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A Model of Community-Based Behavioral Intervention for Depression in Diabetes: Program ACTIVE

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Abstract

Depression affects one in four people with diabetes and significantly affects diabetes health. Earlier studies of the treatment of depression have documented that cognitive behavioral therapy (CBT) and exercise have each been found to be effective in treating depression in people with and without diabetes in the context of medical settings. Individuals in rural areas lack regular access to medical centers and require treatment options that may be adapted for local communities. To date, no studies have combined CBT and exercise for people with diabetes. This article presents a translational behavioral depression intervention study designed for individuals with type 2 diabetes in a rural Appalachian region as a model of an interdisciplinary approach to the treatment of depression in diabetes.

The prevalence of type 2 diabetes continues to rise in epidemic proportions both in the United States and globally,[1] and diabetes remains overrepresented among ethnic minority and other underserved populations such as those in rural areas.[2,3] Depression has been found to co-occur in one in four people with diabetes.[4] As noted in our article elsewhere in this issue (p. 15), depression has been found to be associated with worsened glycemic control,[5] diabetes complications,[6] poorer adherence to diabetes treatment recommendations,[7–9] increased functional disability,[10,11] and early mortality.[12,13]

A number of studies have documented the efficacy of conventional treatment approaches such as anti-depressant medication [14–19] and cognitive behavioral therapy (CBT)[20,21] on depression outcomes in patients with type 2 diabetes. Although these approaches are effective tools in treating depression, access to both medical and mental health care in rural areas may be challenging for patients.[22–24] Additional strategies that address access to care are needed to provide patients with effective approaches to depression treatment in rural communities.

Exercise has been shown to be an efficacious behavioral management strategy for depression in nondiabetic samples and holds the potential for synergistic effects on depression and diabetes outcomes. A variety of studies have examined the antidepressant effects of exercise in nondiabetic patients with clinical depression.[25–26] Blumenthal et al. [25] conducted a 16-week randomized, controlled trial to evaluate the efficacy of aerobic exercise compared to sertraline and combination therapy as a treatment for major depression among older adults. At post-treatment, exercise and combination therapy were as efficacious as antidepressant medication in ameliorating depression (remission rates ranging from 60 to

69%). At the 6-month follow-up,[26] participants in the exercise condition showed the lowest rates of depression relapse (8%) compared to those in the other two treatment conditions (38% for medication and 31% for combination therapy). This relationship remained statistically significant after adjustment for severity of depression at baseline.

Although the independent effect of exercise on physiological outcomes in type 2 diabetes requires further study, exercise interventions have been shown to improve glycemic control in patients with type 2 diabetes[27] and to reduce upper-body visceral adiposity,[28–31] improve insulin sensitivity,[30–33] increase HDL cholesterol,[30,33] reduce triglyceride levels,[34] increase LDL cholesterol particle size,[27] reduce hypertension,[32] and decrease total cholesterol where there are reductions in adiposity.[31]

In sum, depression represents an important risk factor for diabetes outcomes for adults with type 1 or type 2 diabetes. Traditional treatment approaches are effective, but high relapse rates, persistent depressive symptoms, and limited access to mental health providers in under-served areas pose ongoing challenges for patients. Exercise, as an accessible treatment strategy and in conjunction with traditional treatment approaches, may prove effective in providing synergistic effects on both depression and diabetes. A model for the design of a rural community-based combination treatment approach for depression in people with type 2 diabetes is described below.

Program ACTIVE

Program ACTIVE (Appalachians Coming Together to Increase Vital Exercise) was designed to test the effectiveness of a combination behavioral approach to the treatment of depression in adult patients with type 2 diabetes on depression, glycemic control, and cardiovascular risk outcomes. The study received approval from the Institutional Review Board of Ohio University in Athens.

In this article, we describe the methodology, recruitment outcomes, and intervention components of this feasibility trial. The main study outcomes are presented elsewhere. [35]

The primary study aims were:

1. To assess the feasibility of recruitment, retention, and adherence of an at-risk Appalachian type 2 diabetic patient population with major depression to a 12-week interdisciplinary depression treatment protocol combining CBT and community-based exercise
2. To assess changes in depression, glycemic control, and cardiovascular risk factors from baseline to follow-up assessment
3. To assess changes in maximal aerobic capacity (VO_{2max}), exercise tolerance, and resting blood pressure from baseline to follow-up assessment

The secondary aims of Program ACTIVE were to assess changes in quality of life and social support immediately after the intervention and at a 3-month follow-up compared to baseline. In addition, the feasibility of data collection of variables to conduct cost-effective analyses was assessed.

Study Design

Program ACTIVE was a single-arm, repeated-measures pilot and feasibility study conducted in two phases. In Phase I, a culturally consonant CBT manual was created, and exercise protocol materials based on the Diabetes Prevention Program (DPP)[36] were culturally tailored for a rural Appalachian population with type 2 diabetes. Materials were evaluated

for cultural salience, readability, and comprehension by national experts and key informants drawn from the community.

In Phase II, the interdisciplinary treatment protocol was implemented. Individuals responding to advertising were screened by phone for medical and psychiatric eligibility. Participants meeting study inclusion criteria then completed a baseline assessment protocol to further determine appropriateness of the intervention. Those enrolled participated in 10 individual CBT sessions and 12 weeks of concurrent community-based aerobic exercise. Participants completed follow-up assessments immediately after the intervention (denoted below as POST) and 3 months after intervention completion (denoted as 3MFU).

Power analyses indicated that a minimum sample of 36 participants completing POST and 3MFU assessments would provide adequate statistical power to address the primary study aims. A sample size of 50 was the recruitment goal.

Recruitment

Participants for Program ACTIVE were recruited from communities in southeastern Ohio and western West Virginia. Information about the study was distributed to physicians' offices via direct phone contact by the study investigators, flyers, and direct mailings to consenting physician practice panels. In addition, the investigators provided interviews to local newspapers and radio stations and requested public service announcements from these venues. Paid advertising was purchased from local newspapers and radio outlets. Advertising also took place at community events and centers related to health or diabetes.

Eligibility Criteria

To ensure maximum levels of participant safety and appropriateness for the intervention, the following eligibility criteria were used: age ≥ 18 years, ambulatory status, diagnosis of type 2 diabetes of ≥ 1 year's duration, and current major depression lasting ≥ 2 weeks as the primary psychiatric diagnosis with no evidence of psychotic symptoms. Medical exclusion criteria included Stage 2 hypertension as defined by the Joint National Committee of Prevention, Detection, Evaluation, and Treatment of High Blood Pressure VII[37]; recent cardiac events; recent laser surgery for proliferative retinopathy; history of stroke, lower limb amputation, asensory peripheral neuropathy, aortic stenosis or other severe valvular heart disease, atrial fibrillation, severe chronic obstructive pulmonary disease (e.g., basal oxygen), class III or IV heart failure; and medical instability. Psychiatric exclusion criteria included active suicidal ideation or a history of suicide attempt, lifetime history of bipolar depression or any psychotic disorder, and current substance abuse or dependence disorder.

Participants were eligible to enroll if they were not receiving medication or their current medication had remained the same prescription and dosage for ≥ 6 weeks (i.e., sufficient time to ascertain medication failure). Participants who reported a prescribed change in medication dose or type during the previous 6-week period were excluded or deferred for follow-up screening. Participants receiving medication management from a psychiatrist were included, but patients receiving current psychotherapy treatment for depression were encouraged to remain with their original provider. Once enrolled, participants were asked to refrain from changes in dose or type of medication until the conclusion of the study.

Feasibility Outcome Data

Elgibility screening

A total of 336 individuals were screened by phone to assess their medical and psychiatric eligibility. Of these, 23% met eligibility criteria and were referred for baseline assessment.

Nineteen percent (63) declined participation during the screening process. Reasons for declining participation included distance of the exercise venues from the individual's home or that the goals of the study were inconsistent with participant's goals (e.g., participants looking for a diabetes management program rather than a depression treatment program). Fifty-nine percent (197) were not eligible, with the majority (71%) failing to meet psychiatric criteria.

A total of 76 participants were eligible to complete the baseline assessment. Eleven individuals declined participation in the baseline assessment once scheduled. Sixty-five individuals completed the baseline assessment. Of these, 50 (77%) were eligible to participate and were enrolled in the intervention. This rate is comparable to those reported by Blumenthal et al.[25] Thirteen participants were deemed ineligible to participate after baseline assessment (did not meet criteria for major depressive disorder at interview). Two eligible individuals declined enrollment in the intervention because of comorbid medical disorders or competing time demands.

Retention data

A total of 50 participants were enrolled, with 40 completing the intervention and each follow-up assessment (80% retention). The 10 participants (20%) who did not complete the intervention cited development of unrelated medical diagnoses or preference for additional mental health treatment.

Assessment Procedures

The research nurse or project coordinator consented to individuals' participation in the study at the beginning of the baseline assessment. Baseline assessment took place in one or two face-to-face sessions. A description of the sequence of study activities is shown in Figure 1. Each participant completed a 1- to 2-week baseline assessment period followed by the 12-week active intervention period. The POST assessment occurred 1–2 weeks after the intervention. The final 3MFU assessment occurred 3 months after completion of the POST assessment.

Measurements taken at each assessment are shown in Table 1. Participants completed a medical exam, fasting blood draw, psychiatric interview for mood and anxiety disorders (i.e., *Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders*, 4th edition [SCID][38]), and graded maximal exercise stress test (GXT). Participants who met medical inclusion criteria were asked to provide consent for the study team to contact their primary care physician to complete a checklist of medical diagnoses. Participants were given a pedometer and activity diaries to complete during the week after assessment, and these were collected in person or by mail. After a completed baseline assessment, the research team reviewed all data to make an enrollment determination. Participants who met all study criteria were scheduled for their first exercise and CBT sessions within 1–3 weeks of the baseline assessment completion.

Psychological, behavioral, and physiological measurements were administered at each of the three assessment periods with the exception of demographic characteristics (baseline only). SCID interviews were used to assess lifetime history and current Axis I diagnoses at baseline and psychiatric symptoms present during follow-up periods. Physiological measures were repeated at each of the three assessment time points, with the exception of the GXT (baseline and POST only). The medical history interview was administered at each assessment.

Sample Characteristics

Intervention sample

Participants (n = 50) were predominantly female (68%), married (74%), and evenly distributed across educational levels (31% with a high school education or less; 38% trade school or part college; 31% college or greater). The modal annual household income was $21,000–40,000. Participants had a mean age of 57 years (standard deviation [SD] 9.0 years). The mean duration of type 2 diabetes was 11.0 years (S.D. 7.0 years). The mean BMI was 35.1 kg/m^2(SD 7.1 kg/m^2).

Participants who were successfully enrolled in the intervention (n = 50) were compared to those who declined participation once deemed eligible per screening (n = 13) and did not differ significantly across demographic variables (e.g., age, education, marital status, sex, and work status).

Intervention Design

The interdisciplinary intervention was composed of 10 CBT sessions, six classes of supervised exercise, and 12 weeks of community-based aerobic activity. These interventions were administered concurrently to assess feasibility and retention of a combination behavioral treatment arm. CBT sessions were scheduled weekly over the course of the 12-week period, with two weeks available for flexibility in scheduling. The community-based exercise was conducted throughout the 12-week period. It included six exercise classes, an exercise manual, access to a community exercise facility, and weekly contact with study personnel to encourage adherence to the exercise protocol.

CBT intervention

CBT has gained wide acceptance as an efficacious intervention approach for the treatment of depression.[39] Drawn from research and clinical theory in the areas of cognitive and behavioral psychology, CBT involves therapeutic change to thoughts, feelings, and behaviors by changing perceptions of the self, situations, and the future and the introduction of behavioral techniques such as increased daily activity, interaction with social support networks, and assertiveness training.[39] The use of cognitive and behavioral tools modeled in therapy and practiced through the use of take-home activities provides individuals with an opportunity to generalize skills to situations beyond the therapeutic relationship.

Participants received 10 sessions of CBT using a manualized approach based on Beck's model of cognitive therapy.[39] In light of the large array of skills that are possible to include in the CBT framework, selected goals were targeted for a brief therapy format (presentation of CBT model, thought records, cognitive distortions, counterarguments, cognitive refraining, automatic thoughts, core beliefs, and relapse prevention). Session goals were tailored to the needs of participants. Each session began with a review of take-home activities performed during the previous week and an introduction of new concepts and skills. Participants completed weekly self-report depression questionnaires in addition to measures of psychotherapy alliance and expectations of treatment. Measures were reviewed by the therapist and used to document changes in depressive symptoms in session.

Therapist training—CBT therapists completed graduate coursework in CBT and training by author M. de Groot in the manualized training approach to mirror the skill levels of practicing clinicians in the community. Intervention sessions were video- or audiotaped and reviewed for fidelity. Supervision of treatment sessions was provided in a weekly group format by M. de Groot. Sessions took place in the psychology and social work clinic that

serves students at Ohio University and community members in the Athens, Ohio, area and within a private medical office in Belpre, Ohio.

Exercise intervention

The exercise protocol was a culturally tailored community-based exercise intervention based on the aerobic exercise goals used in the study by Blumenthal et al.[25,26] and psychoeducational materials adapted from the Lifestyle Balance behavior arm of the DPP.[36] Exercise in Program ACTIVE was obtained through individualized community-based activities selected by participants. Community partners served as venues for exercise classes and routine physical activity throughout the study. The exercise intervention consisted of three components: exercise classes led by author M. Kushnick, a supervised graduate student, or a community fitness director; a supplemental exercise manual; and weekly physical activity goals.

Exercise classes—To provide participants with the necessary training to begin a safe exercise program, one exercise class per week was offered in weeks 1–4, 6, and 8. In session 1, participants were introduced to exercising safety, including recognition of hypoglycemia and monitoring of blood glucose before initiating a new exercise bout,[40] proper use of exercise equipment, and individual exercise prescriptions generated from the GXT at baseline, with aerobic intensity established at 55–65% of their maximal heart rate response.[40] Subsequent exercise classes reinforced these concepts; elaborated on topics addressed in an exercise manual, including helping participants identify ways to increase their exercise; and established routine exercise practices that would ensure success in meeting their weekly exercise goals (discussed further below). The intensity of exercise progressed to 65–75% of their maximal heart rate response at the baseline GXT at either week 4 or week 6 based on exercise tolerance (ability to complete 30 minutes of continuous aerobic exercise in the established range).

During the baseline assessment and throughout the exercise classes, participants were trained to use the Rating of Perceived Exertion (RPE) in conjunction with heart rate monitors to assess exercise tolerance.[41] Over the course of each class, participants were monitored for up to 60 minutes of exercise by an exercise physiology graduate student, M. Kushnick, or a community fitness instructor. Participants were trained to exercise in a manner consistent with the American College of Sports Medicine (ACSM) recommendations, including 10 minutes of pre-activity (warm-up and stretching); up to 30 minutes of active exercise (endurance; initially beginning at 20 minutes and typically progressing to 30 minutes by week 4); and 10 minutes of post-activity (cool-down, recovery).[42] One-on-one exercise monitoring was available to participants who received feedback throughout the session on their intensity for each activity.

The content of exercise classes in week 6 and week 8 included re-establishing appropriate intensities using the RPE method (correlating heart rates with RPE), increasing the prescription of aerobic intensity, and introducing basic physical strengthening activities (e.g., sit-to-stand, single-arm curl, shoulder press, wall pushups, side bends, and forward lunges using body weight or commonly available items).

During each class, participants were given personalized instruction on proper and safe warm-up, form, intensity, and cool-down of exercise procedures. Exercise modes available during these sessions included walking on an indoor track or using treadmills, stationary recumbent/upright bicycles, or elliptical machines. Participants were provided with passes to the exercise venues for use between and beyond exercise classes for the duration of the intervention period.

Exercise goals—Exercise goals were adapted from the DPP[36] to accommodate the physical and medical restrictions endemic to an older-adult diabetic population. Exercise prescriptions were based on the results obtained from the GXT obtained at baseline. Participants were given exercise goals that represented a total duration of 150 minutes per week with activity that reached 50–85% maximum heart rate consistent with recommendations from the ACSM.[43] Because of the paucity of previous exercise experience of participants in this region, as well as the unique needs of patients with depression and diabetes,[33] exercise duration and intensity goals were increased in a graduated manner during weeks 1–3, beginning with 100 minutes of weekly exercise and increasing to 150 minutes of weekly exercise. Participants recorded the type (e.g., walking, swimming, or stationary cycling) and format (e.g., solitary activity or exercise with a partner/spouse/family member) of activities each week.

Weekly intervention contacts—Participants were asked to complete weekly exercise diaries and to record their number of steps measured using pedometers during the intervention period (weeks 1–12). Data were collected weekly through in-person or phone contacts. The weekly contacts served three functions: *1*) to provide an opportunity to assess and address barriers to exercise adherence, *2*) to collect physical activity and self-monitoring of blood glucose (SMBG) data, and *3*) to monitor any changes to participants' physical condition (e.g., hyperglycemia, hypoglycemia, joint pain, back pain, angina, lightheadedness, or symptoms of hypotension).

Blood glucose monitors were downloaded weekly to examine significant changes in daily blood glucose readings as a result of exercise. Participants who showed increased instances of hyperglycemia (defined as blood glucose levels ≥ 250 mg/dl) or hypoglycemia (defined as blood glucose levels ≤ 80 mg/dl) were contacted by the study physician to consider medication adjustment.

Participants were instructed to check their blood glucose levels before exercise. If their blood glucose was < 80 mg/dl, participants were instructed to eat a snack and recheck their glucose 10–15 minutes later to ensure that it was rising before engaging in exercise. Participants with blood glucose levels > 250 mg/dl were instructed to not exercise until their blood glucose was ≤ 250 mg/dl.

To facilitate adherence to the exercise goals, participants were provided with weekly handouts (toolbox materials) patterned from the DPP.[36] Materials included tracking logs to reflect the goals and total miles achieved throughout the intervention, suggestions of local venues amenable to physical activity, and maps to chart participant progress. Participants were provided with new materials each week to address challenges to exercise and SMBG adherence.

CBT and exercise manuals

An additional component to the translation of this intervention to the community setting was the use of psychoeducational materials for CBT and physical activity. For CBT sessions, a diabetes-specific CBT manual created by the study team incorporated treatment concepts and skills covered in each of the 10 therapy sessions. In the exercise manual, motivational and behavioral strategies for adherence to exercise goals were reinforced using an adapted version of the DPP Lifestyle Balance exercise intervention materials[36] distributed at each exercise class. In both manuals, fictional characters typical of the region shared their personal stories about the ways in which depression affected their diabetes and social lives and modeled the incorporation of the behavioral strategies featured each week.

Challenges to Recruitment and Intervention Implementation

A number of challenges to successful recruitment, retention, and intervention implementation were encountered throughout the study period. Although preliminary survey studies demonstrated the existence of an ample population of individuals with type 2 diabetes and depression, barriers endemic to the rural region became evident. Primary among these were participants' difficulties in allocating time for study activities vis-a-vis child-care and work responsibilities (adding an hour or more with travel time) and transportation costs associated with study visits (e.g., rising fuel costs). Additional barriers included low levels of fitness at study entry in conjunction with high rates of comorbid disorders that limited participation or required additional medical and behavioral attention (e.g., chronic pain presentations, cardiovascular disorders, or cancer).

In response to these barriers, a number of strategies were employed by the study team to adapt to local conditions. To address time and rising gas prices, the study team expanded the availability of exercise outlets and CBT therapy locations to be closer to population centers. These included the communities in Washington County, Ohio (Marietta and Belpre, Ohio), and Wood County, W.V. (Parkersburg, W.V.), extending the radius of the study catchment by 50 miles. In so doing, the team partnered with local exercise and medical facilities, which yielded significant improvements in recruitment and retention.

To address issues arising from comorbid medical conditions, the team tailored exercise prescriptions and provided additional interventions during CBT sessions to address limitations associated with deconditioning, chronic pain management, and cardiac symptoms. Participants were closely monitored during weekly intervention contacts and strongly encouraged to report new and recurring symptoms to their primary care physician. When appropriate, participants were asked by the study medical director to place their exercise training on hold until medical symptoms could be adequately assessed and addressed. Participants were provided with support by team members to communicate effectively with their medical providers for timely resolution of medical symptoms. Taken together, these strategies yielded positive returns for recruitment, retention, and participant safety.

Conclusions

Depression is an important risk factor for adults with type 1 or type 2 diabetes. Depression treatments such as psychotherapy and antidepressant medications have been shown to be efficacious and effective in the short term. Despite these tools, significant barriers to treatment access remain, particularly for underserved ethnic and rural patients. There is a need to expand the treatment repertoire for depression to include accessible long-term behavioral strategies such as exercise.

Program ACTIVE demonstrated the feasibility of recruiting and retaining rural Appalachians with type 2 diabetes into a rigorous combination behavioral treatment of depression. The southeastern region of Appalachian Ohio is largely rural (42%) and characterized by lower education rates, higher unemployment and poverty rates, and decreased access to adequate health care compared to those in other regions of the state and nation.[44] Additional barriers inherent to this region, such as large geographical distances between place of residence and community facilities, gas price vulnerability, and caregiver demands for family members, were identified by participants as pertinent to recruitment and retention in the depression treatment protocol. Lessons learned over the course of the study indicated the need for a network of community partners to provide participants with affordable and convenient exercise outlets and CBT.

Intervention programs such as Program ACTIVE can overcome these barriers if they are flexible in their approach and make use of community resources to facilitate participant self-care. Future studies should examine the relative costs and effectiveness of single treatment approaches (e.g., CBT alone or exercise alone) compared to this combination behavioral treatment tailored for a rural Appalachian region. In so doing, there is great opportunity to expand community capacity to address the significant costs associated with comorbid depression and diabetes for underserved populations.

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Phone Screening	Baseline Assessment	Intervention	POST Assessment	No Contact	3MFU Assessment
–2 weeks	–1 week to time 0	1–12 weeks	13–14 weeks	15– 27 weeks	28–29 weeks

Figure 1.
Study activities schedule.

Table 1

Psychosocial, Behavioral, and Medical Measures Collected at Each Assessment Time Point

Measures	Screening	Baseline	POST	3MFU	Outcome Variable	Covariate	Clinical Monitoring Variable
Psychosocial							
Demographic characteristics		x				x	
Structured Clinical Interview for the DSM-IVTR	x (Screener)	x Lifetime	x Current	x Current	Primary		
Beck Depression Inventory		x	x	x	Primary		
Diabetes Quality of Life		x	x	x	Secondary		
SF-36 Quality of Life Measure		x	x	x	Secondary		
Chronic Illness Resource Survey		x	x	x	Secondary		
Behavioral		x	x	x			
Physical activity diary (1 week)		x	x	x	Primary		
Pedometer (1 week)		x	x	x	Primary		
Physiological		x	x	x			
A1C		x	x	x	Primary		
Blood lipid profile (HDL, triglycerides, total cholesterol, and LDL)		x	x	x	Primary		
Self-monitoring of blood glucose		x	x	x			x
Physical exam		x	x	x		x	x
Medical history interview	x	x					x
Medical status review			x	x			x
Maximal GXT (VO_{2max}; exercise tolerance)		x	x		Primary		
Height		x	x	x		x	
Weight		x	x	x		x	
Waist/hip girth		x	x	x			
Blood pressure		x	x	x	Primary		
Resting heart rate/pulse		x	x	x			x
Perceived exertion (Borg rating)		x	x				