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## Feasibility of Pairing Behavioral Activation With Exercise for Women With Type 2 Diabetes and Depression: The Get It Study Pilot Randomized Controlled Trial

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Major depressive disorder is often comorbid with diabetes and associated with worse glycemic control. Exercise improves glycemic control and depression, and thus could be a parsimonious intervention for patients with comorbid diabetes and major depression. Because patients with diabetes and comorbid depression are often sedentary and lack motivation to exercise, we developed a group exercise intervention that integrates strategies from behavioral activation therapy for depression to increase motivation for and enjoyment of exercise. We conducted a 6-month pilot randomized controlled trial to test the feasibility of the behavioral activation exercise intervention (EX) for women with diabetes and depression. Of the 715 individuals who contacted us about the study, 29 participants were randomized to the EX condition or an enhanced usual care condition (EUC), which represents 4.1% of participants who initially contacted us. Inclusion criteria made recruitment challenging and limits the feasibility of recruiting women with diabetes and depression for a larger trial of the intervention. Retention was 96.5% and 86.2% at 3 and 6 months. Participants reported high treatment acceptability; use of behavioral activation strategies and exercise class attendance was acceptable. No condition differences were observed for glycemic control, depressive symptoms, and physical activity, though depressive symptoms and self-reported physical activity improved over time. Compared to participants in the EUC condition, participants in the EX condition reported greater exercise enjoyment and no increase in avoidance behavior over time. Using behavioral activation strategies to increase exercise is feasible in a group exercise setting. However, whether these strategies can be delivered in a less intensive manner to a broader population of sedentary adults, for greater initiation and maintenance of physical activity, deserves further study.

*Keywords:* physical activity; behavioral activation; major depressive disorder; Type 2 diabetes mellitus

TYPE 2 DIABETES MELLITUS (T2DM) is a significant public health problem affecting 8.3% of adults in the U.S. (Centers for Disease Control and Prevention., CDC, 2011). Depression is highly comorbid with diabetes; 11% to 27% of adults with T2DM have depression and women with T2DM are 2 to 3 times more likely to have depression than men with T2DM (Ali, Stone, Peters, Davies, & Khunti, 2006; Anderson, Freedland, Clouse, & Lustman, 2001; Roupa et al., 2009). Depression in T2DM is associated with worse glycemic control (Krogh, Nordentoft, Sterne, & Lawlor, 2011; Lustman et al., 2000), poor diabetes self-management (Ciechanowski, Katon, Russo, & Hirsch, 2003; Lin et al., 2004), and elevated risk for all-cause mortality (Pan et al., 2011), making depression a treatment priority.

Approaches to addressing comorbid T2DM and depression include antidepressant medication (Lustman et al., 2006) and psychotherapy like cognitive-behavioral therapy (CBT; e.g., (Lustman & Griffith, 1998). Most studies report improvement in depression, but not glycemic control (Baumeister, Hutter, & Bengel, 2014; Semenkovich, Brown, Svrakic, & Lustman, 2015). Addressing depression with medication and/or psychotherapy may not be sufficient to influence the lifestyle changes (e.g., improvements in dietary quality, exercise) required to facilitate glycemic control. Because exercise is recommended for individuals with T2DM to improve glycemic control (Boulé, Kenny, Haddad, Wells, & Sigal, 2003; Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006; D. Thomas, Elliott, & Naughton, 2006) and exercise has initial evidence for treating depression (Cooney et al., 2013), integrating structured exercise into depression treatment may be a parsimonious approach for adults with T2DM and depression.

Two studies examined whether combining CBT with structured exercise improved outcomes in adults with T2DM and depression. In a single arm trial, a 12-week, individually based CBT and structured exercise intervention reduced glycosylated hemoglobin (HbA1c), a marker of long-term glycemic control, at 3 months and depressive symptoms at 3 and 6 months in participants with diagnosed depression and diabetes (Groot et al., 2012). The only previously performed randomized controlled trial (RCT) compared CBT plus a walking intervention to usual care in patients with T2DM and elevated depressive symptoms (Piette et al., 2011). Participants in the intervention reported significant improvements in depression and pedometer steps at 12 months compared to usual care, but neither condition improved in glycemic control (Piette et al.). In these studies, CBT strategies were not used specifically to motivate participants to exercise. Tailoring the behavioral strategies of CBT to focus on exercise may bolster the intervention effect on exercise given the sedentary nature of this population, thus enhancing glycemic control and reducing depressive symptoms via a single mechanism: increased exercise.

Exercise could be used as the sole approach to improve depression and glycemic control. However, adults with T2DM report more exercise barriers, are less likely to engage in exercise, and are more likely to relapse to a sedentary lifestyle after beginning an exercise program, compared to their counterparts without T2DM (Dutton, Johnson, Whitehead, Bodenlos, & Brantley, 2005; Grace, Barry-Bianchi, Stewart, Rukholm, & Nolan, 2007; Morrato, Hill, Wyatt, Ghushchyan, & Sullivan, 2007; Plotnikoff, Brez, & Brunet, 2003). The challenges of exercise are further heightened in adults with T2DM and comorbid depression. Depressive symptoms among individuals with T2DM are associated with less use

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