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Design and methods for a pilot randomized clinical trial involving exercise and behavioral activation to treat comorbid type 2 diabetes and major depressive disorder

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Abstract

Background—The comorbidity of type 2 diabetes mellitus (T2DM) and depression is associated with poor glycemic control. Exercise has been shown to improve mood and glycemic control, but individuals with comorbid T2DM and depression are disproportionately sedentary compared to the general population and report more difficulty with exercise. Behavioral activation, an evidence-based depression psychotherapy, was designed to help people with depression make gradual behavior changes, and may be helpful to build exercise adherence in sedentary populations. This pilot randomized clinical trial will test the feasibility of a group exercise program enhanced with behavioral activation strategies among women with comorbid T2DM and depression.

Methods/Design—Sedentary women with inadequately controlled T2DM and depression (N=60) will be randomly assigned to one of two conditions: exercise or usual care. Participants randomized to the exercise condition will attend 38 behavioral activation-enhanced group exercise classes over 24 weeks in addition to usual care. Participants randomized to the usual care condition will receive depression treatment referrals and print information on diabetes management via diet and physical activity. Assessments will occur at baseline and 3-, 6-, and 9-months following randomization. The goals of this pilot study are to demonstrate feasibility and intervention acceptability, estimate the resources and costs required to deliver the intervention and to estimate the standard deviation of continuous outcomes (e.g., depressive symptoms and glycosylated hemoglobin) in preparation for a fully-powered randomized clinical trial.

Discussion—A novel intervention that combines exercise and behavioral activation strategies could potentially improve glycemic control and mood in women with comorbid type 2 diabetes and depression.

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Background

Type 2 Diabetes Mellitus, Depression and Exercise

Type 2 diabetes mellitus (T2DM) is a significant public health problem affecting 7.8% of US adults (National Diabetes Information Clearinghouse, 2006), and women with T2DM are 3 times more likely to have depression than men (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001). Depression in T2DM is associated with worse glycemic control (Kovacs, Mukerji, Drash, & Iyengar, 1995; Lustman et al., 2000) and poor diabetes self-management (Ciechanowski, Katon, Russo, & Hirsch, 2003; Lin et al., 2004) making it a treatment priority for patients with T2DM. Regular exercise is recommended for the management of T2DM (Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006) and both aerobic and resistance exercise improve glycemic control (Snowling & Hopkins, 2006). Exercise helps regulate glucose (Thomas, Elliott, & Naughton, 2006) and improve insulin resistance and HbA1c (Boule, Kenny, Haddad, Wells, & Sigal, 2003). Additionally, exercise improves cardiovascular disease risk factors (Kadoglou et al., 2007; Lazarevic et al., 2006) and reduces risk of diabetes-related complications like neuropathy (Snowling & Hopkins, 2006). The strength of the evidence led the American Diabetes Association (ADA) to recommend that individuals with T2DM get at least 150 minutes of moderate intensity exercise/week, with no more than 2 days between workouts (Sigal et al., 2006).

Despite the substantial benefits of exercise for individuals with T2DM, only 31% of individuals with T2DM self-reported exercising at or above recommended levels (Nelson, Reiber, & Boyko, 2002), compared to 48% of the general population (Kruger, Kohl, & Miles, 2007). Exercise may be even lower for individuals with comorbid T2DM and depression as one epidemiological study found that, among individuals with T2DM, those with depression were 30% less likely to engage in regular exercise compared with non-depressed (Morrato, Hill, Wyatt, Ghushchyan, & Sullivan, 2007). Depression seems to be an exercise barrier among individuals with T2DM. A survey of primary care patients with T2DM found that depressive symptoms were associated with less use of relapse prevention behaviors, less ability to restructure plans for exercise, greater perception of barriers relative to benefits of exercise and lower self-efficacy for exercise (Vickers, Nies, Patten, Dierkhising, & Smith, 2006). Since exercise intervention studies in individuals with T2DM have not specifically examined those with comorbid depression, little is known about how to facilitate exercise in this seemingly resistant population.

Exercise for Comorbid T2DM and Depression: Rationale for Treatment Development

Exercise may offer a parsimonious approach to improving T2DM and depression given that evidence supports the benefits of exercise on glycemic control (Sigal et al., 2007; Sigal et al., 2006; Snowling & Hopkins, 2006) and depression (National Institute of Health and Clinical Excellence, 2009). However, to our knowledge, no studies have examined whether exercise improves both glycemic control and depression in individuals with the comorbidity. Novel approaches to increasing exercise in this population are warranted. Allen and colleagues (Allen, 2004) recommend that exercise interventions be grounded in theory. One exercise intervention for individuals with T2DM integrated behavioral techniques for increasing exercise self-efficacy and demonstrated that participants receiving the behavioral techniques reported greater exercise adherence and less drop-out at 6 months compared to an exercise only program (Martinus, Corban, Wackerhage, Atkins, & Singh, 2006). Although more work is needed to examine whether behavioral techniques improve exercise adherence, these techniques show promise for increasing exercise.

Behavioral Activation: A Novel Approach to Exercise in Women with T2DM and Depression

Behavioral activation (BA) involves structured attempts to increase healthy behaviors that bring the patient into contact with reinforcing environmental contingencies and produce corresponding improvements in cognitions and mood (Hopko, Lejuez, Ruggiero, & Eifert, 2003). BA begins by helping the patient to understand the impact of their daily activities on their mood and the degree to which daily activities are associated with their life values. BA then focuses on increasing the number of values driven activities in the patient's life, with the ultimate goal of creating a more fulfilling life. This process is the key to overcoming depression. Treatment ends with relapse prevention by encouraging the patient to return to monitoring their activities and mood when they notice a return of symptoms, and again scheduling activities consistent with their core values. These strategies could be specifically applied to exercise behavior.

BA strategies may help individuals with depression and T2DM to: 1) increase awareness of the impact of physical activity on mood, 2) link physical activity with life values (e.g., being an involved parent by playing soccer with one's children), 3) conduct activity experiments to discover activities that enhance mood, and 4) increase social support for physical activity. These strategies will be integrated into a 6 month group exercise class and will exclusively focus on sedentary and physical activity behaviors. Participants will engage in a variety of physical activities in class and receive guidance on using BA strategies to develop an active lifestyle.

Research Goals—The goal of this study is to conduct a pilot randomized clinical trial (RCT) to test the feasibility of the BA-enhanced exercise condition and usual care (EX), compared to a usual care condition alone (UC), among women with comorbid T2DM and depression. The pilot aims to: 1) assess feasibility of the EX condition using recruitment rate, study retention and intervention fidelity; 2) assess intervention acceptability by examining attendance to the EX classes, adherence to physical activity, exercise enjoyment and intervention acceptability; 3) estimate the resources and costs required to deliver the intervention and conduct a fully-powered RCT, 4) estimate the standard deviation of continuous outcomes for glycosylated hemoglobin (HbA1c), depression score, exercise self-efficacy, fitness, blood pressure, weight, waist circumference and quality of life at 3-, 6- and 9- months following randomization and 5) estimate the standard deviation of the proposed continuous process outcomes (i.e., physical activity, social support and behavioral activation).

Sample Size: Given the developmental nature of this project, the primary goal is to obtain reliable estimates of feasibility (e.g., retention rates) and explore magnitude and variations in depression score and HbA1c at 3- 6- and 9-months. We plan to enroll 30 patients per condition. The sample size of 30 ensures that the 95% confidence interval (CI) for the estimated retention rate in the EX condition will be within +/- 18%. We expect that the rate of retention in the exercise intervention condition at 6-months is at least 80%, and a rate of retention lower than 55% will not be acceptable. Thus, the lower limit of the 95% CI for an acceptable observed retention rate should not be lower than 55%. To reach that goal, an observed retention rate of 75% or higher would be satisfying.

Study Procedures

Study Design

This is a pilot RCT where sedentary women with T2DM and depression (n=60) are randomized to either the EX condition or the UC condition. All procedures were approved by the University of Massachusetts Medical School's (UMMS) Internal Review Board.

Recruitment

Recruitment advertisements will specifically target sedentary women with T2DM who report symptoms of depression and/or want to improve management of diabetes. Participants will be recruited from a variety of sources including UMMS primary care and diabetes clinics, mailings to diabetes support groups and diabetes educators, postings at pharmacies, newspaper ads, community health centers, the UMMS student and employee population and on-line resources.

Participants

To be eligible for the study, women with T2DM have to meet the following inclusion criteria: 1) having inadequately controlled T2DM as defined by a HbA1c level ≥ 7 and $\leq 10\%$; 2) meeting criteria for major depressive disorder as defined by the Structured Clinical Interview for DSM-IV disorders (SCID); 3) not physically active defined as engaging in moderate intensity exercise less than 3 times/week for 20 minutes; 4) a body mass index (BMI) ranging from 18.5-45 kg/m² and 5) between the ages of 21-65 years old. Exclusion criteria were derived to: 1) minimize adverse effects of the intervention (e.g., physical limitations, does not receive physician clearance, severe neuropathy); 2) prevent inevitable drop-outs (e.g., plans to move out of the area) and 3) prevent participants who may require more intensive or more appropriate psychological intervention from enrolling in the study (e.g., active suicidal ideation, bipolar disorder, psychotic disorder). Participants who have been taking antidepressant medications for more than 3 months and have no plans to change the regimen will be eligible. Participants currently in psychotherapy will be eligible. While BA is a form of psychotherapy, BA content will exclusively focus on promoting physical activity and will not directly target other life issues relevant to depression (e.g., relationship problems, unemployment), so goals will not be likely to conflict with psychotherapy.

Screening Process and Informed Consent

Interested individuals will contact the study team by phone, the study will be described to them and they will be briefly screened for initial eligibility. Those meeting initial criteria will be invited for a 2-hour screening visit. Participants will learn about the study and provide written informed consent. A Master's level clinician will administer the Hamilton Rating Scale for Depression (HRSD) (Hamilton, 1960) and the SCID (Spitzer, Williams, Gibbon, & First, 1992) to assess depression, suicidality, comorbidities and exclusionary psychiatric disorders. Participants will have their blood drawn to determine whether their HbA1c level is in the eligibility range and height and weight will be measured in stocking feet to determine BMI. For participants eligible after this screening, we will fax their primary care physician (PCP) a form asking for written permission to participate, to confirm the T2DM diagnosis and inquire about whether the participant had a stress test in the past two years. Participants who have received permission from their PCP will be scheduled for a 1 hour baseline visit where they will complete baseline measures and receive instructions on wearing an accelerometer. Participants will be asked to wear the accelerometer for 7 days to confirm that they are sedentary and will receive \$50 upon returning the accelerometer after wearing it at all assessments. Participants eligible following the baseline visit, but who have not had a negative stress test in the past 2 years will be instructed to undergo a maximal

treadmill exercise stress test in the Cardiology Department at the University of Massachusetts Memorial Medical Center.

Measures

Screening measures

Structured Clinical Interview for DSM-IV (SCID): The SCID (First, Spitzer, Gibbon, & Williams, 1996) is a structured clinical interview used to diagnose depression and as well as mood, anxiety, psychotic, alcohol and substance-related disorders and eating disorders. SCID interviews will be conducted by Master's-level counselors blinded to participant condition.

Medical History Questionnaire: Participants will complete a brief medical history questionnaire that focuses primarily on exclusionary physical conditions, such as unstable cardiovascular disease. Positive responses will be followed up by the study cardiologist.

Revised Physical Activity Readiness Questionnaire (rPAR-Q): Participants will complete the rPAR-Q to assess if participants are safe to begin exercising (Thomas, Reading, & Shephard, 1992). The rPAR-Q is considered an appropriate measure to screen individuals prior to their involvement in moderate exercise (American College of Sports Medicine, 1995).

Beck Scale for Suicidal Ideation (BSS): The BSS is a 21-item scale that assess suicide risk and demonstrates adequate reliability and validity (Beck & Steer, 1993). Participants will complete the BSS and individuals with suicidal intent will be excluded.

Intervention Feasibility Measures

Recruitment Rate: The ratio of individuals who complete a telephone screen to those who are randomized will be calculated and compared to recruitment rates for other studies of: 1) individuals with depression and T2DM and 2) of an exercise intervention.

Retention Rate: The total study retention rate and the retention rate for each condition will be calculated and compared between the two conditions and to similar studies.

Participant Adherence: For participants randomized to the EX condition, class attendance will be measured. Each week, the group leader will complete a Class Rating form to indicate whether various tasks (e.g. completing an Activity monitoring form, completing a behavioral contract) were performed between classes. Participants will report weekly the number of minutes spent exercising outside of class.

Treatment Acceptability: A 27-item modified version of the Diabetes Measurement and Evaluation Tool (Paddock, Veloski, Chatterton, Gevirtz, & Nash, 2000) was developed to assess participant's satisfaction with structure, process and outcomes of treatment. This will be administered to EX participants at 3- and 6-months following randomization. The original measure demonstrated good reliability and validity (Paddock et al., 2000).

Group Environment Questionnaire-Exercise (GEQ): The GEQ (Carron, Widmeyer, & Brawley, 1988) is an 18-item inventory that asks participants to rate statements of cohesion using a 9-point scale (where 1=strongly disagree and 9=strong agree). This original scale was modified to address exercise groups and this version demonstrates adequate reliability and validity (Carron et al., 1988; Courneya & McAuley, 1995). Participants randomized to the EX condition will complete it at the 3- and 6-month assessments to assess group cohesion.

Exercise Enjoyment: Participants will complete the Physical Activity Enjoyment Scale (Kendzierski & DeCarlo, 1991) to capture their *general* enjoyment of exercise. This scale demonstrates excellent reliability and content validity (Kendzierski & DeCarlo, 1991).

Costs: Resources (e.g., space, advertisements) and costs (e.g., group leader time for intervention training, supervision and delivery, group materials) will be calculated monthly.

Continuous Outcomes—Participants will complete these measures at baseline, 3-, 6- and 9 months following randomization.

Glycosylated Hemoglobin (HbA1c): Blood samples will be taken and HbA1c will be measured in the X Hospital laboratory. All assays have met the standardization criteria of the CDC-NHLBI Lipid Standardization Program.

Hamilton Rating Scale for Depression (HRSD): The HRSD (Hamilton, 1960), is a 21-item rating scale that assesses depressive symptomatology. HRSD scores are correlated with psychiatrists' global ratings, has concurrent validity with other depression measures (Beck, Steer, & Brown, 1996) and high internal consistency (McDowell & Newell, 1996). The HRSD will be administered by trained staff blinded to participant condition.

Beck Depression Inventory-II (BDI): The BDI (Beck et al., 1996), a 21-item questionnaire of depressive symptoms, is the most utilized depression inventory (Richter, Werner, Heerlein, Kraus, & Sauer, 1998). In a review of validity and reliability studies, the BDI was found to have high internal consistency, high content validity, validity in differentiating between depressed and nondepressed subjects and sensitivity to change (Richter et al., 1998). Because multiple BDI administrations are associated with decreasing scores in the absence of intervention (Ahava, Iannone, Grebstein, & Schirling, 1998), the HDRS will be used as the primary depression outcome. We include the BDI to allow for comparison to other depression studies, given that it is a very heavily utilized depression inventory and that it assesses symptoms of depression (e.g., weight gain and increased sleep) that are not captured by the HRSD.

Fitness measures: Maximal treadmill testing will be conducted in the Cardiology Department at X at baseline (unless the participant has had a negative stress test in the past 2 years) and by an exercise physiologist blind to participant condition for the 3-, 6- and 9-month assessments. The BSU/Bruce ramped protocol, which is used in the Cardiology department (Kaminshy & Whaley, 1998), will be used to calculate exercise capacity in metabolic equivalents and to estimate VO_{2max} . They will be instructed to exercise to fatigue and will be encouraged to persist for an additional 20 seconds when they indicate they are close to discontinuing.

Weight, Height, Waist Circumference: Body weight and height will be measured using standard methodology, with the participant wearing only light clothing and no shoes. BMI will be calculated as weight (kg)/height squared (in meters). Waist circumference will be measured.

Blood pressure: Blood pressure measurements will be taken using a Dinamap XL automated BP monitor. The Dinamap (Critikon) is a well calibrated and accurate BP measurement device which has a mean accuracy of within 3 mm Hg from intra-aortic values.

Self-Efficacy for Exercise Scale: This 9-item scale asks participants to rate their confidence that they will exercise in response to common exercise barriers using a 0-10 rating, where 0=not confident and 10=very confident. This measure has demonstrated adequate reliability and validity with sedentary adults (Resnick & Jenkins, 2000).

Quality of Life: Quality of life will be assessed using the Short Form-v36 (SF-36; (Ware & Sherbourne, 1992). The SF-36 is a well-known measure that assesses physical and mental functioning and general health perceptions. This instrument has been widely used and has been shown to have acceptable reliability and validity (Ware & Sherbourne, 1992).

Process measures—Unless noted, these measures will be completed at baseline, 3-, 6- and 9 months.

Physical Activity: Participants will wear an accelerometer (Actigraph, LLC, Fort Walton Beach, FL; model 7164 WAM) for 7 days for at least 10 hours per day to measure physical activity. ActiGraph counts from treadmill walking and running and under field conditions correlate well with oxygen uptake (Freedson, Melanson, & Sirard, 1998) In a comparison of four accelerometers assessing standardized bouts of treadmill walking, the ActiGraph was found to have the least variability across accelerometers and the highest overall reliability (Welk, Schaben, & Morrow, 2004). The following variables will be computed: number of valid days and average minutes of moderate/vigorous intensity physical activity.

Multidimensional Scale of Perceived Social Support: Social support from family and friends will be measured using the Multidimensional Scale of Perceived Social Support (Zimet, Powell, Farley, Werkman, & Berkoff, 1990). This 12-item scale has demonstrated good reliability and validity (Zimet et al., 1990).

Social Support for Exercise Behavior: The social support for exercise behavior scale (Sallis, Grossman, Pinski, Patterson, & Nader, 1987) is a 26-item questionnaire that asks participants to rate their perception that friends and family support their engagement in exercise. It consists of three factors: family participation, friend participation and family rewards and punishment, which have been validated and demonstrate acceptable reliability (Sallis et al., 1987).

Behavioral Activation for Depression Scale (BADs): Participants will complete the BADs (Kanter, Mulick, Busch, Berlin, & Martell, 2007) to assess changes in participant behavior in response to the intervention. The BADs is a 25 item-scale with four factor-analytically derived subscales for activation, avoidance/rumination, work/school impairment and social impairment subscale.

Potential Covariate—Participants will complete this measure at baseline, 3-, 6- and 9 months.

Brief Medication Questionnaire: Participants will be asked to bring all medication and supplement bottles to each assessment to verify names and doses. We also added items to track whether participants begin, continue or terminate psychotherapy during the study.

Randomization

Eligible participants will be randomized to either the EX or UC condition. Participants will be stratified into 4 strata of possible combinations based on antidepressant medication use (2 categories: present, absent) and HbA1c (2 categories: 7-8.5, 8.6-10). Within each strata, participants will be randomized to the two conditions in randomly permuted blocks of size 2

and 4 using the ralloc program in Stata (Ryan, 1999) to ensure that antidepressant medication status and HbA1c at baseline does not differ between conditions. The study biostatistician generated the randomization sequence, which was then integrated into the study database tracking system (Lotus Notes) by a statistician not associated with the project. Lotus Notes conceals randomization status until the research coordinator clicks a button to randomize a participant. The master's level clinician and exercise physiologist conducting the 3, 6 and 9-month assessments are blinded to participant condition and do not have access to Lotus Notes.

Intervention

Exercise Condition (EX)—The intervention, delivered by a female exercise instructor, will involve one orientation session, 38 group exercise classes over 24 weeks and a final group meeting. The purpose of the orientation will be for participants to meet one another, discuss how to safely increase exercise and introduce the BA strategies. The 90 minute exercise classes will occur 2 times/week for 16 weeks, tapering to 1 times/week for 4 weeks, and once every other week for 4 weeks for a total of 38 exercise classes. At the final group meeting, maintenance goals and relapse prevention strategies will be reinforced. Class size will range from 5-10 participants and classes will take place at the UMMS. Participants receive this intervention in addition to the usual care they receive for diabetes and depression.

Exercise classes will be designed to gradually increase the duration and intensity of exercise to 150 minutes of moderate intensity activity per week as recommended by the ADA (Sigal et al., 2006) to maximize the benefits of exercise on metabolic control in individuals with T2DM. This intensity and amount of exercise improved depression in depressed adults in previous trials (Blumenthal et al., 2007; Craft, Freund, Culpepper, & Perna, 2007). To achieve the recommended dose, participants will be encouraged to exercise at least one day on their own. The amount they will be asked to exercise on their own will gradually increase as the frequency of classes decreases, to reduce their reliance on the exercise class and facilitate the transition to a regimen of their own (see Table 1 for the structure of the exercise classes). Participants who miss classes will be encouraged to make up the missed minutes of exercise on their own to achieve the weekly goal. The leader will ask about exercise outside of classes and problem-solve with participants who do not meet the recommendation.

All classes will last 90 minutes and contain 3 parts: 1) Warm Up; 2) Exercise; and 3) Cool Down and BA content. The time devoted to the exercise portion of class will increase over the course of the intervention, while the time devoted to the BA content will decrease (see Table 1). This will help participants gradually reach their exercise goal. Figure 1 describes the proposed relationship between the components of the group exercise sessions and the proposed effect on depression and glycemic control. Group exercise may have a direct effect on improving glycemic control and depression and may also increase physical activity outside of groups. Exercise counseling and BA content and are intended to indirectly improve glycemic control and depression by increasing physical activity outside of groups. Discussion of the BA content may facilitate group social support, which may in turn reduce depression.

1) Warm-up: Prior to exercise, participant will check their blood glucose levels to ensure that they are in a safe range for exercise. Participants with a safe glucose level (see safety section for more information on safe glucose levels) will be able to exercise during the group. Two items from the Revised Physical Activity Readiness Questionnaire (rPAR-Q)

(Thomas et al., 1992) will be administered prior to exercise as a safety precaution. The leader will then begin a 10-minute warm-up exercise.

2) Exercise: The leader will then transition into the selected exercise for the class. The first 12 weeks of the intervention will feature a different activity every two weeks; subsequent activities for the remaining 12 weeks will be selected based on participants' mean exercise enjoyment ratings after engaging in the 6 different exercise activities. One important aspect of BA is identifying and discovering activities that produce enjoyment and are associated with improved moods. A variety of activities will be offered to increase the likelihood that participants find an activity they enjoy and that positively impacts their mood. The following activities are introduced in this order: walking, Zumba (Latin dance), pilates, step aerobics, cardio-kickboxing, and power yoga. All activities will be provided at a moderate intensity level; the leader adjusts the intensity of the exercise to the needs of the group to ensure that intensity stays in moderate level. At the halfway point, there will be a 1-minute break for water. Participants who note feelings of exhaustion or fatigue will be asked to decrease their intensity.

3) Cool down and BA content: The exercise class will conclude with a cool down activity. Participants will discuss how their mood and energy levels were impacted during and after exercise. After the cool down, the participants will discuss the following BA content from Lejuez and colleagues (Lejuez, Hopko, Acierno, Daughters, & Pagoto, 2011) treatment manual over the course of the 24 week intervention. Although the BA content is delivered in the group, recommendations are tailored to the individual based on their completion of the BA forms. BA content is delivered after exercise so that participants can immediately comment on the relationship between exercise and their mood and to ensure that the full exercise bout is completed.

a) Activity and Mood Monitoring: In BA, patients monitor their daily activities and rate their moods during each activity. For this study, activity and mood monitoring will center exclusively on leisure time sedentary activities and physical activities. Participants will be introduced to the Activity and Mood Monitoring form during the first exercise class and asked to complete one form for the next exercise class. The type of activity is documented along with duration and an enjoyment and importance rating for each activity. Any leisure time physical activity, exercise, or housework could be included, as well as time spent watching TV, at the computer, reading, or other sedentary leisure activities. The Activity and Mood Monitoring Form is based on the one from the brief BA manual (Lejuez et al., 2011).

Participants will bring their activity logs to class to share their observations regarding the enjoyment and importance ratings of their sedentary and physical activities and associated moods. Participants will be encouraged to limit activities that they assign low ratings of enjoyment and importance, while increasing physical activities that produce high enjoyment and/or importance ratings. In the case where a physical activity is associated with a negative mood, they will be encouraged to experiment with strategies that might reduce the negative mood (e.g., change activity) or increase enjoyment (e.g., exercise with a partner). For example, if a participant is self-conscious walking in front of people, they would be encouraged to try an indoor walking DVD to see if that is more enjoyable. As participants develop a better understanding of relationships between different activities and their mood, they will transition from completing this form weekly to only completing it when they attempt a new physical activity or when their feelings of depression increase and they do not have a clear sense of why.

b) Values and Activities Assessment: During week 3, the topic of discussion will be about the importance of daily activities being connected to what they personally value in different life areas including relationships, work, recreation, volunteering, physical and emotional health and daily responsibilities. Over the next 3 weeks, participants will individually generate a list of their life values and ways to connect physical activities to their values, using the Values and Activity Hierarchy Form (Lejuez et al., 2011). See Table 2 for a list of examples for values and activities in each life area. Participants will then set individual weekly goals to engage in these activities, starting with the easiest activities and working gradually towards completing more challenging activities. For example, goals may range from taking a 10 minute walk to completing a 5K race walk. The key to success is to start out with small, manageable activities to build self-efficacy.

c) Activity Experiments: In BA, activity experiments are used to try alternative behaviors to find some that improve mood. The idea is to break up behavioral patterns that promote depression by adopting new activities that help the individual feel that they are living a more fulfilling and satisfying life. Activity experiments will occur during exercise classes when participants are exposed to a variety of different activities. Additionally, participants will be encouraged to conduct their own activity experiments outside of the exercise classes to find ways to make physical activity more enjoyable. A resource library consisting of different types of exercise equipment (e.g., beginner exercise DVDs, yoga mat) will be available to participants to assist with activity experiments at home.

d) Behavioral Contracts: BA uses behavioral contracts to establish a commitment between the patient and a support person to promote positive change. The patient agrees to increase a positive behavior or reduce a depressive behavior and the support person agrees to provide feedback, support and/or rewards when the patient accomplishes the change. Behavioral contracts will be introduced during week 11 and participants will complete at least one behavioral contract with a friend or family member to promote exercise. Participants will be encouraged to develop behavioral contracts with other class members to facilitate maintenance.

e) Exercise Counseling Strategies: The class leader will discuss basic strategies for beginning and maintaining an exercise regimen. Strategies include self-monitoring activity using a pedometer, monitoring their exercise intensity via perceived exertion and heart rate, identifying facilitators to exercise and engaging in problem solving for barriers to exercise.

Usual Care Condition (UC)—Participants in the UC condition will receive a telephone call from a master's level clinician following randomization to inform them of their depression diagnosis and encourage them to discuss treatment options with their PCP. With the participant's permission, their PCP will be contacted and informed of their depression diagnosis. Referrals for depression treatment will also be provided to participants. Participants will be encouraged to follow the advice provided by their PCP regarding diabetes self-management and will be mailed a packet of information available from the ADA that reviews recommendations for nutrition, exercise and glucose monitoring. To minimize attrition in the UC condition, participants will be reminded during this phone call that they will receive a 3-month gym membership upon completion of the 9-month assessment and will meet individually with the PI to develop a personal physical activity plan, which includes coaching on the BA strategies discussed in the EX condition.

Intervention Fidelity

Leader and auditor checklists will be developed and used to monitor fidelity to the intervention, particularly to the delivery of the BA content. These checklists will assess

whether the group leader introduces the BA content (e.g., activity and mood monitoring, values assessment), reviews the weekly assignments with participants (e.g., discusses the values participants identify, inquires about their experience with the behavioral contracts) and covers the general exercise counseling (e.g., perceived exertion, barriers to exercise). The leader will complete a Leader Checklist after each class. A random selection of 10% of audio-recorded classes will be reviewed by a research coordinator and the PI to monitor treatment fidelity. Ultimately, perfect treatment fidelity would be evidenced by 100% of objectives met. When a class is reviewed with less than 85% of treatment-specific objectives met, the auditor will inform the PI who will remediate interventionist training as needed. This process will continue through all treatment waves so that drift can be swiftly corrected.

The leader will not be trained in or have expertise with depression treatment, other than the BA components that are integrated into the exercise intervention. However, participants with depression may spontaneously bring depression into the class discussion. The leader will be trained to stay within the protocol and not engage in problem-solving around depression-specific issues, unless they relate to exercise. She also will notify the PI if a participant requests further help, to determine whether a referral is necessary.

Assessments

Assessments will occur 3-, 6- and 9-months after randomization. Participants will attend a 90 minute visit to complete measures. Once the accelerometer is returned, the participant will be mailed a gift card for \$50. Participants who cannot attend this visit will be offered a home visit; those declining a home visit will be interviewed by phone.

Participant Safety

All participants must receive medical clearance from their PCP and have a negative stress test in the past two years to participate. Participants randomized to the EX condition will be encouraged to increase exercise gradually. The exercise intervention will follow nationally-recognized guidelines for initiating exercise programs in sedentary (U.S. Department of Health and Human Services, 1999) and T2DM populations (Zinman, Ruderman, Campagne, Devlin, & Schneider, 2004). The leader will ask participants questions that will identify potential problems. Two questions from the revised Physical Activity Readiness questionnaire (Thomas et al., 1992) will be asked at each class to determine whether the participant in the present or recent past has experienced chest pain, shortness of breath or dizziness, or has suffered joint or muscle injury while exercising. In the case of a positive response, the study cardiologist will be contacted for consultation. Any participant experiencing symptoms of chest discomfort or new dyspnea during exercise will be asked to stop the activity and the study cardiologist will be consulted, or if symptoms are reported to be extreme, they will be escorted to the emergency room for immediate treatment. The class leader will be trained in cardiopulmonary resuscitation and an automated external defibrillator will be available in the rare case of a cardiac event.

Participants randomized to the EX condition will also receive education on the relationship between exercise and glycemic control during the orientation session and encouraged, as they increase their exercise, to work with their PCP to modify their medication use for diabetes, if necessary. Participants will test their glucose level prior to and following exercise to prevent exercise-related hypoglycemia. Participants will be told to check their glucose 30 minutes before exercise and again just prior to exercise to examine whether their blood glucose level is stable or dropping. Carbohydrate snacks will be available for participants whose pre-exercise glucose levels are < 100 mg/dl (5.6 mmol/l) (Zinman et al., 2004). If a participant registers a blood glucose level > 300 mg/dl, they will not be permitted to exercise during the class and the study endocrinologist will be contacted. Participants will

be instructed to avoid exercising when their insulin is peaking and to work on the timing of exercise according to meals and insulin to prevent their blood glucose from becoming too low. Participants will receive information on proper footwear and will be encouraged to wear clean, smooth-fitting socks and to check their feet after exercise for blisters, warm areas, or redness. If they see foot problems, they will be instructed to contact their PCP.

Participants randomized to the EX condition will complete the Beck Depression Inventory and the Beck Suicide Scale weekly to assess depression and suicidality. If a participant reports suicidal ideation, the PI will be contacted and will meet with the participant to further assess suicidality and refer for alternative psychiatric treatment and/or escorted to the UMass Emergency room, if deemed necessary. The PI will review depression severity scores of participants on a weekly basis. If depression symptoms elevate to 30 or higher on the BDI or 3 or higher on the BSS, alternative treatment will be deemed clinically necessary and the participant will be contacted by the PI, assessed for suicidality and referred to the appropriate service. Participants who miss a session without informing us of their absence will be called to ensure they are not currently suicidal. Participants who report depression at the end of the 24-week intervention will receive written materials about treatment options (the National Institute of Mental Health brochure, *Depression*) and a list of referrals for depression treatment.

Participants randomized to the UC condition will be assessed for suicidal ideation at the baseline, 3-, 6- and 9-month assessments. If a participant reports suicidal ideation with intent she will be referred for alternative psychiatric treatment and/or escorted to the emergency room.

Analytic Plan

This study will compare the EX condition to the UC condition on feasibility and trends of initial efficacy at 3-, 6- and 9- months following randomization. The retention rate and its 95% confidence interval will be estimated for each condition. Between conditions the retention rates will be compared using Chi-square test. For the potential changes after intervention in clinical and psychological outcomes (e.g. HRSD, HbA1c), graphical techniques will be used to assess the pattern of changes over time by condition in those outcomes, and mixed models (Littell, Milliken, Stroup, & Wolfinger, 1996) will be used to estimate the effect of the EX condition on those outcomes over time. Appropriate transformations of data will be undertaken as necessary in order to satisfy model assumptions.

Summary

While exercise interventions exist for both type 2 diabetes and depression separately, these disorders are frequently comorbid and exercise interventions have not been established for when these disorders co-occur. This pilot RCT attempts to demonstrate the feasibility of a group exercise intervention that uses BA strategies to reinforce the connection between activity and mood and to foster an active lifestyle. This is the first attempt to integrate strategies from BA into an exercise intervention for women with T2DM and depression in a research setting. In addition to feasibility, this pilot RCT will provide information on intervention acceptability, the resources and costs required for a fully powered intervention and standard deviation estimates of HbA1c and depressive symptoms to estimate sample size for a larger RCT. If the present study demonstrates that the intervention is feasible, the next step would be to conduct a larger RCT in a research setting and with this study's inclusion and exclusion criteria to test the efficacy of the EX condition on HbA1c and depression, ideally with 6-month and 1-year follow-up assessments. One main design concern for a larger RCT concerns the selection of an appropriate comparison condition.

Potential comparison conditions include: 1) evidence-based depression treatment, 2) a diabetes support group including diet and activity counseling or 3) a group exercise only condition that does not include the BA strategies. The exercise only condition might be considered the strongest test of the intervention, particularly if the comparison condition was matched on contact time, as it would directly examine the additional benefit provided by the BA content.

Ultimately, if a larger RCT demonstrates that the BA exercise intervention is efficacious, studies of the intervention's effectiveness would be warranted. If successful, this intervention could be translated into real world settings such as fitness centers, where personal training staff could be trained in BA strategies, or as a part of diabetes rehabilitation, similar to cardiac rehabilitation, as recently advocated by Sigal and Kenny (Sigal & Kenny, 2010). The present study will demonstrate the feasibility of training exercise instructors in BA strategies, which has implications for implementation in a wide range of settings.

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Figure 1. Proposed process model depicting how the three components of the intervention are hypothesized to influence glycemic control and depression.

Table 1
Structure of the physical activity intervention

Week	Visit frequency (times/week)	Group BA content* (minutes)	Group exercise* (minutes)	Home exercise goal (minutes)	Total exercise goal (minutes)
Weeks 1-2	2	55	20	20	60
Weeks 3-4	2	45	30	20	80
Weeks 5-6	2	35	40	20	100
Weeks 7-8	2	25	50	20	120
Weeks 9-10	2	10	65	20	150
Week 11-12	2	10	65	20	150
Week 13-14	2	15	60	30	150
Weeks 15-16	2	25	50	50	150
Weeks 17-20	1	10	65	85	150
Weeks 21-24	1 (every other week)	20	55	95	150

* All group sessions are 90 minutes in duration. Time not spent in exercise is spent on 5 minute warm-up, the 10 minute cool down and the BA content.

Table 2
List of Life Areas and Example Values linked to Physical Activity

Life Area	Value	Activity
Relationships	Spending quality time with my children	Have a weekly Wii Sports game night with my children
Education / Training	Improving my job skills with classes	Bike to class
Employment / Career	Keeping my stress level under control	Take a 10 minute break during lunch to walk outside
Hobbies / Recreation	Being creative	Create a 15 minute dance routine
Volunteer work / Charity / Political activities	Giving back to my community	Volunteer for Habitat for Humanity
Physical and Psychological Health Issues	Managing my diabetes	Buy comfortable shoes for walking
Spirituality	Staying connected to my church	Help set up the church hall for large events.