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One-Year Changes in Symptoms of Depression and Weight in Overweight/Obese Individuals with Type 2 Diabetes in the Look AHEAD study

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Abstract

Depressed individuals are frequently excluded from weight loss trials because of fears that weight reduction may precipitate mood disorders, as well as concerns that depressed participants will not lose weight satisfactorily. The present study examined participants in the Look AHEAD study to determine whether moderate weight loss would be associated with incident symptoms of depression and suicidal ideation, and whether symptoms of depression at baseline would limit weight loss at 1 year. Overweight/obese adults with type 2 diabetes (n=5145) were randomly assigned to an Intensive Lifestyle Intervention (ILI) or a usual care group, Diabetes Support and Education (DSE). Of these, 5129 participants completed the Beck Depression Inventory (BDI) and had their weight measured at baseline and 1 year. Potentially significant symptoms of depression were defined by a BDI score ≥ 10 . Participants in ILI lost $8.6 \pm 6.9\%$ of initial weight at 1 year, compared to $0.7 \pm 4.8\%$ for DSE ($P < 0.001$, effectsize = -1.33), and had a reduction of 1.4 ± 4.7 points on the BDI, compared to 0.4 ± 4.5 for DSE ($P < 0.001$, effectsize = 0.23). At 1 year, the incidence of potentially significant symptoms of depression was significantly ($RR = 0.66$, $95\% CI = 0.5, 0.8$; $P < 0.001$) lower in the ILI than DSE group (6.3% vs. 9.6%). In the ILI group, participants with and without symptoms of depression lost $7.8 \pm 6.7\%$ and $8.7 \pm 6.9\%$, respectively, a difference not considered clinically meaningful. Intentional weight loss was not associated with the precipitation of symptoms of depression, but instead appeared to protect against this occurrence. Mild (or greater) symptoms of depression at baseline did not prevent overweight/obese individuals with type 2 diabetes from achieving significant weight loss.

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Two questions frequently arise when considering whether depressed, obese individuals should undertake weight reduction. The first is whether dieting and weight reduction precipitate (or exacerbate) symptoms of depression (1–3). The second question is whether individuals with mild or greater symptoms of depression can achieve the same magnitude of weight loss as obese individuals without any symptoms of depression (4,5).

The concern that weight loss may precipitate symptoms of depression arose from a study of normal weight volunteers who lost nearly 25% of their body weight and subsequently experienced adverse emotional reactions, including clinically significant depression (1). Some investigators believe that dieting and weight loss have similar ill effects in overweight/obese individuals (6,7), although studies of weight loss achieved with behavioral treatments have revealed reductions, rather than increases, in symptoms of depression (8–10). With one exception (11), previous studies have been limited by small samples and by the failure to examine the incidence (and resolution) of symptoms of depression. In addition, prior studies typically have not included a control group of non-dieting individuals against which to judge changes in mood observed in individuals assigned to lose weight.

Lack of motivation and concentration, two cardinal features of depression, could undermine efforts to adhere to rigorous diet and activity recommendations, and several studies have shown depression to be a predictor of attrition from weight loss programs (12,13). Studies of whether pretreatment symptoms of depression impede weight loss have yielded mixed results. Several investigations found no relationship between these two variables (5,13,14), while others observed smaller weight losses in patients with greater pretreatment symptoms of depression (4,15,16). All of these studies were limited by small sample sizes and by relatively low levels of baseline depression, the latter occurrence resulting from investigators' tendency to exclude depressed individuals from weight loss trials (17–21).

In the present investigation, we used data from the Look AHEAD (Action for Health in Diabetes) study to: 1) assess the effects of dieting and weight loss on the precipitation (and possible resolution) of symptoms of depression; and 2) examine whether individuals with symptoms of depression at baseline would lose less weight than individuals with no symptoms of depression. Look AHEAD is examining the long-term effects on cardiovascular morbidity and mortality of an Intensive Lifestyle Intervention (ILI), compared with a usual care group, referred to as Diabetes Support and Education (DSE), in 5145 overweight and obese individuals with type 2 diabetes. The fact that overweight individuals with type 2 diabetes are known to be at increased risk of depression (22,23) makes this an excellent sample with which to address the questions outlined above. At the end of the first year of treatment, weight losses for the ILI and DSE groups were 8.6% and 0.7%, respectively (24). In addition, health-related quality of life (which included assessment of symptoms of depression) improved more in the ILI than DSE groups (25). Using this data set, we compared the incidence (as well as resolution) of symptoms of depression in the ILI and DSE groups. Given the generally favorable effects of weight loss on mood, we hypothesized that the ILI group would show a smaller incidence of symptoms of depression than those in DSE. We included an examination of suicidal ideation, given recent concerns that weight loss achieved with weight loss medications (e.g., rimonabant) may precipitate suicidal behavior (26,27). Finally, we hypothesized that individuals in the ILI and DSE groups, who reported symptoms of depression at baseline, would achieve smaller weight losses at 1 year than would those who were free of such symptoms.

Methods

Participants

The Look AHEAD study design and participants have been described in detail previously (28). In summary, overweight/obese individuals with type 2 diabetes were recruited from 16 clinical centers in the United States. Participants were 45–76 years old and had a body mass index (BMI) ≥ 27 kg/m² (or ≥ 25 kg/m² if on insulin). Individuals with inadequate diabetes control (i.e., HbA_{1c} >11%), or with conditions likely to affect treatment adherence, safety, or retention, were excluded from the trial. Individuals diagnosed with psychosis or bipolar disorder, or who had been hospitalized for depression in the past 6 months, also were excluded. All participants provided informed consent, as approved by each site's Institutional Review Board.

The present analysis was based on 5129 participants who enrolled in the study and completed baseline assessments of weight and mood. Baseline demographic information is provided in Table 1. Sixty-three percent of the sample was self-identified as non-Hispanic White, 16% as African American, 13% Hispanic, 5% American Indian, and 1% as Asian/Pacific Islander. Forty percent of participants were male.

Intervention

Participants were randomly assigned to ILI or DSE, both of which have been described previously (24,29). The ILI, modeled after the Diabetes Prevention Program (DPP)'s Lifestyle Balance intervention (30), sought to induce a mean weight loss $\geq 7\%$ of initial weight and to increase physical activity to ≥ 175 minutes a week. Participants received intensive behaviorally-oriented diet and physical activity counseling during the first year. They were provided three group and one individual meeting(s) each month during months 1–6, and two group and one individual session(s) per month during months 7–12. Participants were instructed to consume a diet of 1200–1800 kcal/d (based on body weight) which, during the first 4 months, included replacing two meals and one snack per day with liquid shakes and meal bars. Participants in the DSE group were offered three group meetings during the year and were given educational information on nutrition, physical activity, and social support.

Dependent Measures

Demographics and anthropometric characteristics—Weight was measured at baseline and 1 year (by assessors masked to treatment condition) using a digital scale (Tanita, Willowbrook, IL, model BWB-800). Height was measured at baseline using a wall-mounted stadiometer.

Mood and suicidal ideation—Symptoms of depression were assessed at baseline and 1 year using the Beck Depression Inventory (BDI) (31), a 21-item questionnaire that assesses mood over the previous 2 weeks. This instrument is an effective screening tool for major depression in diabetic patients (32). Total scores range from 0–63, with higher values indicating greater symptoms of depression. In the present study, however, item # 19, which assesses recent weight loss, was excluded from analysis because participants were overweight/obese and were required to be weight stable at entry. Thus, our use of the inventory yielded scores of 0–60. Scores of 0–9 reflect minimal (i.e., subclinical) symptoms, whereas values of 10–18, 19–29, and ≥ 30 indicate mild, moderate, and severe symptoms of depression, respectively (33). Participants who endorsed current symptoms of depression (i.e., scores ≥ 10 on the BDI) were classified as reporting mild or greater symptoms of depression, regardless of whether they were taking anti-depressant medication.

Item #9 on the BDI assesses suicidal ideation, as judged by the following responses: (a) "I do not have any thoughts of killing myself;" (b) "I have thoughts of killing myself, but I would not carry them out;" (c) "I would like to kill myself;" and, (d) "I would kill myself if I had the chance." For the purpose of this study, respondents who endorsed options b, c, or d were deemed to have suicidal ideation.

Binge eating—Binge eating behavior was assessed by self-report using items from the Questionnaire on Eating and Weight Patterns (34). Participants were classified as having binge eating behavior if in the past 6 months they reported one or more episodes of eating a large amount of food in a discrete period of time, experienced a sense of loss of control during that eating episode, and denied use of any compensatory behaviors (such as purging or excessive exercise).

General health and diabetes duration—The Medical Outcomes Study, 36-Item Short Form Survey (SF-36), version 2, was used at baseline to assess general health. The SF-36 is a well-validated measure of health-related quality of life (35). At baseline, participants also indicated the number of years since being diagnosed with diabetes.

Statistical Analyses

All analyses were performed using SAS statistical software, version 9.2 (SAS Institute, Inc., Cary, NC). Mean values (\pm standard deviation) are reported. Differences in demographic variables between participants with symptoms of depression (BDI ≥ 10) and those without symptoms were compared using linear regression models (with gender and clinical site as covariates) for continuous variables. Generalized linear models with a multivariate distribution were used for categorical variables.

In order to examine incidence and resolution of symptoms of depression after 1 year of treatment, we classified each of the ILI and DSE participants into the following four categories based on a BDI score of 10 or above: 1) participants with minimal symptoms of depression at baseline and also minimal symptoms at 1 year; 2) individuals with minimal symptoms at baseline but who endorsed mild or greater symptoms of depression at 1 year; 3) participants who reported mild or greater symptoms of depression at baseline but denied symptoms at 1 year; and 4) individuals who reported mild or greater symptoms of depression at baseline and also at 1 year. The percentages of participants in each group who met criteria for inclusion in each category were compared using chi-squared tests.

Differences in changes in symptoms of depression (continuous scores on the BDI) between participants with and without symptoms of depression at baseline, and between ILI and DSE groups, were compared using a 2-way ANOVA, controlling for the baseline weight, BDI score, gender, age, race, years of education, BED status, general health score and clinical site. In order to determine the effects of baseline symptoms of depression, 1-year symptoms of depression, and treatment group on weight loss at 1 year, a $2 \times 2 \times 2$ (baseline symptoms of depression by 1-year symptoms of depression by treatment group) ANOVA was conducted.

Results

Baseline Characteristics

Demographic characteristics for participants with and without symptoms of depression are presented in Table 1. Participants with BDI scores ≥ 10 at baseline were significantly younger, reported fewer years of education, and were more likely to be female and to be non-White than those with scores < 10 . They also had a significantly higher BMI, were more

likely to report bingeing behavior, and reported poorer general health scores than participants without symptoms of depression. No differences in diabetes duration were found between participants with and without symptoms of depression.

Mean BDI scores for participants by treatment group and depression status are presented in Table 2. The numbers (and percentages) of participants reporting minimal, mild, moderate and severe symptoms of depression at baseline and 1 year are depicted in Table 3. There were no significant differences between ILI and DSE in the percentages of participants with symptoms of depression at baseline (17.9% vs. 16.6%) or in the number of cases of suicidal ideation (SI: 2.9% vs. 2.1%, respectively). All participants with SI endorsed the statement, "I have thoughts of killing myself, but I would not carry them out." No one reported the more serious options, indicating desire or intent to kill themselves. Across the whole sample, significantly more participants with a BDI score ≥ 10 (i.e., with mild or greater symptoms of depression) endorsed suicidal ideation at baseline than among those with a score < 10 (i.e., minimal symptoms of depression) (11.1% vs. 0.7%, RR = 15.8, 95% CI = 10.6, 23.1; $P < 0.001$).

Non-completers—Of the 5129 participants, 327 did not complete BDIs at 1 year, yielding a sample of 4802 for the incidence study. Non-completers had a higher baseline BDI score than participants who completed the 1-year assessment (6.6 ± 5.8 vs. 5.4 ± 4.8 , respectively, ($P < 0.001$, effect size = 0.24), with mean scores for both groups indicating minimal symptoms of depression. Within the ILI, 30.8% (41/133) of non-completers reported mild or greater symptoms of depression, compared with 22.2% (43/194) in DSE (ns). Among participants who completed the 1-year assessment, 16.7% (801/4802) reported symptoms of depression at baseline, compared to 83.3% (4001/4802) who reported no symptoms ($P < 0.001$). No other baseline differences were observed between participants who did and did not complete the 1 year assessment.

Changes in BDI Scores at 1 Year

Changes in BDI scores for participants in ILI and DSE who did and did not report symptoms of depression at baseline are shown in Figure 1. Participants in ILI showed a mean reduction in BDI score of 1.4 ± 4.7 vs. 0.4 ± 4.5 points for the DSE group. The ANOVA showed significant main effects on BDI score change of treatment group ($P < 0.001$, effect size = 0.27) and baseline depression ($P < 0.001$, effect size = 0.99), as well as a significant interaction ($P < 0.035$). As shown in Figure 1, participants within the ILI who reported baseline symptoms of depression showed a decline of 5.3 ± 6.8 points on the BDI at 1 year, compared with a decline of 0.6 ± 3.7 points for individuals reporting no symptoms of depression. Participants with mild or greater symptoms of depression in DSE showed a reduction of 3.7 ± 6.2 points on the BDI, compared to an increase of 0.2 ± 3.8 points on the BDI for participants with minimal symptoms.

Incidence and Resolution of Depression at 1 Year

Table 4 shows frequencies of participants who acknowledged mild or greater symptoms of depression ($BDI \geq 10$) at baseline and 1-year. At the end of the year, 6.3% of ILI participants who did not report symptoms at baseline reported the onset of symptoms of depression (i.e., incident depression), which was significantly (RR = 0.66, 95% CI = 0.5, 0.8; $P < 0.001$) lower than the 9.6% observed in the DSE group. (The lower incidence of symptoms of depression in the ILI group remained statistically significant when the incidence of antidepressant medication use in ILI and DSE [4.3% vs. 2.7%, respectively] was controlled for (RR = 0.64, 95% CI = 0.5, 0.8, $p < 0.001$.) A logistic regression analysis showed that being assigned to DSE significantly increased the odds of reporting symptoms of depression at 1 year (OR = 1.62, 95% CI = 1.3, 2.1; $P < 0.001$). There were no significant differences

between ILI and DSE groups, however, in the numbers of participants who showed resolution of their symptoms of depression; 60.8% and 55.6% of ILI and DSE participants, respectively, reported symptoms of depression at baseline but not at 1 year ($P=0.140$).

The mean BDI score for individuals who reported incident symptoms of depression was 5.8 ± 2.6 at baseline, compared to 13.2 ± 4.4 at 1 year, yielding a mean increase of 7.4 points on the BDI.

Incidence and Resolution of Suicidal Ideation

Incident suicidal ideation was observed in approximately 1.4% of participants in the ILI group and 1.9% of participants in the DSE group; these participants denied thoughts of suicide at baseline but endorsed their occurrence at 1 year ($P=0.266$, Table 4). There were no significant differences in the number of participants in ILI and DSE who showed resolution of suicidal ideation at 1 year (68.2% vs. 72.0%, $P=0.657$).

Baseline Depression and Changes in Weight at 1 Year

As reported previously, the ANOVA revealed a significant main effect of weight loss on treatment group ($P<0.001$, effect size = -1.23), with mean losses of 8.6 ± 6.9 and $0.7 \pm 4.8\%$ for ILI and DSE, respectively. A significant main effect of baseline symptoms of depression also was observed ($P=0.009$, effect size = 0.10); participants with mild or greater symptoms of depression lost $4.3 \pm 7.0\%$, compared with $4.8 \pm 7.1\%$ for those with minimal symptoms. The treatment group by depression status interaction was not significant ($P=0.110$). As shown in Figure 2, within the ILI group, participants with minimal vs. mild or greater symptoms of depression lost $7.8 \pm 6.7\%$ and $8.7 \pm 6.9\%$, respectively, with corresponding losses in the DSE group of $0.4 \pm 5.0\%$ and $0.7 \pm 4.7\%$, respectively.

Changes in Mood Category and Weight at 1 Year

Changes in weight for participants who showed incidence, resolution or maintenance of symptoms of depression are shown in Table 4. The ANOVA revealed a significant ($P=0.006$) 3-way interaction between baseline depression status, 1 year depression status, and treatment group. Participants in ILI ($n=127$) without symptoms of depression at baseline, but who developed mild or greater symptoms of depression during the year (i.e., incident), lost $4.6 \pm 6.4\%$ of initial body weight. This was significantly ($P<0.001$, effect size = 0.65) less than the $9.0 \pm 6.9\%$ lost by participants who showed resolution of their symptoms of depression ($n=254$) and less than ($P<0.001$, effect size = 0.65) the $9.0 \pm 6.8\%$ lost by those who reported minimal symptoms of depression at either baseline or at 1 year (i.e., no symptoms of depression at either time point, $n=1885$). ILI participants who both started and ended the study with a BDI score ≥ 10 (i.e., maintained symptoms of depression, $n=164$) lost $6.2 \pm 6.0\%$ of initial weight, which was significantly less than the weight lost by participants who showed resolution ($p<0.001$, effect size = 0.42), or who reported no symptoms of depression at either time point ($P<0.001$, effect size = 0.42), but was not significantly different from participants who showed incident symptoms of depression ($P>0.05$).

Participants in the DSE group who showed incident symptoms of depression ($n=190$) lost $0.7 \pm 5.2\%$ of initial weight, while those who showed no symptoms of depression at either baseline or at 1 year ($n=1799$) lost $0.7 \pm 4.6\%$, and those who showed resolution of their depression ($n=213$) lost $1.0 \pm 5.1\%$. Participants who both started and ended the study with a BDI score ≥ 10 (i.e., maintained, $n=170$) gained $0.4 \pm 4.7\%$ of their initial weight. Participants in DSE who maintained symptoms of depression lost significantly less weight than those who showed resolution of their symptoms of depression ($P=0.003$, effect size = 0.31), those who showed no symptoms of depression at either baseline or at 1 year ($P=0.002$, effect size = 0.25), and participants who showed incident symptoms of depression at year 1 ($P=0.017$,

effect size = 0.25). There were no other statistically significant differences among the other three groups.

Psychiatric Adverse Events

Adverse psychiatric events were reported on an ad hoc basis. During the year, five participants reported an adverse event involving depression; three of these cases were in the ILI group and two were in the DSE group. None of these events involved suicidal behavior. Of these five participants, none reported symptoms of depression at baseline (defined by BDI ≥ 10), but three participants reported use of anti-depressant medication at baseline.

Discussion

This is the first randomized controlled trial of which we are aware to examine precipitation and resolution of symptoms of depression in individuals who received a lifestyle modification weight loss intervention, compared with participants in a non-dieting control group. At 1 year, participants in the ILI lost a mean of 8.6% of their initial weight, compared to 0.7% for those in DSE (24), and reported significantly greater improvements in symptoms of depression compared with DSE participants (1.4 vs. 0.4 points) (25). Participants in ILI with baseline BDI scores ≥ 10 showed an even larger reduction of 5.3 points, compared to 0.6 for those without baseline symptoms of depression. These findings suggest that moderate weight loss in patients with mild to moderate symptoms of depression is associated with improvements, not worsening, in mood.

In the current study, we observed a significantly lower number of incident cases of symptoms of depression in the ILI group at 1 year than in the DSE group (6.3% vs. 9.6%), which remained significant after controlling for incident use of anti-depressant medications in the two groups. Individuals who reported incident symptoms of depression reported a mean increase of >7 points on the BDI, which is regarded as a clinically significant change by experts (36). These results counter the notion that intentional dieting, with its resulting weight loss, precipitates depression in overweight or obese individuals. Furthermore, the incidence of suicidal ideation at 1 year was not significantly different between participants in the ILI and DSE groups (1.4% vs. 1.9%), suggesting that moderate weight loss resulting from lifestyle change does not precipitate suicidal thoughts in this population.

The DSE group provides useful information about changes in mood that can be expected in overweight persons (with type 2 diabetes) who are not in a weight loss program. As a group, DSE participants who reported mild or greater symptoms of depression at baseline showed improvements in mood at 1 year (as indicated by a 3.7 point decline on the BDI). As noted, 9.6% of participants reported the onset of clinically significant symptoms of depression during the year, whereas 55.6% of those with symptoms of depression at baseline experienced remission of this condition (i.e., BDI < 10). These results indicate that mood was subject to fluctuation over the course of a year in a sample of overweight individuals who were not instructed to lose weight and who remained relatively weight stable. Similar fluctuations in symptoms of depression, as well as in the use of anti-depressant medications, were reported over time in participants in the Diabetes Prevention Program (11). Such results set the bar by which to compare changes in mood associated with various weight loss interventions, including behavioral and pharmacologic approaches. The greater reduction in BDI scores observed in individuals reporting symptoms of depression at baseline in the ILI group (-5.3) versus the DSE group (-3.7) suggests that the behavioral weight loss program augmented the spontaneous improvements in mood that were observed in the DSE group at 1 year.

The second aim of our study was to examine whether individuals who reported symptoms of depression at baseline would lose less weight than those without such symptoms. Collapsing across the ILI and DSE groups, participants with mild or greater symptoms of depression at baseline lost significantly less weight than individuals with no symptoms of depression (4.3% vs 4.8%), but the difference cannot be considered clinically meaningful. Similarly, the difference in mean weight loss between participants with and without symptoms of depression in the ILI (7.8% vs 8.7%) is not clinically meaningful. Thus, our results do not support the routine exclusion of participants with symptoms of depression from weight loss trials (17,18,37–39) based on the belief that they may lose less weight than non-depressed individuals. Rather, these findings indicate that individuals with mild or greater symptoms of depression who enroll in a supervised weight reduction program are able to lose clinically significant amounts of weight and achieve improvements (rather than worsening) in mood. We tentatively conclude that such individuals can be safely encouraged to lose weight and should not be routinely excluded from weight loss trials, as currently practiced.

While the presence of pre-treatment symptoms of depression does not appear to substantially hamper weight loss, the onset of symptoms of depression may impede weight loss. ILI individuals who developed symptoms of depression during the year (i.e., cases of incident symptoms of depression) lost significantly less weight (4.6%) than those who resolved (9.0%), or did not report symptoms of depression at either time point (9.0%), and nominally less than those who maintained symptoms of depression (6.2%). Thus, it appears that the presence of mild or greater symptoms of depression at baseline is not a good predictor of weight loss in a clinical trial; rather the presence of symptoms of depression at the end of treatment (regardless of whether they were present at baseline) may indicate poorer outcomes, with the poorest for those who show incident symptoms of depression. This finding is similar to that obtained recently by Gorin et al. (40), who determined that the presence of binge-eating behavior in Look AHEAD participants at baseline alone did not predict poor weight loss outcomes. Instead, weight loss was poorest in those participants who either developed bingeing behavior during the study or did not resolve their pre-existing binge-eating behavior. The present study was not designed to assess causality; thus, we cannot determine definitively whether individuals who reported incident symptoms of depression lost less weight *because* they developed symptoms of depression, or whether symptoms of depression developed in response to achieving a smaller-than-desired weight loss (or even partial regain of initial weight loss in year 1). Further studies that include more frequent assessment of both mood and weight are needed to identify the nature of the relationship between these two variables.

We observed comparable attrition rates between individuals with and without symptoms of depression, contrary to suggestions that depressed individuals are less likely to complete weight loss trials than their non-depressed counterparts. Across the sample, of the 4802 individuals who completed the 1-year assessment, only 16.7% reported symptoms of depression at baseline, compared to 83.3% who reported no symptoms. There was no significant difference in the number of non-completers who reported mild or greater symptoms of depression at baseline in the ILI vs. DSE groups (30.8% vs. 22.2%, ns), indicating that the intensive lifestyle intervention did not increase the likelihood of individuals with baseline symptoms of depression dropping out of the study.

The prevalence of suicidal ideation, as assessed by a single item on the BDI, was very low at baseline; only 129 of 5129 participants (2.5%) endorsed passive suicidal thoughts. These individuals were more likely to report mild or greater symptoms of depression at baseline; one of every 10 participants with symptoms of depression at baseline acknowledged SI at baseline. The incident rate of suicidal ideation was very low and was independent of treatment group (1.4% vs. 1.9% for ILI and DSE, respectively). Some have argued that the

higher rates of SI (and symptoms of depression) associated with some weight loss medications may be attributable to the effects of the greater weight loss induced by the medication (as compared with placebo), rather than to a possible direct effect of the medication on psychiatric function. Our results suggest that greater weight loss alone, as achieved by the ILI vs. DSE, is not associated with increased SI or symptoms of depression.

Strengths of the present study include the large and ethnically diverse sample, and the inclusion of the DSE group that provided an estimate of spontaneous changes in mood over the course of the year in the absence of intentional dieting and weight loss. Significant limitations of the current study include its reliance on the Beck Depression Inventory (a self-report questionnaire) as the primary assessment of mood, as well as the low level of symptoms of depression in the sample, reflective of the extensive screening process in which those who were deemed unfit to complete the study were excluded from the trial. Future studies should incorporate structured clinical interviews and formal assessments of depression and suicidal ideation at baseline and at several times over the course of treatment. This is the Food and Drug Administration's current requirement for the assessment of new weight loss medications that act upon the central nervous system (41). More frequent assessments of weight and mood would allow determination of whether improvements in symptoms of depression precede weight loss or are a consequence of weight reduction.

In summary, the present findings suggest that overweight and obese individuals with mild or greater symptoms of depression can successfully participate in a behavioral weight loss program and should be encouraged to do so. Further research is needed to assess the effect of such treatment in obese individuals who suffer from severe depression.

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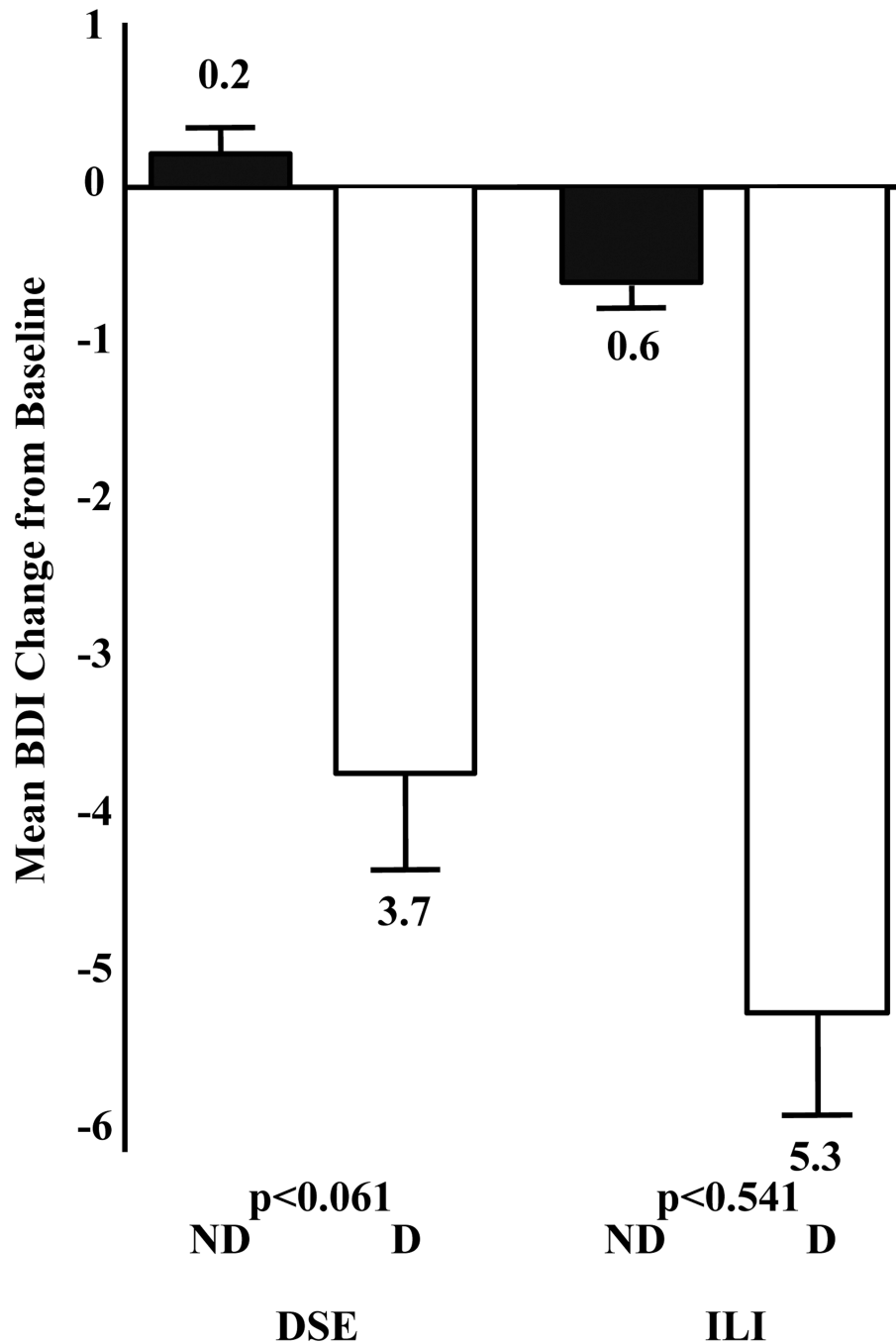


Figure 1.

Change in Beck Depression Inventory (BDI) score (\pm SEM) at 1 Year in Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups by depression status at baseline. D = participants who reported symptoms of depression at baseline; ND = participants with no/minimal symptoms reported at baseline. Mean (\pm SD) baseline BDI scores were as follows: ILI-ND 3.6 ± 2.7 ; ILI-D 14.4 ± 4.5 ; DSE-ND: 3.8 ± 2.8 ; DSE-D: 13.5 ± 3.7 . Symptoms of depression declined significantly more ($P < 0.001$) in the ILI than DSE group, and there was a significant ($P < 0.035$) depression status by treatment group interaction.

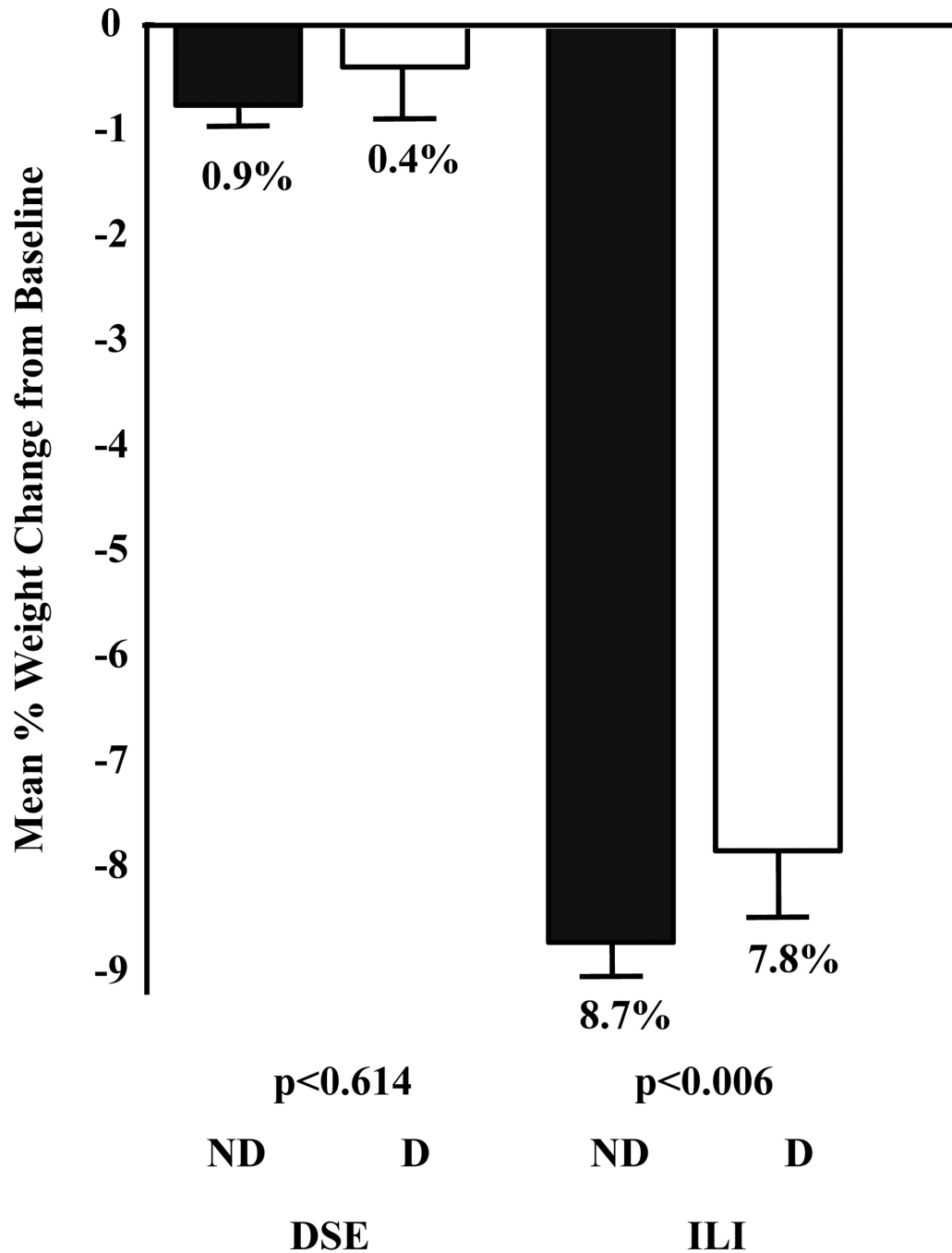


Figure 2.

Mean percent (\pm SEM) of initial weight lost at 1 Year in Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups by depression status at baseline. D = participants who reported mild or greater symptoms of depression at baseline; ND = participants with no/minimal symptoms reported at baseline. A 2×2 ANOVA (i.e., treatment-group by depression-status) revealed that ILI participants lost significantly ($P < 0.001$) more weight than DSE participants and that participants considered free of symptoms of depression at baseline lost significantly ($P < 0.009$) more weight than those who reported mild or greater symptoms of depression. The treatment group by depression status interaction was not significant ($P = 0.110$).

Table 1

Baseline characteristics of all participants (N = 5129), and by depression status at baseline (as determined by BDI score).

Variable	Overall	BDI < 10	BDI ≥ 10	P-value
Age (years)	N=5129	N=4244	N=885	0.022
45 – 55	1620 (31.6)	1302 (30.7)	318 (35.9)	
56 – 65	2638 (51.4)	2187 (51.5)	451 (51.0)	
66 – 76	871 (17.0)	755 (17.8)	116 (13.1)	
Gender	N=5129	N=4244	N=885	<.001
Female	3050 (59.5)	2433 (57.3)	617 (69.7)	
Male	2079 (40.5)	1811 (42.7)	268 (30.3)	
Race	N=5128	N=4243	N=885	0.014
African American / Black (not Hispanic)	800 (15.6)	645 (15.2)	155 (17.5)	
American Indian / Native American / Alaskan Native	257 (5.0)	180 (4.2)	77 (8.7)	
Asian/Pacific Islander	50 (1.0)	40 (0.9)	10 (1.1)	
Hispanic	680 (13.3)	523 (12.3)	157 (17.7)	
Other/Mixed	100 (2.0)	83 (2.0)	17 (1.9)	
White	3241 (63.2)	2772 (65.3)	469 (53.0)	
Years of education	N=5018	N=4155	N=863	<.001
13 – 16 years	1911 (38.1)	1540 (37.1)	371 (43.0)	
< 13 years	1021 (20.3)	783 (18.8)	238 (27.6)	
> 16 years	2086 (41.6)	1832 (44.1)	254 (29.4)	
BMI (kg/m ²)	N=5129	N=4244	N=885	<.001
25 – 27	118 (2.3)	93 (2.2)	25 (2.8)	
27 – 30	645 (12.6)	564 (13.3)	81 (9.2)	
30 – 35	1811 (35.3)	1543 (36.4)	268 (30.3)	
35 – 40	1408 (27.5)	1139 (26.8)	269 (30.4)	
≥ 40	1147 (22.4)	905 (21.3)	242 (27.3)	
BED status	N=5105	N=4231	N=874	<.001
No	4453 (87.2)	3787 (89.5)	666 (76.2)	
Yes	652 (12.8)	444 (10.5)	208 (23.8)	
General health score	47.2±8.9	48.5±8.2	40.6±9.2	<.001
Diabetes duration	6.8±6.5	6.7±6.5	7.2±6.8	0.138

Numbers (and percentages within each category) of participants are presented. For general health score and diabetes duration variables, means (± SD) are presented. P values indicate whether there were significant differences between participants with a BDI score <10, compared with ≥10. BED = binge eating disorder; BMI = body mass index.

Table 2

Mean (\pm SD) baseline Beck Depression Inventory (BDI) scores for participants in the Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups.

		N	Mean (\pm SD) BDI Score	Range
ILI	All	2563	5.5 \pm 5.2	0–35
	With symptoms of depression	459	14.4 \pm 4.5	10–35
	No symptoms of depression	2104	3.6 \pm 2.7	0–9
DSE	All	2566	5.4 \pm 4.7	0–29
	With symptoms of depression	426	13.5 \pm 3.7	10–29
	No symptoms of depression	2140	3.8 \pm 2.8	0–9
All	With symptoms of depression	885	14.0 \pm 4.1	10–35
	No symptoms of depression	4244	3.7 \pm 2.8	0–9

Table 3

Numbers (and percentages) of participants with Beck Depression Inventory (BDI) scores indicating minimal, mild, moderate, and severe symptoms of depression, respectively, at baseline and 1 year in the Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups.

Baseline		ILI		DSE		Overall	
BDI category (score range)							
Minimal (0–9)	2104	(82.1%)	2140	(83.4%)	4244	(82.8%)	
Mild (10–18)	387	(15.1%)	386	(15.0%)	773	(15.1%)	
Moderate (19–29)	67	(2.6%)	40	(1.6%)	107	(2.1%)	
Severe (30+)	5	(0.2%)	0	(0.0%)	5	(0.1%)	
Overall	2563	(100%)	2566	(100%)	5129	(100%)	
Year 1							
BDI category (score range)		ILI		DSE		Overall	
Minimal (0–9)	2139	(83.5%)	2012	(78.4%)	4151	(80.9%)	
Mild (10–18)	246	(9.6%)	303	(11.8%)	549	(10.7%)	
Moderate (19–29)	36	(1.4%)	54	(2.1%)	90	(1.8%)	
Severe (30+)	9	(0.4%)	3	(0.1%)	12	(0.2%)	
Overall*	2563	(100%)	2566	(100%)	5129	(100%)	

* At 1 year, 133 participants in the ILI group, and 194 participants in the DSE group (327 total), had missing BDI values.

Changes in depression status at 1 year, and corresponding changes in weight and Beck Depression Inventory (BDI) score, for participants in the Intensive Lifestyle Intervention (ILI) and Diabetes Support and Education (DSE) groups.

Table 4

	ILI			DSE		
	N (%)	% Weight Loss at 1 Yr	BDI change at 1 Yr	N (%)	% Weight Loss at 1 Yr	BDI change at 1 Yr
No symptoms of depression at baseline	2012 (100)			1989 (100)		
Symptoms at 1 year (Incident)	127 (6.3)	-4.6 ± 6.5	+7.5 ± 5.0	190 (9.6)	-0.7 ± 5.2	+7.3 ± 5.2
No symptoms at 1 year (No symptoms at either time)	1885 (93.7)	-9.0 ± 6.8	-1.2 ± 2.8	1799 (90.4)	-0.7 ± 4.6	-0.5 ± 2.8
Symptoms of depression at baseline	418 (100)			383 (100)		
Symptoms of depression at 1 year (Maintenance)	164 (39.2)	-6.2 ± 6.0	-0.2 ± 7.0	170 (44.4)	+0.4 ± 4.7	+0.7 ± 5.1
No symptoms at 1 year (Resolution)	254 (60.8)	-9.0 ± 6.9	-8.5 ± 4.2	213 (55.6)	-1.0 ± 5.1	-7.3 ± 4.4

Note: Incident depression is shown by persons who reported minimal symptoms of depression at baseline but reported mild or greater symptoms by 1 year. Resolution of depression is shown by persons who reported mild or greater symptoms of depression at baseline but reported minimal symptoms at 1 year. Negative numbers indicate decreases in weight or BDI score.