that this investigation was concerned with identifying a possible mediator of such relationships (self-efficacy), it was more likely that full or partial mediation of

such relationships could be achieved because they were already weak before self-efficacy was even introduced into the model. Little, Card, Bovaird, Preacher, and Crandall warn that "…the smaller an effect is, the easier it is to fully mediate it…It can be misleading to claim that an inconsequential but statistically significant effect is 'fully mediated'" (2007, p. 211). Although the results of this study suggest partial mediation of the relationship between some mental health risk factors and some aspects of diabetes self-management, further research will be needed to determine what other factors (in addition to self-efficacy) may mediate such relationships.

The results of this investigation suggest that improving diabetic patients' self-efficacy may be an important goal towards ensuring treatment adherence and sufficient physical activity, especially for patients identified as experiencing mental health risk factors such as depressive symptoms, anxiety symptoms, or diabetes distress. Thus, for diabetic patients experiencing depressive symptoms, anxiety symptoms, diabetes distress, or some combination of those mental health risk factors, providing interventions aimed at bolstering confidence and hopefulness may lead to improved medication adherence and sufficient physical activity.

Conclusion

Depressive symptoms, anxiety symptoms, and diabetes distress may be considered mental health risk factors for poor diabetes self-management. The relationship between mental health risk factors and diabetes self-management appears not to be fully mediated by diabetes self-efficacy. Yet, interventions aimed at improving diabetes self-efficacy may be more effective than purely educational or informational interventions in producing better clinical outcomes.

PART III:

Investigating Obstructive Sleep Apnea as a Risk Factor for Poor Diabetes Self-Management

Introduction

It has been estimated that obstructive sleep apnea (OSA), a chronic condition characterized by upper airway occlusion during sleep, affects 3% to 7% of the population (Punjabi, 2008). OSA is disproportionately common among patients with type 2 diabetes, with prevalence estimates ranging from 30% to 72% within that population (Souza et al., 2017; Westlake et al., 2016). Recent research has suggested that OSA is a risk factor for the development of type 2 diabetes as well as a risk factor for worse glycemic control among diabetic patients (Wang, Bi, Zhang & Pan, 2013). Short sleep duration and OSA may be considered newly identified risk factors for type 2 diabetes comparable to traditional and familiar risk factors including hypertension, dyslipidemia, physical inactivity, or family history of diabetes, and it has been suggested that OSA and short sleep duration should therefore be screened accordingly in primary care settings (Anothaisintawee et al., 2016).

Several studies to date have focused on biological pathways explaining the relationship between OSA and type 2 diabetes, including the role of sleep duration in the metabolism of glucose and regulation of appetite (Beihl, Liese, & Haffner, 2009; Vgontzas, Liao, Pejovic, Calhoun, Karataraki, & Bixler, 2009), and the role of intermittent hypoxia and sleep fragmentation, the two major characteristics of OSA, in activation of the sympathetic nervous system, hypothalamic-pituitary axis, hypoxic injury to the pancreas, and changes in the inflammatory pathways (Malik, Masoodi, & Shoib, 2017). There is evidence to suggest that the use of continuous positive airway pressure (CPAP) to prevent occlusion of the upper airway during sleep may lead to improved glycemic control among diabetic patients with OSA (Chen et al., 2017; Malik et al., 2017).

However, it is reasonable to suspect that behavioral factors may at least in part explain the relationship between OSA and management of type 2 diabetes as a chronic disease, because daytime fatigue resulting from untreated OSA may affect domains such as learning, short-term memory, attention, processing speed, and mood (Boonstra, Stins, Daffertshofer, & Beek, 2007). Psychological distress may contribute to poor behavioral self-management of diabetes, but previous research has revealed mixed conclusions about the relationship between OSA and psychological distress; some evidence supports OSA as a significant risk factor for both depressive symptoms and anxiety symptoms (Kerner & Roose, 2016), but this finding has not been universally supported (Asghari, Mohammadi, Kamrava, Tavakoli, & Farhadi, 2012).

The present investigation sought to further explore the relationship between OSA and behavioral self-management of diabetes. The purpose of this study was to investigate the associations between OSA and a number of indicators of behavioral self-management of diabetes (i.e. medication adherence, physical activity, and glycemic control). Furthermore, the present study sought to investigate the relationship between OSA and depressive and anxiety symptoms as well as diabetes distress, and to clarify the potential role of such mental health symptoms in affecting the relationship between OSA and behavioral self-management of diabetes.

Methods

This study utilized data collected as part of a randomized controlled trial of a Diabetes Guide educational intervention funded by the Missouri Foundation for Health. Participants in this randomized controlled trial were recruited from six federally-qualified outpatient health centers across three different sites in Missouri. More detailed information about the development and application of the Diabetes Guide intervention has been published elsewhere (Wolf et al., 2014).

Participants

Eligibility: Participation in the study was limited to English-speaking patients 30 years of age or older. All participants had received a prior diagnosis of type 2 diabetes as indicated by their electronic medical record. All participants had at least three prior visits to the clinic from which they were recruited. Visual impairment, hearing impairment, and moderate to severe cognitive deficits were considered exclusionary criteria for participation in this study.

Recruitment and Informed Consent Procedures: Recruitment occurred between August 2008 and January 2010. During that time, staff at each of the six federally qualified clinics worked with research assistants to initiate contact with potential participants and obtain informed consent. Patients whose medical charts included a documented diagnosis of type 2 diabetes were mailed a letter describing the study and instructions for how to opt-out of participation. Those who did not opt-out were contacted by research assistants and asked for their consent. A total of 671 patients were enrolled in the trial, with 575 patients having complete data for this study's analysis due to patient dropout between enrollment and the time-point at which OSA risk was measured. Of the 96 patients who dropped out, 10 dropped out immediately after enrollment and the remaining 86 dropped out after initial baseline measures were collected. Analysis of missing data showed that the remaining 86 patients for whom some amount of baseline data was collected did not differ systematically from the rest of the sample on any sociodemographic or psychosocial variables. The Northwestern University Institutional Review Board, University of Missouri-Columbia, and an independent review board (Copernicus, Raleigh, NC) approved study procedures.

Assessment Procedures and Measures

Demographic data was collected from each participant by means of a self-report demographic questionnaire. Participants were asked to self-identify age, sex, race, income, and highest education level completed.

OSA risk was measured as a proxy for OSA using the Berlin Sleep Questionnaire, a 10-item survey of the presence and severity of snoring symptoms, daytime sleepiness, fatigue, and history of hypertension or obesity (Netzer, Stoohs, Netzer, Clark, & Strohl, 1999). This tool uses participants' responses to determine whether they are "positive" for each of three categories. The first category assesses frequency, intensity, and functional consequences of snoring. The second category assesses frequency, intensity, and functional impairments associated with daytime fatigue. Finally, the third category yields a positive score for those who self-report high blood pressure or who have a BMI > 30. Participants were determined to be at high risk for OSA if they scored positive on two or more of the three risk categories assessed by the Berlin Sleep Questionnaire. Previous research has suggested that the results of the Berlin Sleep Questionnaire are comparable to those of polysomnography in the diagnosis of OSA (Stelmach-Mardas, Iqbal, Mardas, Kostrzewska, & Piorunek, 2017). Multiple studies to date have used OSA risk as determined by the Berlin Sleep Questionnaire as a proxy for the presence of OSA in predicting clinical outcomes (e.g. Correia et al., 2012; Ghazal, Roghani, Sadeghi, Amra, & Kermani-Alghoraishi, 2015, Maia et al., 2017). This instrument has demonstrated strong reliability (Cronbach's $\alpha = 0.75$), validity ($r = 0.81$), specificity, and sensitivity in psychometric testing (Stelmach-Mardas et al., 2017).

Self-reported medication adherence was assessed using the Morisky Medication Adherence Scale, a 4-item measure intended to capture both intentional and unintentional

nonadherence to medication regimen (Morisky, Green, & Levine, 1986) in order to classify patients as having either low or high medication adherence. Scores with three or more positive item responses are considered to indicate high medication adherence. The Morisky Medication Adherence Scale has been found to be a reliable instrument (Cronbach's $\alpha = 0.61$) with predictive and concurrent validity of 0.75 and 0.60, respectively (Morisky, Green, & Levine, 1986).

Participants' level of physical activity was assessed using scales from the Behavioral Risk Factor Surveillance System (BRFSS) and categorized as either meeting US recommendations or not (with the recommended/sufficient amount defined as at least 30 minutes per day, 5 days per week). A systematic review of publications assessing reliability and validity of the BRFSS found the physical activity scale to be reliable ($\kappa = 0.60$) and valid (Pierannunzi, Hu & Balluz, 2013). Glycemic control was assessed by HbA1c measurements extracted from patients' electronic medical records at the closest available time point (within 6 months prior or 2 weeks afterwards) to the date that other measures were administered.

Current depressive and anxiety symptoms were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS). The PROMIS Depression is an 8-item questionnaire for measuring the severity of depressive symptoms over the past week. The PROMIS Anxiety (Cronbach's $\alpha = 0.96$, $r = 0.80$) is a 7-item questionnaire for measuring the severity of anxiety symptoms such as fearfulness, worry, and tension during the past week (Cella et al., 2010).

Diabetes distress was assessed using the Diabetes Distress Scale, a 17-item tool administered during an in-person interview assessing emotional burden of diabetes, physician-related distress, interpersonal distress, and regimen-related distress. Patients were asked to rate

the extent to which various aspects of living with diabetes have been problematic for them over the past month (Polonsky et al., 2005). The Diabetes Distress Scale has demonstrated strong reliability and validity (Cronbach's $\alpha = 0.87$, $r = 0.82$) in psychometric testing (Polonsky et al., 2005).

Statistical Analysis

Bivariate analyses were used to first examine associations between OSA risk, demographic characteristics, behavioral self-management indicators (medication adherence, physical activity, and glycemic control), depressive symptoms, anxiety symptoms, and diabetes distress. Bivariate relationships that were not significant were excluded from further analyses. Multivariable logistic and linear regression models were used to determine whether the relationships between OSA risk and medication adherence, physical activity, and glycemic control were significant with and without statistically controlling for depressive symptoms, anxiety symptoms, and diabetes distress. These models statistically controlled for the covariates of age, sex, race, income, education level, and number of years with diabetes.

Results

The sample included 671 participants, with 575 participants having complete data for this study's analysis. See Table 3.1 for demographic characteristics of the 575 participants with complete data for the present analysis. The average age of participants was 54 years (standard deviation=10.93). The sample was predominantly female (65%) and most participants were White (64%). The majority of participants (60%) reported an annual household income lower than $15,000. College graduates represented a minority of the sample (14%). No significant demographic differences were found between the low and high OSA risk groups.

The sample in general did not exhibit favorable diabetes self-management. More than half of participants (54%) reported low medication adherence. Likewise, the majority of participants (59%) reported an insufficient level of physical activity. Only about a third of participants (33.25%) demonstrated well-controlled blood sugar, as indicated by an HbA1c reading of less than 7.

Study participants were also very likely to exhibit the risk factors associated with OSA. Nearly two-thirds (65%) of the sample scored positive on the "snoring" category of the Berlin Sleep Questionnaire. More than one quarter (26%) of the sample scored positive on the "daytime fatigue" category, and nearly all (95%) of participants scored positive for obesity and/or high blood pressure. In total, 71.48% of the sample was found to be at high risk for OSA, as determined by scoring positive on two or more of the three risk categories assessed by the Berlin Sleep Questionnaire.

See Table 3.1 for bivariate analyses testing the association of medication adherence, physical activity, glycemic control, depressive symptoms, anxiety symptoms, and diabetes distress with OSA risk. High OSA risk was found to be significantly associated with low medication adherence ($\chi^2 = 12.05$, $p < 0.001$). Of those with high OSA risk, 60% reported low medication adherence, whereas only 40% of those with low OSA risk reported low medication adherence. No significant differences were found in physical activity level or HbA1c between the low and high risk OSA groups. Therefore, these variables were excluded from subsequent analyses.

Bivariate analyses showed OSA risk as significantly associated with all indicators of psychological distress (see Table 3.1). Those in the high OSA risk group scored significantly higher on average on the PROMIS Depression than did participants in the low OSA risk group (t

= -3.3, Cohen's d = -0.30, $p < 0.01$). OSA risk was also found to be significantly associated with anxiety symptoms, as those in the high OSA risk group scored significantly higher on average on the PROMIS Anxiety than did participants in the low OSA risk group (t = -2.14, Cohen's d = -0.20, $p < 0.05$). Finally, mean diabetes distress was significantly higher among those at high risk for OSA compared to those at low risk for OSA (t = -2.34, Cohen's d = -0.22, $p < 0.05$).

In multivariable models, the relationship between OSA and indicators of psychological distress remained significant when controlling for covariates and accounting for clustering effects by clinic (see Table 3.2). High OSA risk was associated with a 3.5 point increase in PROMIS Depression score (B = 3.50, 95% CI = 1.52-5.48; $p < 0.01$), a 2.34 point increase in PROMIS Anxiety score (B = 2.34, 95% CI = 0.88-3.81, $p < 0.01$), and a 0.16 point increase in diabetes distress score (B = 0.16, 95% CI = 0.008-0.329, $p < 0.05$).

OSA risk was found to significantly predict medication adherence in a logistic regression model, such that those in the high OSA risk group had 60% lower odds of reporting high medication adherence (see Model 1 in Table 3.2; OR = 0.40, 95% CI = 0.23-0.69, $p < 0.01$). The relationship between OSA risk and medication adherence remained significant and was not attenuated even after controlling for depression symptoms, anxiety symptoms, and diabetes distress in a logistic regression model (see Model 2 in Table 3.2; OR = 0.41, 95% CI = 0.25-0.67, $p < 0.001$). In order to address multicollinearity between depression, anxiety, and diabetes distress, new variables were generated to represent anxiety (with depression score subtracted) and depression (with diabetes distress score subtracted).

Discussion

The findings from this study support previous research indicating that OSA is substantially more common among patients with type 2 diabetes than among the general population. In our sample, 71% of participants were considered at high risk for OSA, consistent with previous research estimating the prevalence of OSA among diabetic populations to be as high as 72% (Westlake et al., 2016). Considering that these data were gathered from a socioeconomically disadvantaged, safety-net population, it is not surprising that participants in this study would be particularly vulnerable to risk factors for OSA.

The results of the present study did not support the hypothesis that high OSA risk would be associated with worse glycemic control. However, these results should not negate the substantial body of pre-existing research demonstrating an association between OSA and glycemic control. Given that the vast majority of our sample was found to be at high risk for OSA and to have poor glycemic control, it is possible that the composition of our sample made our study underpowered to detect this association. Another limitation of the present study that may have prevented detection of such an association was our measurement of OSA risk based on self-report items as opposed to OSA severity based on polysomnography. It was not feasible for the purposes of this investigation to conduct sleep studies for each participant and to correlate each participant's Apnea/Hypopnea Index with their HbA1c reading. However, this may be considered a way of capturing the association between OSA and glycemic control in future studies.

This research demonstrated some of the ways in which having untreated OSA symptoms may severely impact the quality of life and chronic disease self-management abilities of people with type 2 diabetes. High OSA risk was significantly associated with more severe symptoms of

depression, anxiety, and diabetes distress. High OSA risk was significantly associated with poor medication adherence, even after controlling for measures of psychological distress in multivariable models. It is possible that the relationship between high OSA risk and poor medication adherence could be explained by acute cognitive changes associated with insufficient sleep duration and quality, but this analysis did not include measures of cognitive functioning. Future studies may consider exploring cognitive moderators and mediators of the relationship between OSA and poor medication adherence, such as memory, attention, and executive function. As these data were cross-sectional, it is also possible that poor medication adherence led to higher assessment of OSA risk. Medication adherence was assessed for all medications, not just those associated with diabetes specifically. Therefore, it is possible that participants with poor medication adherence were more likely to be at high risk for OSA due to poor self-management of other chronic conditions (such as high blood pressure).

Despite the limitations of our investigation, our findings strongly underscore the importance of early detection and treatment of OSA, especially among patients with type 2 diabetes. The present study reflects that OSA screening practices in primary care settings, particularly those serving socioeconomically disadvantaged patient populations, may not be adequate as they are currently administered. Previous research has suggested that patients rarely present to primary care providers specifically to address OSA-related symptoms, as these symptoms may be chronic and non-specific (Bailes, et al., 2009; Miller & Berger, 2016). This finding makes routine screening of OSA even more important within primary care settings. However, there are currently no practice guidelines in place for routine OSA screening in primary care settings, despite the availability of numerous efficient and inexpensive screening tools demonstrating good specificity and sensitivity (Miller & Berger, 2016). The Berlin Sleep

Questionnaire, Epworth Sleepiness Scale, and STOP Bang are examples of screening tools that have been proposed as routine components of primary care (Surani, 2013).

Given that high risk for OSA was found to be so prevalent in our sample, primary care providers should consider making OSA screening a routine component of medical care for patients with type 2 diabetes. Early detection and treatment of OSA in primary care settings may improve patients' quality of life and health-related outcomes, as OSA appears to contribute to mental health symptoms and negatively impact important aspects of diabetes self-management such as medication adherence.

Conclusion

The results of this study support a strong link between type 2 diabetes and OSA. The majority of participants in this safety-net sample with type 2 diabetes were found to be at high risk for OSA. Those at high risk for OSA were significantly more anxious and depressed and experienced higher levels of diabetes distress than those at low risk for OSA. High risk for OSA was not found to be associated with poor glycemic control or insufficient physical activity, but was associated with poor medication adherence. These results suggest that the relationship between OSA and glycemic control identified by previous research may be mediated by both biological and behavioral pathways.

SUMMARY

The previously described studies have sought to clarify the associations between a number of psychosocial factors and multiple indicators of diabetes self-management among a large sample of socioeconomically disadvantaged patients. Although not all hypotheses were fully supported, several notable findings do stand out as important contributions to the current body of research informing healthcare policies and best practices for diabetes treatment within primary care settings.

First, a finding that stands out across all three studies is the overall poor state of health among the sample considered as a whole. Most participants reported low medication adherence and insufficient levels of physical activity. The vast majority of participants were obese. Very few participants had achieved optimal measures of glycemic control, cholesterol, or blood pressure. The sample was likewise found to be psychologically distressed in general, as a substantial number of participants were found to endorse clinically significant depressive symptoms and/or to have a documented diagnosis of a depressive condition in the past year. These findings are a stark indication of the inadequacy of US healthcare, as they reflect that the "safety net" intended to ensure a basic level of care for socioeconomically disadvantaged individuals is not translating to adequate medical or psychological health. As this dataset was collected prior to the rollout of the Affordable Care Act, it would be worthwhile to consider repeating the collection of this data as a reflection of the current state of healthcare.

From the results of the present studies considered in the context of other research, it can be concluded that there is indeed a strong link between psychosocial factors, including

depression, anxiety, and diabetes distress, and behavioral self-management of diabetes. Furthermore, it is evident that primary care settings are not effectively screening for psychological distress at present and could potentially benefit from introducing routine screenings for depressive symptoms. Patients identified as suffering from significant mental health symptoms could benefit from interventions aimed at increasing their self-efficacy, perhaps through building their self-management skills and their confidence to apply those skills. Finally, it appears that the relationship between obstructive sleep apnea and poor diabetes outcomes, as evident from previous studies, may be explained at least in part by behavioral factors such as poor medication adherence. However, the relationship between obstructive sleep apnea and poor medication adherence does not appear to be explained by psychological distress.

The limitations of the previous studies, including the cross-sectional nature of the analyses and the lack of sufficient power to compare racial/ethnic groups, do not invalidate these findings but do underscore the importance of further research addressing psychosocial aspects of diabetes self-management, particularly among socioeconomically disadvantaged populations.

TABLES AND FIGURES

Table 1.1: Demographic Characteristics of Overall Sample and Four Depression Groups

Variable	**All Participants, %**	**Depression Group, %**				***p***
	N=661	**Group 1 (No symptoms/No Diagnosis)** n=396	**Group 2 (Symptoms/No Diagnosis)** n=55	**Group 3 (No Symptoms/Diagnosis)** n=124	**Group 4 (Diagnosis/Symptoms)** n=86	
Age	mean= 56 (11.4)	56. (11.6)	53 (9.8)	53 (10.5)	51 (9.1)	**<0.001**
Sex						
Male	37	42	49	27	21	**<0.001**
Female	63	58	51	73	80	
Race						
Black or African American	30	34	23	21	28	
White or Caucasian	66	62	71	77	67	0.13
Hispanic or Latino	2	2	2	1	5	
Asian	1	1	2	0	0	
Other	1	1	2	1	0	
Education						
8th grade	7	9	9	5	5	
9th grade	17	17	20	13	26	0.21
12th grade	32	29	33	41	35	
Some college	30	31	25	27	29	
Graduated college	14	14	13	14	5	
Annual Income						
<$10k	29	24	41	31	43	
$10-14.9k	28	26	28	33	31	**<0.001**
$15-24.9k	18	19	13	17	20	
$25k+	25	32	18	19	6	

Column percentages are shown, except for age. Values for which $p < 0.05$ are highlighted in **bold**.

Table 1.2: A Comparison of PROMIS Depression Scores among the Four Depression Groups

	Depression Group, Mean (Standard Deviation)			
	Group 1 (No Symptoms/No Diagnosis) n=396	**Group 2 (Symptoms/No Diagnosis)** n=55	**Group 3 (No Symptoms/Diagnosis)** n=124	**Group 4 (Diagnosis/Symptoms)** n=86
PROMIS Depression Score	mean= 45.15 (SD= 7.91)	65.29 (4.66)	48.58 (7.99)	68.17 (6.41)

Table 1.3: Indicators of Diabetes Self-Management and Health Status among Overall Sample and Four Depression Groups

Variable	All Participants, %	Depression Group, %				*p*
	N=661	**Group 1 (No symptoms/No Diagnosis)** n=396	**Group 2 (Symptoms/No Diagnosis)** n=55	**Group 3 (No Symptoms/Diagnosis)** n=124	**Group 4 (Diagnosis/Symptoms)** n=86	
Medication Adherence						
Low	66	63	73	66	77	0.05
High	34	37	27	34	23	
Physical Activity						
Insufficient amount (<30 min/day, 5x/week)	66	65	73	64	71	0.46
Sufficient amount (≥30 min/day, 5x/week)	34	35	27	36	29	
BMI						
Mean BMI	mean=37.5 (SD=9.6)	37.0 (8.9)	38.9 (12.4)	38.2 (9.7)	38.1 (10.4)	0.42
Healthy (<25)	6	5	6	6	7	
Overweight (25-29.9)	14	15	13	15	10	0.91
Obese (≥30)	80	80	81	79	83	
Glycemic Control						
Mean HbA1c	mean=8.13 (SD=1.8)	8.10 (1.8)	8.45 (2.2)	7.97 (1.6)	8.28 (1.9)	0.36
Well-controlled (<7)	28	30	23	27	26	0.57
LDL Cholesterol						
Mean LDL	mean=97.0 (SD=37.5)	98.5 (37.9)	93.8 (36.0)	95.8 (39.3)	94.2 (34.5)	0.81
Well-controlled (<100)	58.2	56.8	54.5	59.5	63.3	0.81
Blood Pressure						
Mean Systolic	mean=136 (SD=17.0)	137 (17.1)	136 (18.8)	136 (16.3)	134 (16.5)	0.55
Well-controlled (<130/80)	29	28	33	31	27	0.82

Column percentages are shown, unless otherwise indicated. Values for which $p < 0.05$ are highlighted in **bold**.

Table 2.1: Bivariate Relationships between Mental Health Risk Factors, Potential Mediators, and Self-Management Indicators

		Self-Management Indicators					
		Medication Adherence (Cohen's *d*)	**Physical Activity** (Cohen's *d*)	**BMI** (Pearson's *r*)	**HbA1c** (Pearson's *r*)	**LDL Cholesterol** (Pearson's *r*)	**Systolic Blood Pressure** (Pearson's *r*)
Mental Health Risk Factors	Depressive Symptoms	**0.29**	**0.19**	**0.09**	0.07	-0.01	-0.03
	Anxiety Symptoms	**0.35**	0.12	0.02	0.05	-0.02	-0.06
	Diabetes Distress	**0.36**	**0.18**	**0.13**	**0.27**	0.07	-0.05
Potential Mediators	Diabetes Self-Efficacy	**-0.33**	**-0.25**	-0.04	**-0.14**	0.02	**0.08**
	Diabetes Knowledge	-0.002	0.06	0.56	0.03	0.07	-0.04

Cohen's *d* values are shown for binary self-management indicator variables (medication adherence and physical activity). Pearson correlation coefficients are shown for continuous self-management indicator variables. Values for which $p > 0.05$ are highlighted in **bold.**

Table 2.2: Bivariate Relationships between Mental Health Risk Factors and Potential Mediators

Mental Health Risk Factors	**Diabetes Self-Efficacy** (Pearson's *r*)	**Diabetes Knowledge** (Pearson's *r*)
Depressive Symptoms	**-0.34**	-0.03
Anxiety Symptoms	**-0.26**	0.02
Diabetes Distress	**-0.41**	**0.09**

Pearson correlation coefficients are shown. Values for which $p>0.05$ are highlighted in **bold**.

Table 2.3: Results of Linear and Logistic Regression Models Showing Mediational Effects of Self-Efficacy

	Medication Adherence						Physical Activity						HbA1c					
	Model 1			Model 2			Model 1			Model 2			Model 1			Model 2		
	OR	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**B**	**95% CI**	***p***	**B**	**95% CI**	***p***
Depressive Symptoms	0.97	0.96-0.99	<0.01	0.98	0.96-1.00	0.05	0.98	0.97-0.99	<0.01	0.98	0.97 - 0.99	<0.01	-	-	-	-	-	-
Anxiety Symptoms	0.97	0.95-0.98	<0.01	0.98	0.95-0.99	0.02	-	-	-	-	-	-	-	-	-	-	-	-
Diabetes Distress	0.61	0.50-0.74	<0.01	0.70	0.54-0.91	0.01	0.74	0.63-0.87	<0.01	0.84	0.72 - 0.98	0.03	0.55	0.36 - 0.73	<0.01	0.49	0.26 - 0.72	<0.01

Covariates included in all models were age, sex, race, income, education level, and number of years with diabetes. Model 1 included the given mental health risk factor. Model 2 included the given mental health risk factor and diabetes self-efficacy.

Table 3.1: Comparison of Low OSA Risk and High OSA Risk Groups

Variable	All Participants, %	OSA Risk		*p*
		Low	**High**	
	N=575	(n=164)	(n=411)	
Age	mean= 54 (SD=10.9)	54 (11.4)	54 (10.7)	0.97
Sex				
male	35	35	35	0.96
female	65	65	65	
Race				
Black or African American	33	30	33	
White or Caucasian	64	67	64	
Hispanic or Latino	2	2	2	0.61
Asian	>1	1	>1	
Other	>1	0	>1	
Education				
8th grade	7	8	7	
9th grade	19	18	19	
12th grade	30	29	30	0.99
some college	30	31	30	
graduated college	14	14	14	
Annual Income				
<$10k	30	27	32	
$10-14.9k	30	32	29	0.41
$15-24.9k	18	16	19	
$25k+	22	29	20	
Medication Adherence				
Low	54	40	60	**<0.01**
High	46	60	40	
Physical Activity				
Insufficient amount (<30 min/day, 5x/week)	59	56	61	0.30
Sufficient amount (≥30 min/day, 5x/week)	41	44	39	
Glycemic Control				
Mean HbA1c	mean=7.87 (SD=1.69)	7.85 (1.69)	7.92 (1.72)	0.69
Well-controlled (<7)	33	29	35	0.32
Indicators of Psychological Distress				
Mean PROMIS Depression Score	mean=50.62 (SD=11.56)	48.12 (11.14)	51.61 (11.58)	**<0.01**
Mean PROMIS Anxiety Score	mean=52.76 (SD=11.42)	51.14 (11.29)	53.41 (11.42)	**0.03**
Mean Diabetes Distress Score	mean=1.99 (SD=0.81)	1.86 (0.78)	2.03 (0.82)	**0.01**

Column percentages are shown, except when indicated. Values for which $p < 0.05$ are highlighted in **bold**.

Table 3.2: Linear Regression Models Examining OSA as Predictor of Psychological Distress

	Depressive Symptoms			Anxiety Symptoms			Diabetes Distress		
	B	**95% CI**	***p***	**B**	**95% CI**	***p***	**B**	**95% CI**	***p***
OSA Risk	3.50	1.52 - 5.48	0.002	2.34	0.88 - 3.81	0.004	0.16	0.008 – 0.329	0.04

Covariates included were age, sex, race, income, education level, and number of years with diabetes.

Table 3.3: Logistic Regression Models Examining Predictors of Medication Adherence

	Medication Adherence					
	Model 1			Model 2		
	OR	**95% CI**	***p***	**OR**	**95% CI**	***p***
OSA Risk	0.40	0.23-0.69	<0.01	0.41	0.25-0.67	<0.01
Depressive Symptoms	-	-	-	0.98	0.95-1.00	0.16
Anxiety Symptoms	-	-	-	0.97	0.95-0.99	<0.01
Diabetes Distress	-	-	-	0.89	0.69-1.13	0.35

Covariates included in both models were age, sex, race, income, education level, and number of years with diabetes.

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