

# **Pathways to Glycemic Control: Diabetes Distress as a Mediator of the Impact of the EPICC Intervention in Veterans with Type 2 Diabetes**

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## **Abstract**

Empowering Patients in Chronic Care (EPICC) is a patient-centered intervention that leverages a group-based approach, collaborative goal-setting, and motivational interviewing techniques to improve diabetes outcomes. However, the process by which EPICC's collaborative goal-setting results in improved diabetes outcomes differs from traditional self-management and may be related to emotion regulation rather than disease centric goals. This study examines the role of diabetes distress in reduction of HbA1c following the EPICC intervention. A cohort of 224 participants with treated but uncontrolled type 2 diabetes were randomized to receive either EPICC or enhanced usual care (EUC). Examination of direct and indirect effects of the relationship between treatment group and improvements in HbA1c revealed that relative to EUC, Veterans in the EPICC group had lower HbA1c post-intervention indirectly through reduction in diabetes distress. These findings underscore the role of psychosocial well-being in diabetes management.

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## **Introduction**

Diabetes represents a significant health concern both globally and within the United States (Ong et al., 2023). The annual mortality rate among Veterans with diabetes is nearly double that of Veterans without diabetes (Miller, et al., 2004). Thus, addressing the burden of diabetes among Veterans is a priority for improving health outcomes and reducing healthcare costs. However, managing diabetes is challenging. Effective type 2 diabetes management requires ongoing patient engagement in treatment and self-care (American Association of Diabetes Educators, 2020). The demands of managing a chronic illness often lead to diabetes-related distress, including concerns about disease control, provider interactions, and support (Fisher et

al., 2009; Skinner et al., 2019). A paternalistic approach that overlooks individual needs can exacerbate this distress and hinder self-management (Skinner et al., 2019).

Adults with type 2 diabetes typically report moderate distress, with mean Diabetes Distress Scale (DDS) scores between 2.1 and 2.4 in community samples (Fisher et al., 2012) and slightly higher scores, around 2.5, among Veterans (Lewinski et al., 2021). Distress can overwhelm individuals, leading to pessimism and reduced self-efficacy (Bhaskara et al., 2022), and is linked to poorer self-care and higher HbA1c levels (Schmidt et al., 2018). Health behavior theories such as Self-Regulation Theory (Baumeister & Vohs, 2016) and Social Cognitive Theory (Bandura, 1991) support a causal ordering in which psychological factors, including distress, influence self-

management behaviors, which in turn affect glycemic control and metabolic outcomes like HbA1c. However, traditional models often overlook the role of emotion in moving from intention to action. Models incorporating stress, coping, and self-efficacy offer stronger explanations for improving diabetes control (Zamani Alavijeh et al., 2018).

A recent model for diabetes management among Veterans, Empowering Patients in Chronic Care (EPICC), is a collaborative, patient-centered intervention that uses a group-based approach and individual motivational interviewing techniques to improve diabetes outcomes (Naik et al., 2011; Woodard et al., 2019; Woodard et al., 2022). EPICC uses collaborative goal-setting to help patients set personalized diabetes goals, communicate with providers, and develop action plans (Arney et al., 2018; Woodard et al., 2019), potentially reducing provider-related and interpersonal distress. EPICC participants attend six one-hour group sessions over three months on collaborative goal-setting and motivational interviewing, each followed by a 10-minute individual visit with trained healthcare professionals to address concerns, adjust goals, and review care plans. Goal-setting theory promotes structured planning to enhance control and reduce regimen-related distress (Locke & Latham, 2002), while motivational interviewing may reduce emotional distress by addressing ambivalence and clarifying values. By aligning care with what matters most to patients, EPICC targets both behavioral and emotional aspects of diabetes distress. Compared to enhanced usual care, EPICC led to greater post-intervention reductions in both HbA1c and diabetes distress, with sustained improvements in diabetes distress (but not HbA1c) during a 6-month maintenance period (Woodard et al., 2022). However, the mechanisms contributing to EPICC's pathway to post-

intervention glycemic control are not well understood.

The current study seeks to evaluate the indirect effect of EPICC on improved glycemic control post-intervention through reductions in diabetes distress. We hypothesize that diabetes distress mediates the relationship between treatment condition (i.e., EPICC versus enhanced usual care (EUC)) and improved glycemic control immediately post-intervention, with Veterans who receive the intervention experiencing greater improvements than controls.

## Methods

### Study Design

This randomized clinical trial, conducted from July 1, 2015, to June 30, 2017, included patients with treated but uncontrolled type 2 diabetes. The VA central IRB and clinic-based research committees approved the protocol, and verbal informed consent was obtained. The trial used a hybrid design to assess EPICC effectiveness on diabetes outcomes in two VA health systems. Enhanced Usual Care Patients were equally randomized to one of two treatment groups: a 3-month EPICC intervention or enhanced usual care (EUC), with primary outcomes of changes in HbA1c and diabetes-related distress. Participants randomized to the EUC arm received usual care, which included: (1) educational materials on diabetes management and (2) access to any self-management resources available at their site, such as standard diabetes education, nutrition counseling, medication management, or weight loss programs; with the addition of (3) communication with their healthcare provider indicating the participant's interest in additional diabetes-related support.

Participants were randomized 1:1 in random blocks of 4, 6, or 8 using SAS (RANUNI) to balance groups without

predictable allocation. Blinded staff enrolled participants and scheduled follow-ups and HbA1c tests at local VA clinical laboratories. Intervention clinicians were unblinded. Further details about study design and outcomes can be found in the trial protocol (Woodard et al., 2019) and main results manuscript (Woodard et al., 2022).

## Participants and Eligibility

Using the VA's Corporate Data Warehouse, we identified participants who had uncontrolled type 2 diabetes (HbA1c >8.0% in the prior 6 months). Exclusion criteria included hearing or vision impairment, active substance use disorder, bipolar or psychotic disorder, dementia, severe hypoglycemia, limited life expectancy, or death. Among the 273 participants with complete baseline data on key variables (i.e., self-reported diabetes distress and HbA1c), this study reports on the 224 participants with relevant baseline covariates ( $n = 13$  were missing baseline insulin or PHQ-8) and post-intervention follow-up data for both diabetes distress and HbA1c ( $n = 36$  were missing DDS and/or HbA1c).

## Measures

At baseline, we assessed current insulin use (yes/no), prior diabetes education (yes/no), and depressive symptoms using the validated 8-item PHQ-8 (score 0–24; higher scores indicate greater severity) (Kroenke et al., 2009; Pressler et al., 2011). We assessed HbA1c levels and diabetes-related distress outcomes following the intervention. Diabetes distress was measured with the 17-item Diabetes Distress Scale (DDS), which assesses emotional, physician-related, regimen-related, and interpersonal stressors over the past month on a 6-point scale (1 = “not a problem” to 6 = “very serious

problem”) (Polonsky et al., 2005). Sample items include “Feeling that I am often failing with my diabetes routine” and “Feeling overwhelmed by the demands of living with diabetes.” Scores are the mean of all items, with higher scores indicating greater distress. The DDS shows excellent reliability ( $\alpha = 0.93$ ) and validity through associations with depression, self-care, and lipid control (Polonsky et al., 2005; Owens-Gary et al., 2019).

## Statistical Analyses

To assess selection bias, we compared 224 participants with complete data to 49 with missing baseline ( $n=13$ ) or follow-up data ( $n=36$ ) using independent samples t-tests for baseline DDS and HbA1c and a chi-square test for treatment group. We also compared demographics and baseline variables between EPICC and EUC groups using independent samples t-tests for continuous and chi-square tests for categorical variables. We subsequently employed path analysis to assess the direct and indirect effects of treatment group on post-intervention HbA1c, mediated by post-intervention DDS. The key outcome variables were total diabetes distress and HbA1c at 4 months from baseline (immediately post intervention). The primary exposure was treatment group (1 = EPICC or 0 = EUC). For these analyses, maximum likelihood estimation was used, and bias-corrected, bootstrapped confidence intervals (CIs) for all effects were estimated based on 10,000 bootstrap samples. The indirect effect for the proposed mediation was calculated, and statistical significance was determined if zero fell outside the bias-corrected estimated 95% CIs. Given their associations with glycemic management (Woodard et al., 2022), depression, insulin use, and prior diabetes education were included as covariates. Baseline values for the two outcomes, DDS and HbA1c, were also

Table 1. Baseline Characteristics and Evaluation of differences between EPICC and EUC

	Total (N = 224)	EPICC (n = 111)	EUC (n = 113)	p-value for EPICC/EUC comparison
Age (in years), mean (SD)	67.18 (8.31)	67.34 (8.63)	67.02 (8.02)	0.77
Female, n (%)	12 (5.36)	6 (5.41)	6 (5.31)	0.97
Baseline values				
HbA1c, mean (SD)	9.06 (1.39)	9.01 (1.44)	9.10 (1.35)	0.62
Total Diabetes Distress, mean (SD)	2.37 (1.00)	2.37 (1.05)	2.37 (0.95)	0.99
PHQ-8, mean (SD)	8.23 (6.55)	8.35 (6.61)	8.10 (6.52)	0.78
Insulin use, n (%)	164 (73.21)	76 (68.47)	88 (77.88)	0.11
Prior diabetes education, n (%)	129 (57.59)	55 (49.55)	74 (65.49)	0.016

included as covariates. Analyses were conducted using MPlus version 8.8 (Muthén & Muthén, 1998–2023) and reporting guidelines for mediation analyses of randomized controlled trials were followed (Lee et al., 2021).

### Results

There were no significant differences in baseline DDS, HbA1c, or treatment group between those with complete and incomplete data (all  $p$ s > 0.05). The sample was predominately male (94.64%) with an average age of 67.18 years ( $SD = 8.31$ ). There were no significant differences between those randomized to EPICC and EUC in baseline characteristics, with the exception of prior diabetes education (See Table 1). Compared to those receiving EUC, a lower percentage of those receiving EPICC reported diabetes education prior to participating in the study (49.55% versus 65.49%),  $\chi^2(1) = 5.82, p = 0.016$ .

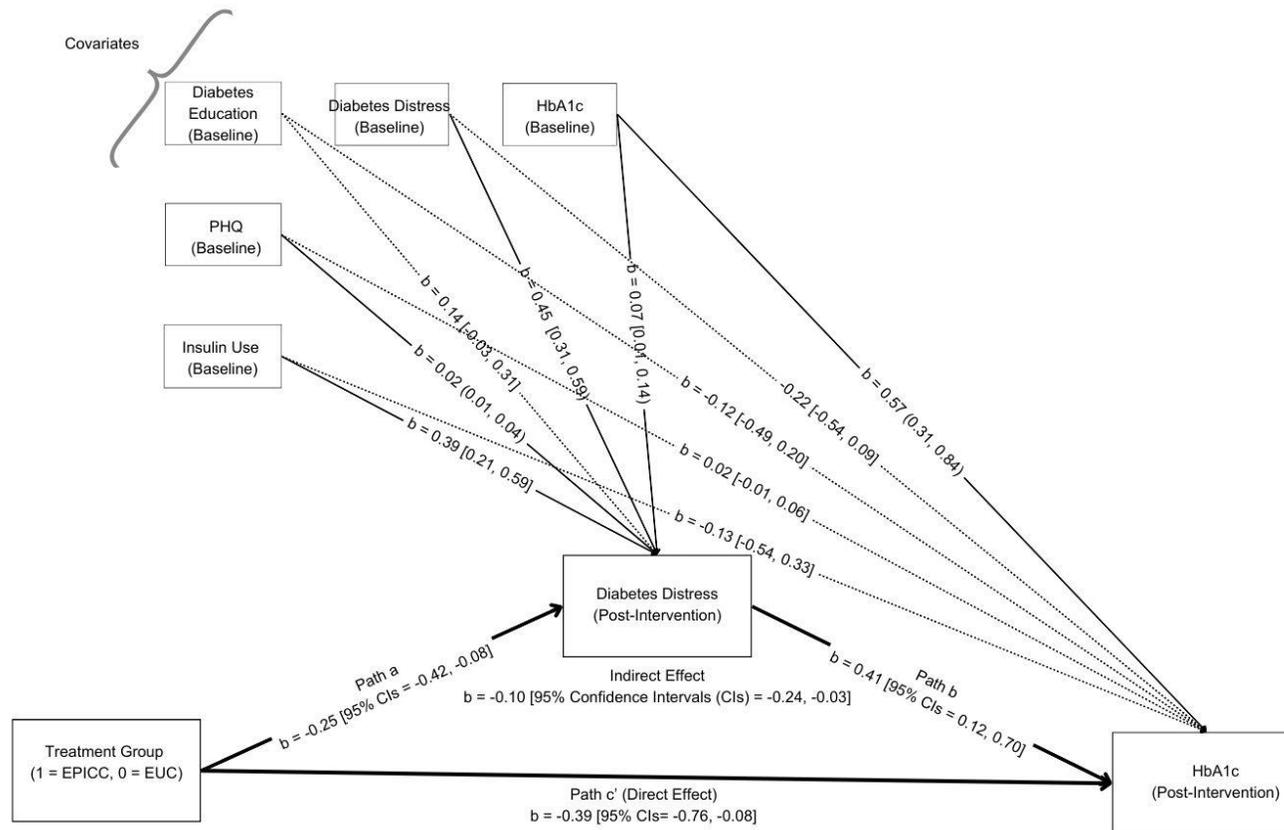
Relative to EUC, those who received EPICC reported lower post-intervention HbA1c independent of treatment group effects on post-intervention diabetes distress (Direct effect Path  $c'$ :  $b = -0.39, SE = 0.17, 95\%$  Confidence Intervals (CIs) = -0.76 to -

0.08). Treatment group was a significant predictor of diabetes distress (Path a:  $b = -0.25, SE = 0.09, 95\%$  CI = -0.42 to -0.08); those who received the EPICC intervention had lower DDS compared to those in EUC. Furthermore, diabetes distress was a significant predictor of post-intervention HbA1c (Path b:  $b = 0.41, SE = 0.15, 95\%$  CIs = 0.12 to 0.70), such that greater diabetes distress was associated with greater HbA1c. The bias-corrected bootstrap CIs for the indirect effect of treatment on post-intervention HbA1c was entirely below zero (Indirect effect Path a x b:  $b = -0.10, SE = 0.05, 95\%$  CI = -0.24 to -0.03). Figure 1 presents all effects of the mediation model.

### Discussion

In this multi-center randomized clinical trial of Veterans undergoing self-management for uncontrolled diabetes, we examined diabetes distress as a mediator of the effect of participation in the EPICC program on improvements in glycemic control. EPICC was independently associated with a reduction in both HbA1c and cumulative diabetes distress compared to EUC at four months post-intervention. The indirect effect of EPICC treatment on HbA1c through diabetes distress was statistically

Figure 1. Results of Path Analysis Predicting Post-Intervention HbA1c



significant, suggesting that the intervention improved glycemic control in part through its association with reduced diabetes-related emotional burden. These findings support theory-driven models of health behavior change that recognize affective and cognitive components of chronic disease management.

The findings are consistent with Self-Regulation Theory (Baumeister & Vohs, 2016), which emphasizes that individuals manage goal-directed behavior by monitoring progress, evaluating discrepancies, and adjusting actions to achieve valued outcomes. In the context of diabetes, psychological stressors like diabetes distress can emerge as a consequence of the challenges of goal pursuit, potentially disrupting motivation and adherence. EPICC may promote self-regulation by helping Veterans clarify values, set achievable goals, and develop skills to navigate challenges in diabetes care. The observed mediation effect suggests that reductions in diabetes distress may have facilitated better engagement in these self-regulatory behaviors, ultimately contributing to improved glycemic control. In addition, Goal-Setting Theory (Locke & Latham, 2002) emphasizes that specific, challenging goals paired with clear action plans promote behavioral adherence. EPICC's structured goal-setting process, grounded in this theory and supported by motivational interviewing, may be associated with augmented confidence and focus (Burke et al., 2003), contributing to reductions in distress and improved self-management behaviors (Li et al., 2020).

Our primary finding of significantly improved HbA1c and diabetes distress outcomes aligns strongly with those of previous studies investigating EPICC intervention for diabetes self-management (Naik et al., 2011; Woodard et al., 2022). Furthermore, by effectively reducing diabetes distress, EPICC was associated with

improved glycemic outcomes, highlighting the interconnectedness of emotional well-being and physical health in chronic disease management (Banks et al., 2023). This dual effect underscores the potential value of integrated interventions that address both psychological and physiological aspects of diabetes care. The current findings contribute to a growing body of literature supporting the use of motivational, patient-centered, and peer-supported strategies grounded in behavioral change theory to improve both psychosocial and clinical outcomes in diverse populations (e.g., Naik, 2023). Our study thus builds on existing literature by identifying the reduction of diabetes distress as a crucial intermediary factor in the effectiveness of the EPICC intervention for improving glycemic control.

These findings hold particular significance for Veteran populations. The dual benefit observed with EPICC aligns with a broader trend in chronic disease management toward holistic, patient-centered care, where addressing emotional well-being becomes integral to achieving optimal health outcomes (e.g., Rodríguez-Gutiérrez et al., 2021). While our results are meant to supplement, not replace, best current practices on HbA1C control, we recognize that psychosocial management pathways will vary based on individual patient needs within each program. Future research should further explore these pathways to understand how distress reduction strategies could be customized across varied demographic groups, maximizing EPICC's efficacy and scalability in diverse healthcare settings.

## **Limitations**

There are limitations to be considered. First, the low percentage of female participants and the older Veteran sample may limit external validity, suggesting that

further studies in younger and more diverse populations are needed. Furthermore, given that the mediator and outcome were measured concurrently at post-intervention, the temporal ordering between variables cannot be empirically verified. As such, while the hypothesized mediation pathway is theoretically grounded, causal interpretations regarding the mediator-to-outcome relationship should be made with caution. Lastly, participants in the EPICC group (relative to EUC) experienced increased contact with healthcare providers. Thus, it is not possible to determine the extent to which observed effects were attributable to the specific intervention components versus the additional attention provided. Addressing these factors in future studies could further strengthen the evidence base for EPICC, helping to optimize and expand its use for diverse populations in varied healthcare environments.

### **Implications for Health Behavior Theory**

The results of this study offer valuable insights into the psychological components that may underlie diabetes self-management interventions such as EPICC. Specifically, we found that reductions in diabetes distress mediated the effect of the EPICC intervention on improved glycemic control, underscoring the important role of emotional well-being in chronic disease management. According to self-regulation theory, effective health behavior change requires individuals to monitor their behavior, set appropriate goals, and adjust their strategies in response to challenges (e.g., Baumeister & Vohs, 2016). Elevated diabetes distress may disrupt these self-regulatory processes by overwhelming individuals and contributing to inconsistent self-care. The observed indirect effect suggests that EPICC helped reduce participants' self-reported diabetes-related burden, which in turn was associated with

better glycemic outcomes. Given emotional burden is one component of diabetes distress, these findings raise the possibility that explicitly targeting emotional barriers could strengthen the impact of self-management interventions.

### **Discussion Questions**

Given the demonstrated mediation effect of diabetes distress on HbA1c improvement, how might future interventions systematically incorporate psychological support within diabetes self-management frameworks to optimize both physiological and emotional outcomes?

Considering higher incidence of type 2 diabetes and unique challenges Veterans face in managing the disease, what specific patient-centered strategies could be implemented to enhance engagement and adherence to interventions like EPICC, particularly among diverse or high-risk subpopulations?

How does motivational interviewing and goal setting in diabetes management contribute to reduction in diabetes distress?

### **Ethical Approval Statement**

We recruited participants from three hospital-based primary care clinics and two community-based outpatient clinics. The clinics are part of two distinct regional networks of the United States Department of Veteran Affairs (VA), the largest healthcare organization in the US. The Central Institutional Review Board for the Department of Veterans Affairs (CIRB 14-24) as well as each of the hospital-based Research & Development committees approved this study

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