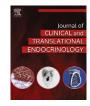
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# **Original Research**

# Volunteer peer support, diabetes, and depressive symptoms: Results from the ENCOURAGE trial



Yulia Khodneva <sup>a,\*</sup>, Monika M. Safford <sup>a</sup>, Joshua Richman <sup>b</sup>, Christopher Gamboa <sup>a</sup>, Susan Andreae <sup>a</sup>, Andrea Cherrington <sup>a</sup>

<sup>a</sup> Department of Medicine, School of Medicine, University of Alabama at Birmingham, 1720 2nd Ave S, Birmingham, AL 35233, United States <sup>b</sup> Department of Surgery, School of Medicine, University of Alabama at Birmingham, 1720 2nd Ave S, Birmingham, AL 35233, United States

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#### ABSTRACT

*Aims:* Depression in diabetes mellitus (DM) is common and is associated with poor health outcomes. Peer support DM interventions include encouraging interactions that could improve depressive symptoms. We examined intervention effects for those with and without depressive symptoms in a peer support trial.

*Methods:* The 1-year ENCOURAGE trial included 424 persons with DM living in rural Alabama. Intervention participants worked with community volunteers who encouraged participants to engage in daily self-management; control arm participants received usual care. Outcomes included HbA1c, body mass index (BMI) and quality of life (QoL) with EuroQuol-5D (range 0.0–1.0). Depressive symptoms were assessed with the Patient Health Questionnaire (PHQ-8, range 0–24). Generalized Additive Models (GAM) examined control–intervention differences in changes in HbA1c, BMI, and QoL for those with PHQ-8  $\geq$  5 and PHQ-8 < 5.

*Results:* Of the 424 participants enrolled at baseline, 355 completed follow-up and had data were that could be included into the study; they were aged  $60.2 \pm 12.1$  years, 87% African American, 75% female, and 39% insulin-treated. In an overall GAM adjusting for imbalance across trial arms and time-related covariates, depressive symptoms improved for all, but after 15 months of follow-up intervention, participants experienced greater reduction in PHQ-8 score than control participants (p = 0.01). In stratified analyses, those with PHQ-8  $\ge$  5 had unchanged HbA1c, lost weight (p = 0.03) and improved QoL (p = 0.04). Those with PHQ-8  $\le$  5 also had unchanged HbA1c and lost weight, but did not improve QoL (p = 0.06). *Conclusions:* Peer support improved depressive symptoms for all, but resulted in greater weight loss and gains in QoL for those with baseline depressive symptoms compared to those without.

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# Introduction

Both diabetes and depression are among the most prevalent medical conditions affecting Americans, and they commonly cooccur in the same patient. The prevalence estimates for depression among adults with diabetes range from 5.0 to 34.4% [1]. Several mechanisms may underlie the diabetes–depression association. Both receiving the diagnosis of diabetes and the complexity of diabetes self-management can lead to depressive symptoms [1]. Additionally, at the metabolic level, relationships between diabetes and depression may be mediated by increased cortisol, hyperactivity of the hypothalamus–pituitary–adrenal axis, and activation of proinflammatory cytokines in the central nervous system [2–4]. Untreated depression in diabetic individuals is associated with poor glycemic control [5,6]; increased risk of complications [7], including diabetic polyneuropathy, microvascular angiopathy and diabetic foot ulcers [8]; increased health expenditures [9]; risk of cardiovascular disease [10] and excess mortality [11]. Thus, in a 2014 position statement, the American Diabetes Association placed special emphasis on recognizing and managing subclinical and clinical depression among patients with diabetes, and included recommendations on screening and treatment of depression into the current diabetes clinical practice guidelines [12].

Although the need for interventions that simultaneously target depression and diabetes has been articulated, there is mixed evidence regarding the effectiveness of available interventions. Recent systematic reviews found that psychological interventions focused on depressive symptoms in individuals with diabetes may have reduced depressive symptoms, but did not improve glycemic control [13,14]. Based on data from nineteen randomized clinical trials (RCT),

<sup>\*</sup> Corresponding author. Tel.: +205 934 7157; fax: +205 934 7959. *E-mail address:* khodneva@uab.edu (Y. Khodneva).

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a Cochrane review concluded that there was low evidence of improved glycemic control in psychological intervention trials, including both individual and group cognitive-behavioral, interpersonal, or supportive psychotherapy of depressive symptoms among individuals with diabetes [15]. The Cochrane review also mentioned that among depressed individuals with diabetes health-related quality of life did not significantly improve in the 3 trials included in the review, and medication adherence was investigated only in one trial [15].

A potential approach to addressing the challenge of depression and diabetes may lie in peer support. Peer support or peer coaching interventions increasingly show promise for improving health outcomes among diabetic patients, especially in settings with limited medical resources or a low level of organized self-management support [16–19]. Previous research has demonstrated that compared to usual care peer coaching improves glycemic control [18], increases protective high density lipoprotein (HDL) cholesterol [19], reduces body mass index [19] and reduces hospitalizations among patients with diabetes [20]. However little evidence exists regarding whether peer coaching can decrease depressive symptoms among adults with diabetes or specifically improve health outcomes in diabetes associated with depression. Therefore, we examined the effects of a peer support intervention among mostly African American participants, with and without depressive symptoms from a community-based trial in rural southern Alabama. We hypothesized that, compared with usual care, the peer support intervention would decrease depressive symptoms and would have greater effects among participants with depressive symptoms than among those without depressive symptoms, namely greater improvements in glycosylated hemoglobin A1c (HbA1c), body mass index (BMI) and health related quality of life (QoL).

#### Methods

#### Setting and participants

This study utilized data from the 1-year cluster-randomized community-based ENCOURAGE pragmatic trial, conducted in 2010-2012 in rural Alabama counties that are part of a region known as the Black Belt (Fig. 1). This region is characterized by a high burden of chronic diseases like diabetes and limited medical resources. Details of participant recruitment, study design, and the main results are described elsewhere [21-23]. Briefly, 424 participants with diabetes were recruited in 8 partnering communities via respondent driven sampling [21]. Participants were eligible if they had been told by a doctor or nurse that they had diabetes and if they were willing to work with a peer coach to help with diabetes self-management. Exclusions were the absence of a regular primary care provider, advanced medical illness that limited life expectancy, and unwillingness to work with a peer coach. Peer coaches were recruited from the same communities and had to be diabetic themselves or to have personal experience caring for someone with diabetes. All participants provided written informed consent, and the University of Alabama at Birmingham Institutional Review Board approved the study protocol. The trial is registered at Clinicaltrials.gov; registration number NCT02460718.

# Peer support intervention

Peer coaches were identified by community coordinators/ community partners, and those, who completed training and were certified became study interventionists. Peer coaches were compensated for a total of \$790 for their effort. Prior to the start of the intervention, peer coaches received 12 hours of training over 2 days covering the basics of diabetes, diabetes self-management, moti-



**Figure 1.** Alabama counties included into ENCOURAGE trial. Displays the map of the State of Alabama. Recruitment of the participants for the ENCOURAGE trial took place in the counties, highlighted in orange. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

vational interviewing, research ethics, and the study protocol. Peer coaches were also trained to help participants develop and achieve realistic diabetes management goals, provide social and emotional support, and maximize the utility of visits to the doctor. Peers who completed the training successfully were paired with 2–14 (mean 6–7) intervention participants [22].

Each coach-participant pair had a 45–60 minute initial phone or in-person meeting followed by weekly phone meetings over next 2 months and then monthly meetings over the last 8 months. Peer coaches were allowed to make more contacts with participants if needed. Contacts were focused on selecting individualized selfmanagement goals and providing coaching on how to achieve the goals. Some contacts were scheduled prior to regular visits to the diabetes care provider and focused on planning for the physician encounter. The median duration of the peer coach-participant encounter was 9 min with maximum up to 47 minutes. Contacts were highly individualized and mostly unstructured.

### Usual care

Both intervention- and control-arm participants received a one hour group diabetes education class at enrollment covering basics of diabetes and its self-management emphasizing healthy eating and physical activity; stress reduction; and visits to the doctor [22]. All participants were presented with a personalized diabetes card including their baseline HbA1c and body weight, followed by a 5-minute counseling session explaining the results.

#### Study design

The study was a cluster RCT with the initial plan calling for randomization of medical practices to either the intervention or control arm. However, participant recruitment at the practices lagged and was expanded to surrounding communities [21]. Thus, since there was one practice enrolled per community, the cluster or unit of randomization became the community. Clusters were randomly assigned to a trial arm by a random number generator. Since the intervention acted at the individual level, analyses were conducted at the individual level, and peer coaches and participants were not blinded to the arm assignment [22].

#### Depressive symptoms

Depressive symptoms were measured at baseline and followup using the 8-item Personal Health Questionnaire (PHQ-8), which has been validated for use in this population [24]. The PHQ-8 results in a single summary score ranging from 0 to 24; a PHQ-8 score  $\geq$  5 represents mild or greater depressive symptoms, and a PHQ-8 score  $\geq$ 10 represents moderate or greater depressive symptoms [24].

#### Outcomes

Changes in HbA1c, BMI, and QoL from baseline to follow-up were contrasted between intervention and control arms separately among participants with and without depressive symptoms. Baseline and follow-up data were collected by trained and certified study personnel following a standardized protocol in community venues: churches, schools, libraries, community centers and very small number were collected at participants' home. HbA1c was measured using point-of-service equipment and capillary finger stick blood (National Glycohemoglobin Standardization Project compliant DCA2000), and BMI was calculated as weight in kilograms divided by the square of height in meters. Health-related QoL was assessed using the Euroqol EQ-5D, a widely validated instrument applicable to a wide range of health conditions and treatments and measuring self-reported levels of mobility, self-care, usual daily activities, pain/discomfort and anxiety/depression [25].

#### Statistical analysis

We used student t-tests and chi-square tests to compare intervention participants and controls on baseline characteristics, separately among those reporting mild or greater depressive symptoms (PHQ- $8 \ge 5$ ) and those reporting no depressive symptoms (PHQ-8 < 5). Baseline characteristics included age, race, education, income, duration of diabetes in years, use of insulin, and season of data collection (since HbA1c values vary by season) [26].

The follow-up time for this study was extended from the initially planned 12–15 months to maximize follow-up data collection and to accommodate community members who wanted to provide follow-up data, concordant with the community-engaged research framework [22,23]. The length of trial extension after 15 months was up to 177 days. The prolonged follow-up improved generalizability, an important objective of pragmatic trials, but necessitated the use of non-traditional approaches to analyze the trial's results. Specifically, generalized additive mixed models (GAMMs) were employed, which also revealed markedly non-linear effects over time [23]. GAMMs were constructed to assess the difference in changes in PHQ-8 score over time between the intervention and control arms, as well as differences in the study outcomes stratified on PHQ-8 scores (<5 and  $\geq$ 5). All models were adjusted for clustering, season of data collection, calendar time between baseline and follow-up, baseline PHQ-8 score, and imbalance in participant characteristics across trial arms, specifically race, age, income, and education. All analyses were intention-to-treat. SAS version 9.4 and R statistical programing language version 3.01.1 were utilized to conduct the analyses.

#### Role of the funding source

Funding for this research was provided by the American Academy of Family Physicians Foundation through the Peers for Progress program with support from the Eli Lilly and Company Foundation. Representatives of the funding agency have not been involved in the collection, management, analysis, or interpretation of the data.

#### Results

Of the 424 enrolled trial participants, 360 were available at follow-up. Five participants had missing PHQ-8 scores at baseline; therefore, the analytic sample was comprised of 355 individuals. At baseline, 50% (n = 177) had PHQ-8 scores  $\geq$ 5 and 25% (n = 90) had PHQ-8 scores  $\geq$ 10. The mean age of trial participants was 60 years, 87% (n = 313) were African Americans, and 75% (n = 271) were women.

Table 1presents participants' baseline characteristics contrasted between trial arms among those with PHQ-8 scores  $\geq$ 5 and <5. Among those with PHQ-8  $\geq$  5, intervention and control participants were similar at baseline except that the intervention group included more African Americans (95.5% vs. 84.3%, respectively). Among those with PHQ-8 < 5, intervention-arm participants were significantly more likely to be African American (93.7%, vs. 77.6% among controls), and to be younger (mean age 59.5 vs. 63.2 years among controls). Among those with PHQ-8 < 5 control participants had slightly higher mean PHQ-8 score than the intervention group (p = 0.08). The season of data collection differed in both those with and without depressive symptoms.

Fig. 2a presents plots from the GAMM model, displaying controlintervention differences in PHQ-8 score changes from baseline to follow-up in the overall sample. The higher panel presents the raw change in PHQ-8 scores for intervention and control arm participants. The lower panel depicts the adjusted change in PHQ-8 score attributable to the intervention. Changes in PHQ-8 scores differed significantly between the control and intervention group over time (p = 0.03). As can be seen from the high estimated degrees of freedom (EDF = 8), the intervention effects varied over time in a non-linear fashion. Early in follow-up, between 12 and 15 months, control participants had a greater improvement than intervention participants, whereas, to the contrary, after about 15 months, intervention participants had a greater improvement in depressive symptoms.

Fig. 2b presents control–intervention differences in changes in PHQ-8 scores for those with PHQ-8 < 5 and  $\geq$ 5. Among participants with baseline PHQ-8 < 5, there were no statistically significant control–intervention differences in changes in PHQ-8 scores (p = 0.29). In contrast, among participants with PHQ-8  $\geq$  5 at baseline, there was a statistically significant trend in the control–intervention difference in change in PHQ-8 scores over time (p = 0.04). As can be seen in the upper panel, both intervention and control participants improved their scores, but early in follow-up, improvements were greater in the control group.

Fig. 3a, 3b and 3c present control-intervention differences in the changes in HbA1c, BMI, and QoL over time, stratified on PHQ-8 < 5 and  $\geq$ 5 at baseline. For both those with and without depressive symptoms, there was no statistically significant effect of the intervention on change in HbA1c, after adjustment (Fig. 3a). Fig. 3b presents

#### Table 1

Baseline characteristics of ENCOURAGE participants by depressive symptoms at baseline

	Overall n = 355 n, (%)	Depressed (PHQ- $8 \ge 5$ )			Not depressed (PHQ-8 < 5)		
		Intervention (n = 88) n, (%)	Control (n = 89) n, (%)	P-value	Intervention (n = 80) n, (%)	Control (n = 98) n, (%)	P-value
African American	313(87.4)	84(95.5)	75(84.3)	0.01	74(93.7)	76(77.6)	0.003
Female	271(75.3)	69(78.4)	66(74.2)	0.51	62(77.5)	71(72.5)	0.44
<high education<="" school="" td=""><td>111(31.2)</td><td>32(37.2)</td><td>29(32.6)</td><td>0.52</td><td>21(26.3)</td><td>27(27.8)</td><td>0.81</td></high>	111(31.2)	32(37.2)	29(32.6)	0.52	21(26.3)	27(27.8)	0.81
Annual household income < \$40,000	289(90.3)	74(94.9)	77(92.8)	0.58	64(91.4)	74(82.2)	0.09
Insulin therapy	142(39.6)	39(44.2)	43(48.3)	0.59	28(35.0)	29(29.6)	0.44
Season of baseline data collection				<.0001			<.0001
Spring	92(25.9)	36(40.9)	11(12.4)		35(43.8)	10(10.2)	
Summer	235(66.2)	52(59.1)	67(75.3)		45(56.3)	71(72.5)	
Winter	28(7.9)	0	11(12.4)		0	17(17.4)	
	Mean ±SD	Mean ±SD	Mean ±SD		Mean ±SD	Mean ± SD	
Age, years	$60.2 \pm 12.1$	59.0 ± 11.3	58.8 ± 11.7	0.91	$\textbf{59.5} \pm \textbf{12.4}$	63.2 ± 12.4	0.046
HbA1c, %	$7.9 \pm 2.0$	$8.0 \pm 2.0$	$8.1 \pm 1.9$	0.76	$8.0 \pm 2.1$	7.7 ± 1.8	0.24
Time with diabetes, years	$13.3 \pm 11.9$	$12.9 \pm 11.6$	$12.5 \pm 10.6$	0.84	$12.9 \pm 11.4$	13.8 ± 13	0.63
Diabetes distress score	$2.1 \pm 1.2$	$2.6 \pm 1.4$	$2.7 \pm 1.2$	0.44	$1.6 \pm 0.8$	$1.6 \pm 0.8$	0.88
PHQ-8 score	$6.4 \pm 5.6$	$10.6 \pm 4.6$	$10.9 \pm 5.0$	0.64	$1.8 \pm 1.4$	$2.2 \pm 1.5$	0.08
Body mass index, kg/m2	$36.3 \pm 8.5$	$36.6 \pm 6.8$	$37.2 \pm 9.8$	0.85	$36.4 \pm 8.6$	35.0 ± 8.3	0.27
Systolic blood pressure, mmHg	$135.2 \pm 21.4$	$136.9 \pm 22.4$	$133.6 \pm 21.1$	0.32	$132.1 \pm 20.8$	137.6 ±21	0.08
Diastolic blood pressure, mmHg	$83.0 \pm 12.9$	85.0 ± 12.0	$83.0\pm12.6$	0.27	$82.2 \pm 11.8$	81.7 ± 14.7	0.81
EuroQuol index	$0.8 \pm 0.2$	$0.6 \pm 0.2$	$0.7 \pm 0.2$	0.05	$0.8 \pm 0.1$	$0.8 \pm 0.1$	0.82

Bold indicates p < .05.

changes in BMI attributable to the intervention, with nonlinear effects for both those with and without depressive symptoms. For those without depressive symptoms, the intervention resulted in greater weight loss early and late during follow-up with less weight loss from 13 to 18 months (p = 0.05, EDF = 4). For those with depressive symptoms at baseline, intervention participants followed after 15 months experienced greater weight loss than control participants (p = 0.02, EDF = 3). Fig. 3c presents changes in QoL attributable to the intervention, with highly nonlinear effects. For those without depressive symptoms at baseline, there were borderline intervention effects (p = 0.06, EDF = 7). For those with depressive symptoms at baseline, there were statistically significant intervention effects with modestly lower gains in QoL at 15 months and greater gains in Qol after 17–18 months of follow-up among intervention participants compared to the control participants. (p = 0.04, EDF = 8).

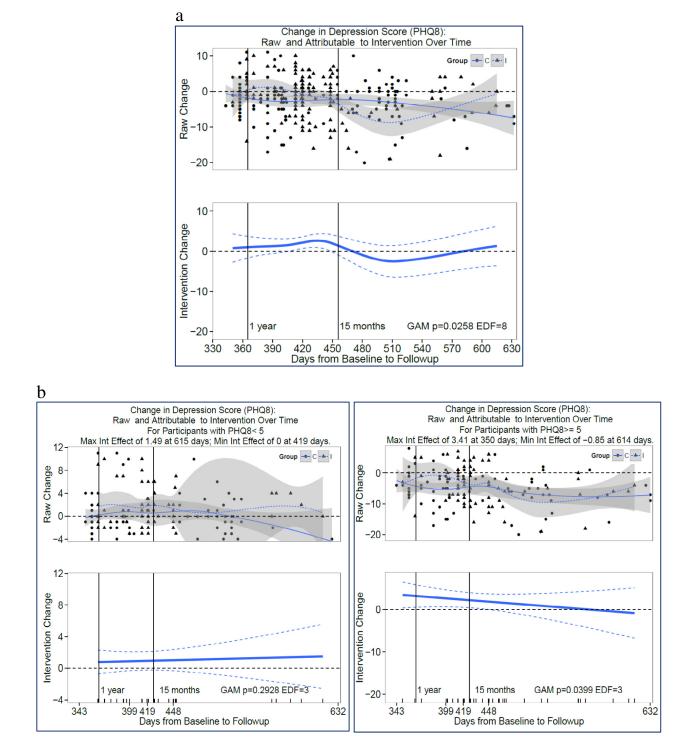
# Discussion

This study presents data from a pragmatic cluster-randomized effectiveness ENCOURAGE trial of the peer coaching intervention, conducted among diabetic, mostly African American participants in rural Alabama with limited access to medical resources. As previously reported, the peer-coaching intervention may have promoted weight loss, reduction in systolic blood pressure, and improved quality of life compared to the control in participants who were followed after 15 months [22]. In addition to the trial's main results, summarized by Safford et al., the present study assessed the intervention effects separately among subgroups of participants with or without elevated depressive symptoms at baseline. Overall after initial worsening the peer-coaching intervention improved depressive symptoms at/after 15 months of follow-up. Our examination of the intervention effects on participants with and without depressive symptoms revealed no effects on glycemic control, but more significant intervention effects on weight loss and improvements in quality of life for those with baseline depressive symptoms than for those without depressive symptoms, especially seen in the later follow-up period.

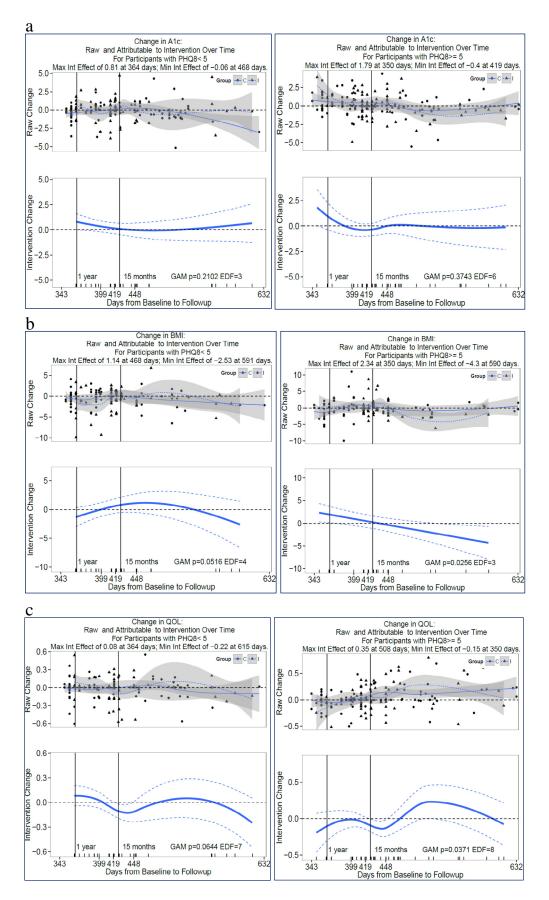
Our study supports the previous research findings showing that peer coaching might be an especially effective intervention for the situation when diabetes is complicated with poor mental health. The RCT conducted by Chan et al. among 628 Hong Kong patients with type 2 diabetes has demonstrated that peer coaching intervention has reduced overnight hospitalizations, day admissions and improved medication adherence only among patients with elevated baseline diabetic distress [20]. These intervention effects were not seen among those with no diabetic distress at baseline [20]. In another study of patients with diabetes and comorbid emotional disorders, peer education intervention reduced anxiety, depression and distress and improved self-management skills and quality of life [27].

Several mechanisms can explain why peer coaching may be more effective for individuals with diabetes and with depressive symptoms than among non-depressed. Peer support interventions may reduce symptoms of depression through encouraging, supportive interactions that minimize isolation and buffer stress by sharing health and self-management information, and providing positive role modeling [28,29]. By its nature peer support entails group or one-on-one communication between non-professionals with similar stressors or health problems, and can be delivered in person or over the telephone or the Internet [29]. Enhanced social support via frequent contact with a peer may be a mediator of the greater benefits of the intervention that we observed among participants with both depressive symptoms and diabetes.

The study's strengths include an ability to build a network of trained peer coaches and deliver highly personable and individualized intervention to the group of participants with diabetes who are very hard to reach by traditional medical services. This analysis used GAMMs to accommodate the prolonged follow-up experienced in this study, resulting in retention of 85% of the study's mostly minority participants. This analytic method allowed potential differential intervention effects over time to emerge, and suggested that intervention effects may be greatest after 15 months, a possibility supported by the fact that peer coaches and participants often continued their relationships well beyond the conclusion of the study. Different times between baseline and follow-up data collection (shorter for some participants vs. longer for others) did not explain the observed differences between the trial arm, as shown in the report of the trial's main results [22]. However, the use of



**Figure 2.** (a) Overall change in depressive symptoms over time. Control (C)-intervention (I) arm differences in change in depressive symptoms (measured by PHQ-8) for all study participants, showing raw change scores and change scores from generalized additive models adjusting for differences in time from baseline to follow-up, season, baseline value, clustering, education, and race. The top graph presents the raw change scores for each participant, with circles and solid lines signifying control arm and triangles and dotted lines signifying intervention arm. The x axis shows the time in days between baseline and follow-up. Vertical lines show the 12- and 15-month follow-up points. The bottom graph presents the differences between intervention and control change scores form generalized additive models with p-values from tests of statistical significance of the difference between control and intervention arms. EDF = estimated degrees of freedom; GAM = generalized additive models. (b) Change in depressive symptoms over time, stratified by baseline PHQ-8 score. Control (C)-intervention (I) arm differences in change in depressive symptoms (measured by PHQ-8) for participants with baseline PhQ-8 < 5 (left panel) and with PHQ-8  $\geq$  5 (right panel), showing raw change scores (top of each panel) and change scores from generalized additive models adjusting for differences in time from baseline to follow-up, season, baseline value, clustering, education, and race. The top graph presents the raw change scores for each participant, with circles and solid lines signifying control arm and triangles and dotted lines signifying intervention arm. The x axis shows the time in days between baseline and follow-up. Vertical lines show the 12 and 15-month follow-up points. The bottom graph in each panel presents the raw change scores for generalized adjusting for differences in time from baseline to follow-up, season, baseline value, clustering, education, and race. The top graph presents the raw change scores for each participant,



**Figure 3.** (a) Change in HbA1c over time, stratified by baseline PHQ-8 score. (b) Change in BMI over time, stratified by baseline PHQ-8 score. (c) Change in QoL over time, stratified by baseline PHQ-8 score. Control (C)-intervention (1) arm differences in change in hemoglobin HBA1C (HbA1c – Fig. 3a), body mass index (BMI – Fig. 3b) and quality of life (QoL – Fig. 3c), separately, for participants with baseline PHQ-8 < 5 (left panel) and with PHQ-8 > 5 (right panel) on each graph, showing raw change scores (top of each panel) and change scores from generalized additive models adjusting for differences in time from baseline to follow-up, season, baseline value, clustering, education, and race. The top graph presents the raw change scores for each participant, with circles and solid lines signifying control arm and triangles and dotted lines signifying intervention arm. The x axis shows the time in days between baseline and follow-up. Vertical lines show the 12- and 15-month follow-up points. The bottom graph in each panel presents the differences between intervention arm. EDF = estimated degrees of freedom; GAM = generalized additive mixed models.

GAMMs to analyze the data has several disadvantages. First, there is an inability to conclude whether he intervention effects were significant at any given time, and second, there is the unfamiliarity of this method in reporting trial results. Additional limitations worth noting include the single geographic region, which may limit generalizability. Because the intervention was delivered in the community, we could not account for differences in peer-coaching style or use of skills acquired during training.

In conclusion, this peer coaching intervention may have had differential effects for participants with and without depressive symptoms. Participants with mild or greater depressive symptoms at baseline may have experienced greater weight loss and gains in quality of life compared to those without depressive symptoms after receiving peer coaching intervention. The intervention did not result in improved glycemic control regardless of the presence or absence of depressive symptoms. Peer support intervention may also have a delayed effect representing the possibility that some behavioral changes require time to occur. Peer support holds promise for the treatment of comorbid diabetes mellitus and depressive symptoms, especially in settings with few medical resources.

### **Conflict of interest**

The authors declare they have no conflicts of interest.

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