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Effects of a Multicomponent Life-Style Intervention on Weight, Glycemic Control, Depressive Symptoms, and Renal Function in Low-Income, Minority Patients With Type 2 Diabetes: Results of the Community Approach to Lifestyle Modification for Diabetes Randomized Controlled Trial

Ashley E. Moncrieft, PhD, Maria M. Llabre, PhD, Judith Rey McCalla, PhD, Miriam Gutt, PhD, Armando J. Mendez, PhD, Marc D. Gellman, PhD, Ronald B. Goldberg, MD, and Neil Schneiderman, PhD

ABSTRACT

Objective: Few interventions have combined life-style and psychosocial approaches in the context of Type 2 diabetes management. The purpose of this study was to determine the effect of a multicomponent behavioral intervention on weight, glycemic control, renal function, and depressive symptoms in a sample of overweight/obese adults with Type 2 diabetes and marked depressive symptoms.

Methods: A sample of 111 adults with Type 2 diabetes were randomly assigned to a 1-year intervention ($n = 57$) or usual care ($n = 54$) in a parallel groups design. Primary outcomes included weight, glycosylated hemoglobin, and Beck Depression Inventory II score. Estimated glomerular filtration rate served as a secondary outcome. All measures were assessed at baseline and 6 and 12 months after randomization by assessors blind to randomization. Latent growth modeling was used to examine intervention effects on each outcome.

Results: The intervention resulted in decreased weight (mean [M] = 0.322 kg, standard error [SE] = 0.124 kg, $p = .010$) and glycosylated hemoglobin (M = 0.066%, SE = 0.028%, $p = .017$), and Beck Depression Inventory II scores (M = 1.009, SE = 0.226, $p < .001$), and improved estimated glomerular filtration rate (M = 0.742 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$, SE = 0.318 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$, $p = .020$) each month during the first 6 months relative to usual care.

Conclusions: Multicomponent behavioral interventions targeting weight loss and depressive symptoms as well as diet and physical activity are efficacious in the management of Type 2 diabetes.

Trial Registration: This study is registered at Clinicaltrials.gov ID: NCT01739205.

Key words: Type 2 diabetes, life-style intervention, depression, obesity, glycemic control, renal function.

INTRODUCTION

Excess body weight (1), poor glycemic control (2), and renal function decline (3) are independently associated with increased risk of complications, poor cardiovascular

BDI-II = Beck Depression Inventory II, **CALM-D** = Community Approach to Lifestyle Modification for Diabetes, **eGFR** = estimated glomerular filtration rate, **HbA1c** = glycosylated hemoglobin, **RMSEA** = root mean square error of approximation

SDC Supplemental Content

From the Department of Psychology (Moncrieft, Llabre, McCalla, Gellman, Schneiderman), University of Miami, Coral Gables, Florida; and Behavioral Medicine Research Center (Moncrieft, Llabre, McCalla, Gutt, Mendez, Gellman, Goldberg, Schneiderman) and Diabetes Research Institute, Department of Medicine, Division of Endocrinology, Diabetes and Metabolism (Mendez, Goldberg), Miller School of Medicine, University of Miami, Miami, Florida.

Address correspondence and reprint requests to Ashley E. Moncrieft, PhD, Clinical Research Building, Room 1516, 1120 NW 14th Street, Miami, FL 33136. E-mail: amoncrieft@psy.miami.edu

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outcomes, and mortality in individuals with Type 2 diabetes. A number of previous studies indicate life-style interventions targeting diet and physical activity may improve weight management, glycemic control (4), and renal function in Type 2 diabetes populations (5,6). However, depressive symptoms, which are common in patients with Type 2 diabetes (7), are associated with poor adherence to various self-care behaviors in Type 2 diabetes, including glucose monitoring, medication use, and diet and physical activity recommendations (8). As such, improvements in weight and glycemic control are often difficult to achieve in patients with significantly depressed affect.

Psychosocial interventions have been shown to successfully alleviate depressive symptoms among patients with diabetes (9). Research also shows that patients with poorly controlled diabetes and depression benefit more from integrated management of medical and psychological illness when compared with usual care (10). In fact, previous studies have reported that in addition to constituting an effective treatment of depression, cognitive behavioral therapy combined with diabetes education (11) or enhanced usual care (12) may also be associated with improved glycemic control. These findings suggest that interventions aimed at improving Type 2 diabetes management would benefit from incorporation of psychosocial techniques. However, few interventions have combined life-style and psychosocial approaches in the context of Type 2 diabetes management.

Few randomized trials have examined the impact of life-style interventions on management of Type 2 diabetes among underserved populations (13). Ethnic minorities and individuals with low socioeconomic status with Type 2 diabetes are more likely to be overweight or obese, have poor glycemic control, experience depressive symptoms, and develop renal disease (14,15). Individuals belonging to these subgroups may face unique barriers to successful diabetes management related to diabetes-related knowledge, community resources, social support, or access to quality care (16,17). The purpose of this study was to examine the effects of a 1-year multicomponent life-style intervention involving diet, physical activity, and cognitive behavioral training on weight, glycemic control, renal function, and depressive symptoms in a sample of low-income, overweight/obese ethnic minority participants with Type 2 diabetes and depressive symptoms.

PATIENTS AND METHODS

Participants

Participants were enrolled in a randomized controlled trial designed to evaluate the efficacy of a structured life-style intervention titled: Community Approach to Lifestyle Modification for Diabetes (CALM-D). Goals of the intervention were to reduce weight, increase physical activity, and improve stress management/coping. Participants were recruited at local community health clinics or referred by word of mouth. Eligible participants were overweight or obese (body mass index ≥ 27 kg/m^2), between the ages of 18 and 70 years, with self-report of Type 2 diabetes confirmed by medical records, current treatment, or verification by study physician (fasting plasma glucose ≥ 7 mM or 2-hour plasma glucose value after a 75-g glucose load ≥ 11 mM), and significant depressive symptoms (Beck Depression Inventory II [BDI-II] total score ≥ 11). Exclusionary criteria included any factors that could limit participant life span, affect the safety of the intervention, limit adherence to intervention, or affect conduct of the trial including advanced renal disease (dialysis, urine dipstick protein +4, serum creatinine ≥ 132 μM for men and ≥ 124 μM for women), blood pressure $\geq 160/100$ mm Hg, fasting triglycerides ≥ 7 mM, and glycosylated hemoglobin (HbA1c) ≥ 97 mmol/mol (11%), inability to walk, and severe mental illness. Participants with BDI-II scores at least 35 were excluded if the magnitude of depression was deemed likely to prevent effective participation in the program. Participants with preexisting cardiovascular disease were eligible if they met the functional criteria for inclusion (as determined during a submaximal exercise stress test) and diagnosis of the condition occurred at least 6 months before screening.

Procedures

Data collection for this analysis occurred between June 2008 and April 2012. The study protocol, including the screening and full study informed consent form, was approved by the University of Miami Human Subjects Research Office, Institutional Review Board, Medical Sciences Committee A. During screening, patients were administered screening informed consent, medical eligibility form, and BDI-II. Demographic, medical history, anthropometry, blood pressure, psychosocial, and urine and blood measures were taken during two baseline assessment visits. For participants not recruited at community health clinics, the first baseline assessment occurred on the same visit as screening for eligibility. Full-study informed consent was administered to eligible participants. Of the 340 individuals screened, 99 (43%) had BDI-II scores that were out of range for study eligibility (see Fig. 1 for flow diagram). In a parallel groups design, a total of 111 participants were then randomized to either 12 months of life-style intervention ($n = 57$; CALM-D) or a usual care control condition ($n = 54$) using a stratified randomized block design. Strata were designated on the basis of participant language preference (English or Spanish). Random sequences were generated in blocks of 4 to 10 participants which were paired with participant subject numbers. All sequences were concealed before the assignment of treatment conditions. Assessments were repeated at 6 and 12 months after randomization by blinded assessors. Participants in both arms received laboratory results at all assessment time points and were encouraged to share results with their primary care providers.

Participants randomized to intervention received a 17-session, structured life-style intervention based on the protocol used in the Diabetes Prevention Program (18). The intervention was administered by trained therapists, in either English or Spanish in a clinical setting. Treatment fidelity was not assessed. All intervention sessions were approximately 1.5 to 2 hours in duration. Participants first received two individual sessions followed by two weekly and four bi-weekly group sessions. The remaining nine group sessions were scheduled monthly. To maximize participant retention, therapists maintained a flexible approach to session scheduling, including early morning, evening, and weekend sessions. In some cases, it was necessary to provide sessions individually rather than in a group format to accommodate participant schedules and ensure timely delivery of the intervention.

A detailed description of the intervention session topics is available in Table 1. Briefly, intervention components consisted of diet and physical activity largely consistent with the Diabetes Prevention Program protocol combined with cognitive behavioral and social learning approaches to address depressive symptoms. Each participant received a weight loss goal (7% of initial body weight) at the beginning of the intervention. To achieve the weight loss goal, participants also received goals for physical activity (150-minute aerobic activity/wk) and caloric intake (based on initial body

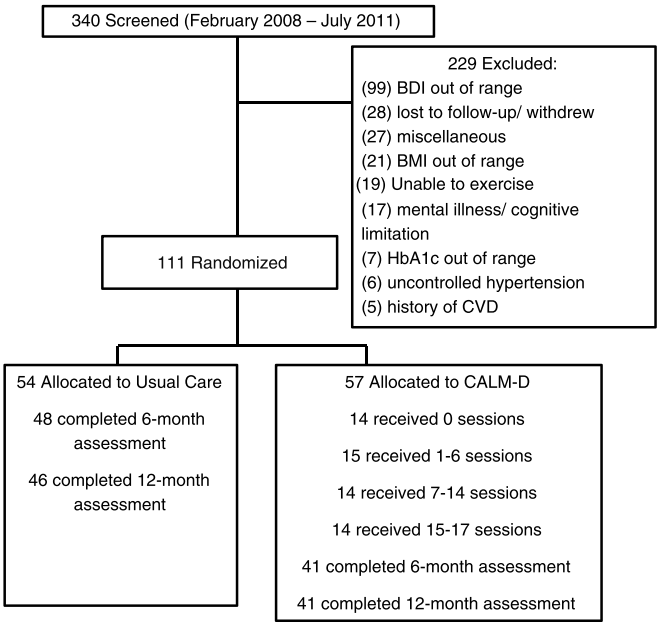

FIGURE 1. CONSORT flow diagram. BDI = Beck Depression Inventory; BMI = body mass index; HbA1c = glycosylated hemoglobin; CVD = cardiovascular disease; CALM-D = Community Approach to Lifestyle Modification for Diabetes.

weight). Therapists provided dietary suggestions and recommended brisk walking as a suitable activity for achieving exercise goals; however, no supervised exercise sessions or meals were provided as a part of this intervention. Intervention participants were provided materials to track progress toward program goals including a scale, materials to monitor and record daily food intake, and an activity monitor to record physical activity. Strategies to address depressive symptoms included behavioral activation, active problem solving, alteration of dysfunctional automatic thoughts,

TABLE 1. CALM-D Intervention Session Topics

Frequency	No.	Title	Topics
Weekly	1	Getting Started Being Active, Losing Weight and Managing Stress	CALM-D goals; Deep breathing
	2	Where's the Fat?/Three Ways to Eat Less Fat	Using fat counter; Identify ways to eat less fat; Food logging
	3	Move those Muscles/Being Active: A Way of Life	Life-style activity; Preventing injury; Physical activity goal
	4	Negative Thoughts and Emotions	Types of negative thinking; Emotional eating
Biweekly	5	Taking Your Medications/Stress and You	Doctor patient communication; Stress effects on the body; Pleasurable activities
	6	Healthy Eating	Calorie goals; Food pyramid; Rate your plate
	7	Tip the Calorie Balance/Communication	Calories and weight loss; Body language; Listening techniques
	8	Take Charge of What's Around You/Social Support	Identifying and changing food and activity cues; Social support
Monthly	9	Problem Solving	5 steps of problem solving; Action plans
	10	Four Keys to Healthy Eating Out	Practice four keys to eating out
	11	The Slippery Slope of Lifestyle Change	Identify potential slips
	12	Challenging and Changing Negative Thoughts	Identify negative thoughts; Challenge negative thoughts
	13	Jump Start Your Activity Plan	FITT principles; Heart rate monitoring; Target heart rates
	14	You Can Manage Stress	3As of stress management; Unavoidable stressors
	15	Assertiveness/Make Social Cues Work *for* You	Assertiveness; Social cues
	16	Life Goals	Set personal goals
	17	Ways to Stay Motivated/Review	Develop action plan to maintain motivation

CALM-D = CALM-D = Community Approach to Lifestyle Modification for Diabetes.

stress management, coping skills training, and modification of behavioral, environmental, and cognitive factors to promote healthy levels of social support. During the first 6 months, participants learned and implemented strategies to achieve physical activity and dietary goals; the second half of the intervention focused on problem solving and maintenance of behaviors.

Participants assigned to usual care received a short educational booklet that covered topics related to diabetes management, but were not formally instructed to make any life-style changes. Participants in both arms were also expected to be treated in accordance with ADA Clinical Practice Guidelines (2005) by their primary care providers whenever possible. Of note, 53 (48%) participants, including 27 (50%) usual care and 26 (46%) intervention participants, were not recruited at community clinics but via word of mouth. Because having a primary care provider was not necessary for study participation, quality of usual care may vary significantly by recruitment site. All participants received compensation for completing assessments at baseline ($225) and 6 and 12 months ($100 each), as well as free transportation to and from the study site. Intervention participants were also compensated ($10) for attendance at individual sessions.

Measures

Primary outcomes for this study included weight, glycemic control, and depressive symptoms. Renal function was also evaluated as an additional outcome. All outcomes were assessed at baseline and 6 and 12 months after randomization by study staff blind to participant treatment condition. Covariates age, sex, diabetes duration, smoking status, and medication usage were also assessed at baseline.

Body weight was measured using a Tanita Body Composition Analyzer (TBF-300A). Depressive symptoms were assessed using the BDI-II total score. The BDI-II has demonstrated internal reliability, convergent, and discriminant validity in older community-based samples (19) and comparable reliability and validity between English and Spanish language versions (20). HbA1c served as the primary measure of glycemic control. Both HbA1c and cystatin C were assessed from blood samples. For all laboratory measures, blood was drawn after a 12-hour fast by an experienced phlebotomist.

Estimated glomerular filtration rate (eGFR) served as an indicator of renal function and was calculated based on cystatin C and creatinine concentrations using the CKD-EPI equation (21), which has been shown to have advantages over the equation using creatinine alone. Evidence indicates that formulas using cystatin C (alone or in combination with serum creatinine) may be more suitable for evaluating renal function in obese participants (22), participants with normal or elevated GFR (23), and participants with Type 2 diabetes (24).

Statistical Analyses

Data were examined for normality and outliers. Intervention and control participants were compared on baseline characteristics using t tests and χ^2 tests of independence for continuous and categorical variables, respectively. For nonnormal variables, t tests were conducted on log-transformed values. Based on results of previous studies, a target sample size of 87 participants per arm was calculated to provide 78% to 95% power to detect effect sizes ranging from 0.420 to 0.564 in weight (25), depression (26), and HbA1c (27) in a two-tailed, two-group comparison at an α of .05. We used intent-to-treat analysis; therefore, data from all eligible participants for whom baseline blood or urine measures were available were included in these analyses.

An extension of latent growth modeling was used to evaluate intervention effects on outcome variables (28). Full-information maximum likelihood was implemented to account for missing data. Traditional latent growth models use longitudinal data to capture two unobserved factors involved in linear change processes, an intercept (initial level) and a slope (magnitude and direction of change). A useful application of this technique in the evaluation of intervention effects involves the partitioning of change into normative and intervention-associated change. The normative slope captures normal change in the outcome variable expected to occur in all participants, in the absence of intervention, as a function of time. The intervention effect corresponds to additional change in the outcome variable among intervention participants after accounting for normative change. An advantage of this approach is the ability specify unique, nonlinear trajectories for normative and intervention-associated change. Results of a mixed-model analysis indicated that only change in eGFR varied significantly as a function of intervention condition when evaluating linear change over the entire 12-month period. However, a test of model fit indicated that a constant slope did not fit the intervention data (see Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/PSYMED/A294). Using latent growth modeling, normative change in each outcome was specified to occur in a linear fashion over the entire 12-month period for each outcome, whereas the intervention effect was expected to occur over the first 6 months of the intervention and be maintained during Months 6 to 12. As indicated by Muthén and Curran (28), estimates of the mean and variance for the intercept and normative slope were held equal across intervention and control groups. Mean, variance, and covariances of the intervention effect were set at 0 for the control group and estimated only for the intervention group.

Mean estimates for normative change and intervention effects are reported as unstandardized regression coefficients (b). The b for normative change can be interpreted as expected monthly change in a variable in the absence of intervention. Positive estimates indicate a monthly increase, whereas negative estimates indicate a decrease. Positive intervention effect estimates indicate an increase after accounting for any normative change in an outcome. Likewise, negative intervention effect estimates indicate a decrease among intervention participants after accounting for expected normative change. We also examined the influence of additional covariates, including age, sex, medication use, and diabetes duration when there was heterogeneity in change defined by a significant variance estimate. Although significant heterogeneity was observed in normative change of both weight and BDI-II scores, as well as the intervention effect on weight, this variability was not explained by any of the covariates examined (data not shown). Finally, Cohen d was computed as an estimate of treatment effect size by multiplying regression coefficients by 6 and dividing by baseline standard deviation for each outcome using the equation (29,30).

Intervention Dose

Given that only 25% of participants completed the entire intervention and 51% completed less than seven sessions, we conducted analyses to determine if greater session attendance was associated with additional improvements. Therefore, in addition to intent-to-treat analyses, we compared intervention participants completing seven or more sessions to those completing six or less using t tests for each outcome.

RESULTS

Table 2 displays sample characteristics at baseline. The sample comprised mostly middle-aged women (71.2%) of minority status (95.5% black [10.8%] or Hispanic [84.7%]) who were in the low-income range (mean household income = $14,382 [$10,832]). In addition, participants were overweight or obese, with inadequately controlled blood glucose and moderate depressive symptoms. Mean eGFR was 86.95 (17.94) $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$ and 6 (7%) participants had eGFR estimates less than 60 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$ at study onset. Fifty-two (47%) of participants were recruited via word of mouth, whereas 48% were recruited at community health clinics. Participants assigned to intervention and control groups differed as a function of

TABLE 2. Baseline Sample Characteristics

Variable	Total	Control	Intervention	*p*
n	111	54	57	
Women, *n* (%)	79 (71.2)	42 (77.8)	37 (64.9)	.14
Ethnicity				.042
Hispanic	94 (84.7)	42 (77.78)	52 (91.2)	
Black	12 (10.8)	7 (13)	5 (8.8)	
White	5 (4.5)	5 (9.1)	0 (–)	
Smoking status, *n* (%)				.14
Never	62 (55.9)	32 (59.3)	30 (52.6)	
Previous	41 (36.9)	16 (29.6)	25 (43.9)	
Current	8 (7.2)	6 (11.1)	2 (3.5)	
Antidepressive medicines, *n* (%)	18 (16.22)	10 (18.52)	8 (14.04)	.52
Antihyperglycemic medicines, *n* (%)	93 (83.8)	44 (81.5)	49 (86)	.52
Age, M(SD), y	54.81 (7.36)	54.78 (6.34)	54.84 (8.27)	.96
Diabetes duration, M(SD), y	6.89 (7.38)	7.56 (8.43)	6.26 (6.20)	.39
Household income, M(SD), $	14,382 (10,832)	14,096 (9730)	14,674 (11,956)	.80
Years of education, M(SD)	12.46 (3.36)	12.27 (3.57)	12.64 (3.16)	.57
Body mass index, M(SD), kg/m^2	32.6 (4.7)	32.9 (5.5)	32.3 (3.7)	.57

M = mean; SD = standard deviation.

p Values evaluate significance of difference between control and treatment frequencies (χ^2 test of independence) and means (*t* test).

ethnicity, with participants identifying as white being overrepresented in the control group. There were no other significant differences at baseline between intervention and control participants.

Table 3 displays means and standard errors for each outcome among intervention and control participants at each time point as well as mean change at 6 and 12 months. Figure 2 displays model implied means in addition to observed means for both groups at each time point for each outcome. All latent growth models demonstrated good fit of the data. Results of the latent growth analysis, including model fit statistics and parameter estimates for each outcome, are available in Table 4.

Weight

Compared with usual care participants, intervention participants showed an average decrease in weight of 1.22 kg. In addition, 24% of participants assigned to intervention

TABLE 3. Means and SDs for Study Outcomes at Baseline and 6 Months and 12 Months After Randomization

		Control			Intervention			Total		
Variable	Time Point	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Weight, kg	Baseline	54	85.57	16.20	56	85.04	12.22	110	85.30	14.25
	6 mo	47	85.21	16.05	40	81.78	12.56	87	83.63	14.57
	12 mo	46	84.19	15.48	41	82.03	12.58	87	83.17	14.15
HbA1c, %	Baseline	51	7.77	1.23	55	7.67	1.40	106	7.72	1.32
	6 mo	47	7.89	1.45	40	7.36	1.48	87	7.65	1.48
	12 mo	46	7.93	1.37	41	7.39	1.46	87	7.68	1.43
BDI-II total	Baseline	54	21.21	7.12	57	19.28	7.08	111	20.22	7.13
	6 mo	48	16.09	9.15	42	10.75	7.76	90	13.59	8.90
	12 mo	46	16.00	10.80	41	9.85	8.86	87	13.10	10.35
eGFR, ml/min	Baseline	40	85.17	20.47	44	88.57	15.35	84	86.95	17.94
	6 mo	22	91.33	18.91	15	91.90	20.67	37	91.56	19.36
	12 mo	35	85.61	17.30	31	91.15	14.61	66	88.22	16.21

SD = standard deviation; HbA1c = glycosylated hemoglobin; BDI-II = Beck Depression Inventory II; eGFR = estimated glomerular filtration rate.

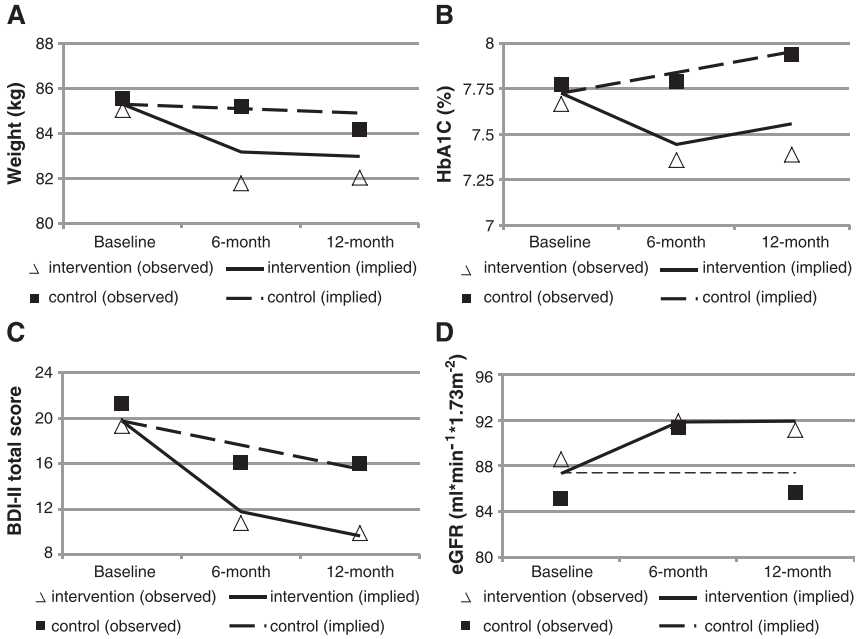

FIGURE 2. Observed and model implied means for weight (A), glycemic control (B), depressive symptoms (C), and renal function (D) among intervention (white triangles, solid lines) and control (black squares, dashed lines) participants at each time point. Observed means were calculated using available data at each time point and should be interpreted with caution due to data missingness. Model-implied means are calculated using model-derived parameter estimates (intercepts and β coefficients). Full-information maximum likelihood was used to account for missing data in estimation of model parameters. BDI-II = Beck Depression Inventory II; eGFR = estimated glomerular filtration rate; HbA1c = glycosylated hemoglobin.

achieved weight loss of 5% or greater compared with 11% of control participants. The intervention effect on weight was significant ($b = -0.322$, $p = .010$), indicating an average of 0.32 kg of weight loss per month over the first 6 months of intervention, which was maintained through the 12-month assessment. This was a small effect ($d = -0.136$, 95% confidence interval [CI] = −0.239 to −0.033). In contrast, normative weight change over the 12-month period was not significant ($b = -0.033$, $p = .39$).

Glycemic Control

Participants assigned to intervention demonstrated an overall decrease in HbA1c of 4.9 mmol/mol (0.45%) relative to usual care participants. The intervention had a significant effect on HbA1c ($b = -0.066$, $p = .017$), as participants in the intervention group showed a monthly decline in HbA1c of 0.7 mmol/mol (0.066%) over the first 6 months of intervention. This was a medium effect ($d = -0.3$, 95% CI = −0.549 to −0.051). The mean normative slope in HbA1c indicated no significant change over the year in the absence of intervention ($b = 0.019$, $p = .11$).

Depressive Symptoms

Intervention participants also showed a decrease in BDI total scores of 3.01 units compared with participants assigned to usual care. The intervention effect on BDI-II scores was significant ($b = -1.009$, $p < .001$), indicating a decline of approximately 1 unit per month among intervention participants over the first 6 months. This large effect ($d = -0.85$, 95% CI = −1.223 to −0.477) was in addition to the normative change in BDI-II scores, which was also significant ($b = -0.355$, $p = .001$), signifying a decline in BDI-II scores of 0.36 units per month, for 12 months, which was unrelated to the intervention.

Renal Function

Compared with participants assigned to usual care, intervention participants exhibited an increase in eGFR of 5.57 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$. The mean of the intervention effect on eGFR was significant ($b = 0.74$, $p = .020$), indicating an increase in eGFR among intervention participants at a rate of .74 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$ each month over the first 6 months of intervention. This was a medium effect ($d = 0.248$, 95% CI = 0.040-0.456). The mean normative change in eGFR was not significant ($b = 0.011$, $p = .91$), suggesting no overall change in eGFR in the absence of intervention.

Intervention Dose

Of the 57 participants allocated to the intervention condition, 25 participants attended at total of seven sessions or more (>40% of the intervention) and completed the 12-month follow-up assessment. These participants showed significantly greater reductions in weight ($\bar{D} = 3.92$ kg, standard error = 1.18, $p = .002$) and HbA1c ($\bar{D} = 0.89\%$, standard error = 0.31, $p = .008$) compared with participants assigned to intervention who completed less than

TABLE 4. Model Fit and Parameter Statistics

Model Fit Statistics	Weight	HbA1c	BDI-II Total	eGFR
χ^2	15.152	16.579	15.062	11.951
df	10	11	12	10
p	.13	.12	.24	.29
RMSEA	0.097	0.096	0.068	0.067
90% CI [LL, UL]	[<0.001, 0.190]	[<0.001, 0.185]	[<0.001, 0.161]	[<0.001, 0.185]
p	.21	.20	.35	.38
Parameter estimates				
Intercept				
Mean	85.310	7.726	19.752	87.338
(SE)	(1.350)	(0.125)	(0.661)	(1.890)
p	<.001	<.001	<.001	<.001
Variance	197.602	1.241	21.579	286.291
(SE)	(26.96)	(0.240)	(5.867)	(47.204)
p	<.001	<.001	<.001	<.001
Normative change				
Beta	−0.033	0.019	−0.355	0.011
(SE)	(0.039)	(0.011)	(0.108)	(0.104)
p	.39	.11	.001	.91
Variance	0.049	<0.001	0.355	0.139
(SE)	(0.020)	(0.002)	(0.102)	(0.130)
p	.013	.83	<.001	.29
Intervention effect				
Beta	−0.322	−0.066	−1.009	0.742
(SE)	(0.124)	(0.028)	(0.226)	(0.318)
p	.010	.017	<.001	.020
Variance	0.626	—	—	1.016
(SE)	(0.250)	—	—	(0.606)
p	.012	—	—	.094

Results and fit statistics of latent growth models examining change in each outcome.

HbA1c = glycosylated hemoglobin; BDI-II = Beck Depression Inventory II; eGFR = estimated glomerular filtration rate; RMSEA = root mean square error of approximation; CI = confidence interval; LL = lower limit; UP = upper limit; SE = standard error.

$\alpha = .05$.

seven sessions. On average, participants who completed seven or more sessions lost a mean of 3.42 kg (7 lb 8 oz), decreased HbA1c by 0.53% (5.8 mmol/mol), decreased their BDI-II score by 9.8, and increased their eGFR by 6.08 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$. In contrast, the 16 participants who attended less than seven sessions gained 0.5 kg (17.6 oz), increased HbA1c by 0.35% (3.8 mmol/mol), decreased BDI-II score by 7, and increased eGFR by 4.51 $ml \cdot min^{-1} \cdot 1.73\ m^{-2}$ (see Fig. 3).

DISCUSSION

This behavioral intervention resulted in beneficial effects on weight, glycemic control, renal function, and depressive symptoms in a sample of overweight/obese adults with Type 2 diabetes and depressive symptoms. These findings are promising given the implementation in this particularly vulnerable sample. Whereas previous similar interventions have typically been conducted in patient populations with adequate resources to satisfy health care needs (4,31,32), participants in the present sample are at increased risk for poor outcomes because they represent an underserved population with reduced access to health care resources. In addition, the present intervention used was less structured and required fewer resources compared with similar life-style interventions conducted in Type 2 diabetes populations. For example, a number of components used in the LOOK AHEAD trial, including pharmacotherapy, meal replacements, and supervised exercise interventions, were not implemented in the present intervention. Although improvements in weight loss (2.3% versus 8.6%) and glycemic control

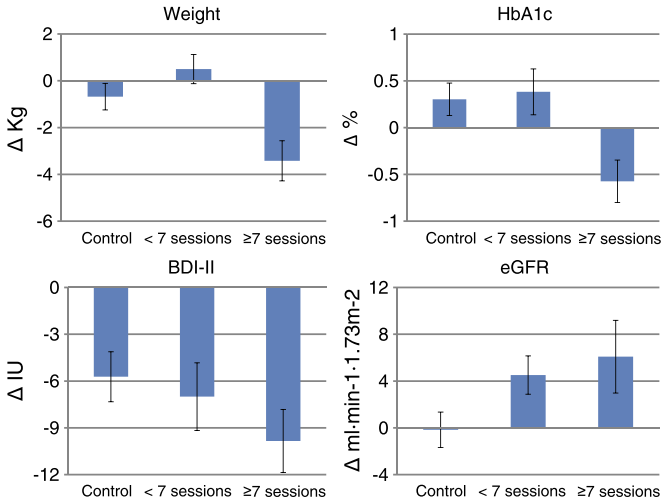

FIGURE 3. Means and standard errors for change in weight, glycemic control, depressive symptoms, and renal function for 12 months among control participants (n = 46), intervention participants completing less than seven sessions (n = 16), and intervention participants completing at least seven sessions (n = 25). BDI-II = Beck Depression Inventory II; eGFR = estimated glomerular filtration rate; HbA1c = glycosylated hemoglobin. Color image is available only in online version (www.psychosomaticmedicine.org).

(0.45 versus 1.3% decline) were not as pronounced as those reported in LOOK AHEAD, the present intervention may have greater potential for widespread implementation and long-term maintenance of life-style changes.

The observed improvements in glycemic control, depressive symptoms, and renal function occurred in the context of relatively modest weight loss, with only 24% of participants achieving at least 5% decline in initial body weight. Although we suspect the observed intervention effects, especially improved glycemic control, will translate to reduced risk of future diabetes related complications (33), it is difficult to gauge the clinical significance of these findings in the absence of a more direct measure of patient functioning, such as diabetes-specific distress, or long-term follow-up measures. Of note, 84% of participants in the present sample were prescribed antihyperglycemic medications at study onset; thus, effects reported here reflect improvements beyond what was achieved using pharmacological management of blood glucose alone and may be partially attributable to improved treatment adherence and/or disease-related coping among participants.

There is growing evidence indicating that a decline in GFR often occurs early in participants with diabetes who later progress to renal disease (34,35). Currently accepted strategies for prevention of renal disease in Type 2 diabetes mainly involve pharmacological management of hyperglycemia, blood pressure, and lipids (36). Although previous research has demonstrated that behavioral interventions may slow the rate of GFR decline in individuals with Type 2 diabetes and existing nephropathy (5,6), present results suggest for the first time that early behavioral interventions may prevent or slow deterioration of renal function before the development of clinically significant renal insufficiency. It is unlikely that this effect is the result of changes in concomitant medications, as there was no evidence of differential medication use among intervention and control participants.

The present analysis was limited by the relatively small sample size and short follow-up period. Recruitment and retention of depressed (37,38), low-income (39,40), and minority (38,40–42) populations has historically presented challenges for researchers. We implemented a number of strategies to facilitate participant retention, including compensation for attendance, flexible scheduling of intervention sessions, and provision of free transportation. However, a significant percentage of participants were lost to follow-up or declined further participation before study randomization. In addition, although 75% of participants assigned to intervention attended at least one session, 25% were unwilling or unable to attend any intervention sessions. This loss of participants could be related to a number of factors including limitations caused by mental health difficulties or financial instability in this population. Our results showed that participants attending at least seven sessions demonstrated significantly greater improvements in weight and glycemic control compared with those attending less than seven sessions. Therefore, ensuring participants receive an effective intervention dose presents a worthy challenge for future researchers working with similar populations.

The present study did not achieve the randomization goal of 200 participants. However, using an intent-to-treat model, the intervention demonstrated significant, although modest effects among individuals with Type 2 diabetes, who were also overweight/obese and socioeconomically disadvantaged with symptoms of depression. Moreover, we have increased confidence in the precision and reliability of study findings given the use of a statistical method that allowed for the specification of separate trajectories

corresponding to normative and intervention-associated change for each outcome. Although no significant observations are reported here, an additional benefit of this approach is the ability to evaluate the effect of baseline status and other covariates on normative and/or intervention-associated trajectories.

In conclusion, this intervention resulted in improvements in cardiometabolic risk factors that were maintained for 6 months after completion of the active portion of the intervention in a high-risk sample of individuals with existing Type 2 diabetes. Many interventions targeting weight loss do not adequately address challenges associated with life-style change and thus do not show lasting effects (43). However, interventions incorporating behavioral techniques have shown long-term effects in diabetes prevention (44), highlighting the role of behavioral modification in long-term risk reduction. Importantly, this intervention placed minimal demands on interventionists and participants, consisting of unsupervised low- to moderate-intensity exercise (brisk walking), sustainable dietary changes, and cognitive behavioral techniques; in this regard, implementation in community settings and maintenance of behavioral changes after study termination seem feasible. However, given significant challenges encountered here related to retention of participants and delivery of an effective intervention dose, future studies may benefit from increased efforts to recruit and retain particularly difficult to reach populations including identification and elimination of logistical barriers to participation, the use of lay health workers and community-based recruitment approaches, and maintaining frequent and consistent contact with prospective participants.

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