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A Psychoeducational Intervention (SWEEP) for Depressed Women with Diabetes

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Abstract

Background—Clinically significant depression is present in 25 % of individuals with type 2 diabetes, its risk being doubled in women.

Purpose—To examine the effectiveness of the Study of Women's Emotions and Evaluation of a Psychoeducational (SWEEP), a group therapy for depression treatment based on cognitive behavioral therapy principles that was developed for women with type 2 diabetes was conducted.

Methods—Women with significantly elevated depression symptoms (Center for Epidemiologic Studies Depression Scale ≥16) were randomized to SWEEP (n=38) or usual care (UC, n=36).

Results—Multilevel modeling indicated that SWEEP was more effective than UC in reducing depression (mean difference of –15 vs. –7, p<.01), decreasing trait anxiety (mean difference of –15 vs. –5, p<.01), and improving anger expression (mean difference of –12 vs. –5, p<.05). Although SWEEP and UC had improvements in fasting glucose (mean difference of –24 vs. –1 mg/dl) and HbA1c (mean difference of –0.4 vs. –0.1 %), there were no statistically significant differences between groups.

Conclusions—SWEEP was more effective than UC for treating depressed women with type 2 diabetes. Addition of group therapy for depression meaningfully expands the armamentarium of evidence-based treatment options for women with diabetes.

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Conflict of interest The authors have no conflicts of interest to disclose.

Keywords

Diabetes; Depression; Women

Introduction

Depression is present in 25 % of persons with type 2 diabetes and occurs twice as often in women than men with diabetes. Cost for treatment of depressed persons with diabetes is almost four times higher ($247 million) than treatment for nondepressed persons with diabetes ($55 million) [1, 2]. Although treatment of depression in persons with diabetes by antidepressants has been successful [3–5], they may disrupt glycemic control [6, 7]. Problems such as glucose intolerance and diabetes have been reported with some antidepressants [8–10] as well as weight gain [11–13]. Data from the Diabetes Prevention Program demonstrated that continuous antidepressant use was associated with increased diabetes risk in the placebo arm (2.60, CI=1.37–4.94) and in the intensive lifestyle arm (3.39, CI=1.61–7.13) [14]. In mild or moderate depressive symptoms, evidence suggests that the benefit of antidepressant medication may be minimal or nonexistent [15, 16]. Thus, the need for nonpharmocological treatment for depression, such as cognitive behavioral therapy (CBT), becomes increasingly important for persons with diabetes.

CBT is recognized as an effective treatment for depression [17] with lower relapse rates than antidepressant medications [18, 19]. An important study by Lustman and colleagues [20] examined individual CBT (administered by licensed therapists) for treatment of depression in 51 persons with type 2 diabetes. One group (n=25) received CBT for 10 weeks, and the other group received usual care (n=26). Both groups received diabetes education during the treatment phase. Depression remission was 85 % for the CBT group compared to 27.3 % for the controls (p<.0001). In addition, at 6 months follow-up, the CBT group had significantly lower HbA1c compared to the controls (p=.03), indicating a delayed benefit of CBT on glycemic control. These findings are particularly important because depression and depressive symptoms have been found to negatively impact glycemic control and have been attributed to poor self care, particularly for women [21–24].

Following the study of Lustman et al., several other studies have explored whether depression treatment improves metabolic control. However, without the inclusion of diabetes education with depression treatment, one large randomized trial of collaborative care for diabetes and depression (n=329) reported greater improvement in depression outcomes for the treatment group as compared to usual care, but no differences in HbA1c were observed [25]. Recently, Gonzalez et al. [26] reported improvements in depression, HbA1c, and self-care behaviors using a collaborative team approach (psychologist, nurse educator, and dietician). Patients received individual CBT for 10–12 sessions, which focused both on diabetes treatment adherence and depression. A more recent systematic review has suggested that targeted health behaviors combined with depression treatment may be needed to maximize outcomes in persons with diabetes [27].

Anxiety and anger are prevalent in persons with diabetes [28–34]. Women have reported that in addition to depression, anxiety and anger impact their self-care and, more importantly, their relationships with their family members and health-care providers [21, 35]. It has also been reported that women have greater reliance on social support to discuss their anger experiences [36]. Good communication with the health-care provider is critical for persons with diabetes. Swenson et al. [37] reported that patients with diabetes who have depressive symptoms are more likely to have poorer communication with their health-care provider. Patient recognition of depression symptoms is important for better management of

their health [38]. Recognition, communication, and treatment of depressive symptoms are particularly important in diabetes care. Gonzalez et al. [39] reported that continuous depressive symptoms, even low levels, are better predictors of nonadherence to diet, exercise, and medications than major depression.

Depression significantly impacts the quality of life of persons with diabetes [40–42]. Negative moods are associated with poorer quality of life in persons who have diabetes [43, 44]. Studies have also reported that health improvements can occur with effective CBT programs for depression and stress in persons with diabetes [20, 45]. In addition, other studies are using a CBT approach to treat mild and major depression in persons with diabetes [46, 47].

Currently, although there are programs targeting depression and depressive symptoms, there are no programs that target recognition and treatment of depression combined with treatment of other moods (anxiety and anger) for persons with diabetes. The Study of Women's Emotions and Evaluation of a Psychoeducational (SWEEP) Program (study intervention) was a group CBT program delivered by a nurse for the recognition and management of depression and other moods (anxiety and anger) in women with type 2 diabetes. The primary aim of the study was to examine the effects of the SWEEP program on depression, anxiety, and anger among women with type 2 diabetes. The secondary aim was to examine the effects of the SWEEP program on glycemic control and health-related quality of life.

Methods

Participant Recruitment

To participate in the study, the inclusion criteria were women: (1) aged 18 and older, (2) having type 2 diabetes >6 months and being medically managed, and 3) having an average score of ≥16 on the Center for Epidemiologic Studies Depression Scale from two screenings (phone and baseline) within 4 weeks of each other. The exclusion criteria were the following: (1) current alcohol or substance abuse disorders, a history of bipolar depression, or any other psychotic disorder; (2) a diabetes knowledge score <70 % on the Brief Diabetes Knowledge Test (since the program emphasis was not diabetes education); and (3) severe complications of diabetes (blindness, renal failure, or amputation). The study took place in a major midwestern medical center in the USA where there are over 800 outpatient visits per month for the treatment of diabetes. The IRB approved study included a recruitment flyer that briefly identified depression symptoms in women with type 2 diabetes and a nurse contact if there was interest regarding the study. The flyers were distributed at the diabetes center and the primary care clinics. In order to increase minority recruitment, a large ministry group within the immediate area was also informed. Potential participants phoned the nurse, the study was described, and then they were screened for inclusion and exclusion criteria. For participants who were depressed and not eligible, a list of counseling centers was provided. If women were not successful on the diabetes knowledge test, they were mailed a basic diabetes information book, called for retesting, and enrolled if they were still eligible.

Design

A randomized, repeated measures, experimental design was used. Women were randomized to either usual care (control group) or the SWEEP program (intervention group). Data were collected on all women at baseline, 12 weeks (i.e., 3 months), and 24 weeks (i.e., 6 months) follow-up. Phone contact was made for all participants at 10 and 22 weeks to schedule follow-up visits. All contact points were used to monitor for potential adverse events.

Following randomization, women in the SWEEP program attended eight weekly sessions and two booster sessions (weeks 14 and 22) to reinforce the content learned in class.

Procedures

Enrollment—There was a two step process for enrollment, which included a phone screen and a baseline assessment. Women were phone screened for participation (see recruitment). Once there were 20–24 women (cohort) who met the study criteria, they were invited for a baseline screening. These two screenings occurred within 4 weeks of each other. Subjects came to the School of Nursing Research Laboratory after fasting for 10 h and were told to bring their medications with them. They were informed that the testing would take 1.5–2 h. Upon arrival at the study site, consent was obtained followed by laboratory and physical measures done by a nurse. Subsequently, women were provided breakfast, reminded to take their prescribed medications, and instructed to complete a questionnaire booklet, which included the Center for Epidemiologic Studies Depression Scale. These procedures were followed at the 3- and 6-month follow-up visits. The Diagnostic Interview Schedule based on the Diagnostic and Statistical Manual of Mental Disorders IV was also administered at baseline to verify the mental health exclusion criteria and to prevent women with suicidal ideation who needed immediate treatment from enrolling in the study. For women who reported using psychoactive medications (antidepressants and/or antianxiety) and/or psychotherapy (e.g., psychologist, psychiatrist, social worker) prior to entry into the study, they were allowed to remain on them and participate in the study if they had significant depressive symptoms.

Randomization—Sample size was estimated using data from Lustman's randomized, controlled, CBT trial for persons with type 2 diabetes and depression [20]. Using a Fischer's exact test with an alpha of .05 and power of .80, it was estimated that at least 19 persons per group would be needed to see differences in depression at 3 months and 33 per group at 6 months. To account for possible attrition, it was determined that 80 women (40 per group) would be enrolled with each cohort being 20 (10 treatment and 10 control).

Assignments to the groups were made after the baseline assessment. Because of the small sample size, women were matched on their level of depression (±1.0 standard deviation). It was anticipated that there would be four cohorts of women. Thus, four randomization lists were generated using a random seed number by the statistician. Four cohorts of women were enrolled over the course of the study, which lasted 24 months. Each participant was contacted by phone regarding their assignment, and a follow-up letter was sent with a list of resources for mental health services (this was provided in class to the treatment group). The participants, the data collector, and the intervention staff (nurse and psychologist) were not blinded to the group assignment.

Retention Strategies—Methods for the successful retention of the women in both groups included (1) data collection visits and CBT sessions at convenient times, (2) an honorarium in a stepped compensation manner for data collection visits, (3) paid parking, and (4) reminder phone calls and letters for scheduled visits. SWEEP participants were also provided with a bag that contained a binder for class materials and a compact disc player (valued at $20). In addition, at the end of every weekly SWEEP session, name tags were used for a random drawing of one small gift (e.g., body lotion valued at $10), which facilitated group camaraderie. These retention methods have been previously reported [48].

Interventions

Intervention (Treatment Group)—Women assigned to this group received the SWEEP program, which was a psychoeducational intervention delivered by a trained nurse (who was

different than the nurse collecting the participant data) in a group. The program educated women with type 2 diabetes about (1) recognizing the signs and symptoms of depression and other moods (anxiety and anger), (2) the relationship between moods, metabolic control and self-care behaviors, and (3) the management of depression, anxiety, and anger using CBT. The SWEEP program was developed from the experiences of women with type 2 diabetes who participated in focus groups addressing the psychological impact of living with diabetes [21]. The SWEEP Program is synonymous with "cleaning the mind and body of negative thoughts and emotions." The program was 8 weeks with each session lasting 1 h. Women were invited to arrive 30 min prior to the group session to socialize and refreshments were provided. There has been evidence that booster sessions combined with cognitive therapy is as successful as medication therapy in the treatment of depression [18, 49]. Thus, two booster sessions were also done to review the learned skills, to have group sharing regarding their experiences with the skills, and to assist with retention.

The SWEEP program used elements of pre-existing programs for treating depression, anxiety, and anger. Permission to use elements from each program was obtained. For depression management, the "Reality Management Approach for Persons with Depression" developed by Munoz and colleagues [50, 51] at the University of California San Francisco was used. This group CBT program for depression has practical skills to change mood-related thoughts or behaviors and personal projects to reinforce skill development between group sessions. For anxiety management, a progressive muscle relaxation CD developed by Surwit et al. [45] for persons with diabetes was used. For anger management, The Williams LifeSkills System for Managing Stress and Anger (video and workbook) was utilized [52, 53]. It addresses how to reduce anger, build relationships, manage anxiety, resolve conflict, learn assertive skills, and build positive attitudes. The SWEEP program utilized many of the techniques addressed by Abraham and Michie [54], which include providing information on health behavior, general encouragement, goal setting, self-talk, and stress management. The SWEEP program objectives with established program content for each week are delineated in Table 1. Homework was an essential part of the SWEEP program as previous research has indicated that engagement in the homework component of CBT is important for its success [55]. As recommended by Munoz et al., the term "personal projects" was used as the term "homework" often has a negative connotation. A sample is provided in Fig. 1. One of the key components of SWEEP was mood and glucose monitoring for participants to understand the relationship between their mood, metabolic control, and health behaviors. Another example of a "personal project" has been previously published [48].

Intervention Fidelity—The SWEEP program was delivered by a nurse who had undergone training for the CBT. There was standardization of the treatment in terms of the content presented (Table 1). A licensed clinical psychologist attended all of the class sessions and evaluated the nurse for fidelity to the sessions and provided feedback.

Usual Care (Control Group)—Women assigned to this group received no study-related intervention but were allowed to receive treatment for diabetes and depression outside of the study as needed. According to Freedland et al. ([56], p. 330), a "treatment development trial testing whether a novel intervention has any effect at all can use a pure no-treatment control condition if nonstudy care is available." Patients were offered the SWEEP program after completion of the study if their depression level met the enrollment criteria. All UC participants were given the stress relaxation CD used in the SWEEP program upon completion of the study. Six subjects (17 %) participated in the SWEEP program after first serving as a control.

Patient Safety—For the protection of all the patients, the informed consent document stated that in the event of suicidal ideation upon baseline assessment or during the course of

the study, the study psychologist would be contacted, and the primary health-care provider would be informed so that appropriate referral and treatment could be done.

Measurements

Primary Outcome of Moods

Depression: The Center for Epidemiologic Studies Depression Tool is 20 items and measures "depressive symptoms" and their severity. This tool was administered over the telephone for screening and by questionnaire at subsequent time points. Participants were asked to report their symptom severity for the past few weeks with the following choices: (1) rarely or none of the time, (2) some or a little of the time, (3) occasionally or a moderate amount of time, and (4) most or all of the time. It is a well-accepted tool for screening for depressive symptoms in primary care. The tool has excellent internal reliability (Cronbach alpha from .85 to .90) and established validity by correlations with other self-report measures, clinical ratings of depression, and factor analysis [57, 58]. Most recently, it was cited as a tool for effective use in persons with diabetes [59]. For the current study, the Cronbach alpha reliability ranged from .87 to .92 for the three time periods.

Anxiety: The State–Trait Anxiety Inventory is a 40-item scale, which differentiates between the temporary condition of "state anxiety" and the more long-standing quality of "trait anxiety." There is a four-point Likert scale (1=not at all to 4=very much so) delineating the degree to which an individual experiences the described feeling "at the present time" to measure state anxiety (20 questions). There is another four-point likert scale (1=almost never to 4=almost always) describing the way an individual "generally feels" for trait anxiety (20 questions). The mean score for adults is 35 for each subscale with higher scores reflecting more anxiety. The alpha reliability has been reported, and construct validity has been established [60, 61]. For the current study, the Cronbach alpha ranged from .90 to .95 for both state and trait anxiety.

Anger: The State–Trait Anger Expression Inventory is a 44-item tool that measures the experience of anger as an emotion (State Anger), the predisposition to experience any feelings as a personality trait (Trait Anger), and the manner in which anger is expressed (Anger Expression). For adult females, the mean score for state and trait anger is 18 for each, and for female psychiatric patients, it is 24 and 20, respectively. The mean score for the index of anger expression is 32 for normal female adults and about 37 for female psychiatric patients. Reliability and validity of the tool has been established [62]. The Cronbach alpha reliability ranged from 76 to .95 for the current study at the three time points.

Diagnostic Interview Schedule: This is a structured mental health interview that uses the criteria specified in the Diagnostic and Statistical Manual of Mental Disorders IV to generate diagnoses that can be used for research purposes [63, 64]. It has been reported that results of the Diagnostic Interview Schedule correlate significantly with clinical diagnoses [65–67]. For this study, it was used to obtain a history of depression and to screen for suicidal ideation, which was an exclusionary criterion for participation.

Secondary Outcomes of Glycemic Control and Health-Related Quality of Life

Glycemic Control: For fasting blood glucose, the LDX system, which uses enzymatic methodology and solid-phase technology was used to measure glucose (Cholestech Corporation, Hayward CA). Precision for the LDX ranges between 2 and 6 %, depending on the analyte.

Hemoglobin A1c was measured using the Bayer DCA 2000 (Miles Diagnostic Division). The coefficient of variation for the within-run precision of this measurement is from 2.1 to 4.5 %, and the between-run precision is from 0.8 to 4.4 % [68]. Controls were run on each day to ensure reliable results.

Health-Related Quality of Life: For life satisfaction, the Ferrans and Powers Quality of Life Index—Diabetes III Version was used to assess quality of life. This tool consists of 34 items that measures satisfaction (1=very dissatisfied to 6=very satisfied) and importance (1=very unimportant to 6=very important) in four areas of life (health and functioning, social and economic, psychological/spiritual, and family) that impact quality of life for persons with diabetes. Reliability and validity of the tool is well established [69, 70]. For the current study, the Cronbach alpha ranged from .68 to .93 for the three time points.

For functional status, the SF-12 developed by Ware, Kosninski, and Keller is a well-recognized measurement of perceived health status. It is a shorter version of the Medical Outcomes Study SF-36 and includes the physical component summary and the mental component summary, with Cronbach alpha at .87 and .84. A confirmatory factor analysis also provided evidence of validity [71–73]. For the current study, the Cronbach alpha ranged from .77 to .80 at the various time points.

Other Measures: Other measures include demographics. The Diabetes Care Profile from the Michigan Diabetes Research and Training Center has a section on demographics that was used. Information collected included age, marital status, ethnicity/race, level of education, and employment status. The profile also had a diabetes history, which included current treatment, comorbidities (e.g., complications of diabetes), and medications. Development, validity, and reliability of the Diabetes Care Profile have been reported [74].

Another measure is diabetes knowledge. The Michigan Diabetes Research and Training Center's Brief Diabetes Knowledge Test was used and included 23 questions with a multiple choice response format. For persons not on insulin, only 14 of the 23 items were asked. The test was updated to reflect current diabetes practices. The reliability of the tests has been established [75].

Data Management and Analysis

Data collection forms and a study operations manual were developed before recruitment. All data were recorded by study personnel on protocol specific data forms. An electronic data tracking and management system was developed to assure that forms were completed in a timely fashion and to check for potential data errors. SPSS 17.0, and Hierarchical Linear Models 6.08 were used for data analysis.

Results

Participant Characteristics

There were 84 women who completed baseline enrollments of whom 10 were not eligible (4 psychiatric reasons as verified by psychologist, 2 not depressed, 1 grief depression, 2 medical conditions, and 1 alcohol abuse) (Fig. 2). Of those who were eligible (n=74), there were no baseline differences between the treatment or control group on key variables (Table 2). There was also no significant difference on self-reported use of psychoactive medications (36 %) or psychotherapy (13 %) between groups. Following randomization, 4 patients never showed up for treatment, leaving 70 persons who actually participated in the trial. At 3 months, 65 remained (92 % retention). Reasons for attrition included one medical problem, one family issue, one no transportation, and two needing psychiatric treatment. At 6 months,

60 remained in the study (85 % retention from baseline), and attrition was due to new medical conditions (1 brain tumor, 2 cardiac, 1 orthopedic surgery, and 1 unknown). Of the women with diabetes and comorbid depression enrolled, 60 (26 treatment and 34 control) completed baseline, 3 and 6 month measures.

Treatment Session Participation

There were eight treatment sessions and two booster sessions over the 6-month study period. For those who had missed a group session, materials from that week were provided to the participant, and they were encouraged to review them. For the treatment sessions, 82 % of women completed six or more sessions. For those women who attended less than four sessions, none participated in the follow-up booster sessions. For women who had attended six or more group sessions, the attendance at the two booster sessions was 68 % for both sessions and 21 % for one session, and 11 % of women did not attend any boosters.

Changes in Primary Outcomes

To examine the effectiveness of SWEEP among those women who completed the study (N=60), a repeated measures analysis of variance (ANOVA) was employed on the primary outcomes and post hoc tests (contrasts) were used to test the hypothesized differences at respective time points if interactions were found to be significant (Table 3 and Fig. 3a–c). The mean raw score for each primary outcome at the respective time points is presented in Table 3 for both the treatment and UC group. Because the intent to treat (ITT) is the more widely accepted method for analysis of controlled, clinical trial, multilevel modeling was employed to examine the primary and secondary outcomes as well. The ITT approach takes into consideration all participants, regardless of whether or not they completed the study (N=74). This analysis examined individual change and variability over time (level 1 model) and treatment effect while controlling for cohort (level 2 model).

For those who completed the study, repeated measures ANOVA results yielded a significant main effect of time [F(2, 116)=34.26, p<.001], indicating a decrease in depression over the course of the study on average. More importantly, there was a significant interaction between time and SWEEP [F(2, 116)=3.78, p<.05], and post hoc tests indicated, that at 3 and 6 months, those in SWEEP had significantly lower levels of depression compared to UC (p=.003, p=.001, respectively; Fig. 3a). Using ITT, results demonstrated a significant decrease over time on average (β_{01}=–5.41, SE=0.76, p<.01), and those in SWEEP had a significantly greater rate of decline in depression compared to UC (β_{11}=–3.96, SE=1.43, p<.01). Therefore, results indicate that SWEEP was more effective than UC at reducing depression. Given that 100 % of women were categorized as depressed at baseline, changes in the categories of depressed versus not depressed were examined. At 3 months, 48 % of women in SWEEP and 70 % of women in UC remained depressed (p=.083). During this period of time, two patients were withdrawn from the study, as it was deemed by the psychologist that they needed individualized psychiatric care. By 6 months, only 35 % of those in SWEEP, while 80 % of those in UC remained depressed (p<.001), indicating continued depression improvement for those who had received SWEEP. Over the course of the study, one woman in the treatment group and two in the control group initiated medications to treat their mood, but there was no change in the number of women receiving psychotherapy.

For the outcome of trait anxiety, repeated measures ANOVA results yielded a significant main effect of time [F(2, 116)=27.21, p<.001], indicating a decrease in trait anxiety over the course of the study on average for those who completed the study. More importantly, there was a significant interaction between time and SWEEP [F(2, 116)=4.95, p<.01], and post hoc tests indicated that, at 6 months, those in SWEEP had lower levels of trait anxiety

compared with UC (p=.005; Fig. 3b). Using ITT, results demonstrated a significant decrease across time on average (β_{01}=–4.59, SE=0.76, p<.01), and those in SWEEP had a significantly greater rate of decline in trait anxiety compared to UC (β_{11}=–4.28, SE=1.46, p<.01). Results indicate that SWEEP was more effective than UC at decreasing trait anxiety.

For the outcome of state anxiety, repeated measures ANOVA results yielded a significant main effect of time [F(2,116)=7.32, p<.001], indicating a decrease in state anxiety over the course of the study on average. However, there was no significant interaction between time and SWEEP, indicating no differences in the rate of change between SWEEP and UC. Similarly, ITT results indicated a significant decrease in state anxiety over time on average (β_{01}=–3.39, SE=0.97, p<.01), but those in SWEEP did not have a significantly greater rate of decline in state anxiety compared to UC. Findings indicate that SWEEP was not more effective than UC at alleviating state anxiety.

For the outcome of anger expression, repeated measures ANOVA results yielded a significant main effect of time [F(2,114)=21.62, p<.001], indicating a decrease in anger expression over the course of the study on average. The interaction between time and SWEEP indicated a trend towards significance [F(2, 114=3.03, p=.052] (Fig. 3c). ITT results indicated a significant decrease in anger expression over time on average (β_{01}=–1.56, SE=0.27, p<.01), and those in SWEEP had a significantly greater rate of decline in anger expression compared to UC (β_{11}=–1.26, SE=0.22, p<.05). Thus, SWEEP was more effective at reducing anger expression compared to UC using the ITT approach.

For the outcome of trait anger, repeated measures ANOVA results yielded a significant main effect of time [F(2,116)=18.73, p<.001], indicating a decrease in trait anger over the course of the study on average for those who completed the study. However, there was no significant interaction between time and SWEEP. Using ITT, results demonstrated a significant decrease across time on average (β_{01}=–1.59, SE=0.29, p<.001), but those in SWEEP did not have a significantly greater rate of decline in trait anger compared to UC. Results indicate that SWEEP was not more effective than UC at decreasing trait anger.

For the outcome of state anger, repeated measures ANOVA results did not yield a significant main effect of time, and there was no significant interaction between time and SWEEP. Using ITT, there were no significant findings. Results indicate that SWEEP was not more effective than UC at decreasing state anger.

Changes in Secondary Outcomes (Table 3)

For the outcome of fasting glucose and HbA1C, both repeated measures ANOVA, and IIT results indicated there was no significant decrease in fasting glucose or HbA1c over time, and there were no differences in the rate of change on either glycemic outcome between SWEEP and UC, suggesting that SWEEP was not more effective at improving metabolic control relative to UC over the course of the study. Of clinical relevance, however, was the decrease in HbA1c (–0.4 %) and fasting glucose (–22 mg/dl) for those in SWEEP from baseline to 3 months.

For overall quality of life, repeated measures ANOVA results yielded a significant main effect of time [F(2, 116)=22.25, p<.001], indicating an increase in quality of life over the course of the study on average. There was no significant interaction between time and SWEEP, indicating no differences in the rate of change between SWEEP and UC. The ITT results yielded a significant increase over time on average (β_{01}=1.43, SE=0.24, p<.01), and those in SWEEP had a significantly greater rate of increase in overall quality of life compared to UC (β_{11}=1.05, SE=0.47, p<.05). These results suggest that SWEEP was more effective than UC at improving quality of life using an ITT approach.

For the outcome of health and functioning, repeated measures ANOVA results yielded a significant main effect of time [$F(2, 116)=22.40$, $p<.001$], indicating an increase in health and functioning over the course of the study on average. In addition, there was no significant interaction between time and SWEEP, indicating no differences in the rate of change between SWEEP and UC. Similarly, the ITT results indicated a significant increase over time on average ($\beta_{01}=1.61$, SE=0.29, $p<.01$), but those in SWEEP did not have a significantly greater rate of increase in health and functioning compared to UC. Overall, these results suggest that SWEEP was not more effective than UC at improving health and functioning.

For the outcome of psychological and spiritual satisfaction, repeated measures ANOVA results yielded a significant main effect of time [$F(2, 116)=24.23$, $p<.001$] indicating an increase in psychological and spiritual satisfaction over the course of the study on average. However, there was no significant interaction between time and SWEEP, indicating no differences in the rate of change between SWEEP and UC. The ITT results indicated a significant increase over time on average ($\beta_{01}=1.99$, SE=0.33, $p<.01$), and those in SWEEP had a significantly greater rate of increase in psychological and spiritual satisfaction compared to UC ($\beta_{11}=1.58$, SE=0.63, $p<.05$). Thus, results suggest that SWEEP was more effective than UC at improving psychological and spiritual satisfaction with the ITT approach.

For the outcome functional status (mental health), repeated measures ANOVA results yielded a significant main effect of time [$F(2, 116)=16.47$, $p<.001$], indicating an increase in mental functional status over the course of the study on average. However, there was no significant interaction between time and SWEEP, indicating no differences in the rate of change between SWEEP and UC. The ITT results indicated a significant increase over time on average [$\beta_{01}=4.33$, SE=0.81, $p<.01$] and those in SWEEP had a significantly greater rate of increase in mental functional status compared to UC ($\beta_{11}=3.79$, SE=1.54, $p<.05$). Overall, these results suggest that SWEEP was more effective than UC at improving functional status (mental health) with the ITT approach. No effects emerged for functional status (physical health) with either statistical approach.

Intervention Evaluation

The SWEEP program was evaluated by patients with a structured questionnaire (1=not helpful to 4=very helpful). The most helpful content aspects of the program were learning about the signs/symptoms of dysphoric symptoms ($M=3.87$), learning techniques to stop negative thinking (i.e., thought stopping, thought records, and relaxation) (M03.81), and improving communication ($M=3.89$). The most helpful skills learned were examining daily blood sugar levels and mood ($M=3.71$) and sharing experiences with others ($M=3.90$). In terms of what they would change about SWEEP were that (1) it should have more than two follow-up sessions and (2) it should include diabetes self-management education following SWEEP. Participants indicated that a key benefit of the program was understanding the relationship between their thoughts, emotions, and blood sugar levels.

Discussion

Primary Outcomes

This study demonstrated the effectiveness of a group program delivered by a nurse trained in CBT for depression treatment for women with type 2 diabetes. This has important clinical significance, as women with type 2 diabetes have a disproportionately greater risk for depression and poorer health outcomes than men with type 2 diabetes [22, 76]. For women in SWEEP, there was not only a reduction in depression symptoms over time that was

significantly greater than usual care, but also the percent who were depressed by 6 months was substantially less than those who had received usual care (35 vs. 85 %). Women in SWEEP also experienced a greater reduction in trait anxiety. These improvements in mental health are important, given that recent evidence indicates that antidepressant medications may have suboptimal effectiveness and can be associated with side effects, which contribute to negative metabolic outcomes [6–13].

CBT is a well-accepted therapy for persons who have depression [17–19]. In the clinical depression trial by Lustman et al. [20], there was a significant improvement in depression in persons with diabetes who received 10 weeks of individual CBT. The present study also found significant improvement in depression in women with type 2 diabetes who received 8 weeks of group CBT. The 6-month remission rate was also comparable between these two studies (75 vs 65 %, respectively). Most previous depression studies of persons with diabetes have included individual CBT sessions delivered by psychologists [20, 26, 77, 78] rather than group CBT by other health professionals [25, 79, 80]. An important contribution of this study is that a nurse trained in CBT for depression treatment delivered the group program. Nurses are the most frequent contact for the patient with diabetes in the health-care system. Thus, the SWEEP program may be a cost-effective strategy for treating depression and improving health outcomes for persons with diabetes.

SWEEP was developed from the experiences of women with type 2 diabetes who participated in focus groups examining the psychological impact of living with diabetes [21]. In the present study, women reported feeling comfortable in their ability to express their emotions with other women. Recently, a large, randomized trial using a group-based psychosocial intervention to reduce stress for women following a myocardial infarction was published. Women reported feeling more comfortable in discussing sensitive topics like marital and other stressors with other women and received support from each other that was important in their recovery. The gender-specific intervention had a positive effect on reducing mortality (p=.007) [81]. This study was especially important since the Enhancing Recovery in Coronary Heart Disease Patients trial for the treatment of depression following myocardial infarction did not demonstrate a significant benefit for women [82]. Thus, further study of the benefit of group interventions for depression treatment that target specific gender and racial groups is needed.

Because other emotions may be associated with depression, these outcomes were also examined in the present study. Trait anxiety was noted to improve more so with SWEEP. The significance of SWEEP in modifying trait anxiety suggests that the program had an impact on an anxiety that was more durable and perhaps amendable to change. Surwit et al. [45] has demonstrated an improvement in anxiety in persons with type 2 diabetes when using their stress relaxation CD. That CD was used in the present study, and women identified it as their “personal time,” which was very therapeutic. Women in SWEEP also had a greater decline in anger expression. It has been reported that “anger” towards self (e.g., for not taking better care of oneself) and towards others (e.g., constantly on them about what to eat) is a symptom experienced by women with type 2 diabetes, particularly in conjunction with depression and anxiety [21]. Thus, it may be an important emotion that deserves additional study.

Of particular significance is that women in the present study were generally not cognizant of the impact that emotions had on their blood glucose fluctuations, which was learned through the daily use of their mood logs (Fig. 1). There is limited research that addresses the relationship between glucose self-monitoring and its impact on mood [83, 84]. The need to understand this relationship is important since poor self-management decisions may be due

to depression or other emotions that make it difficult to adhere to recommended therapies [21].

Secondary Outcomes

In terms of glycemic control, there were no statistically significant differences between groups in fasting glucose and HbA1c over time. However, the study was not powered to detect for changes in glycemic control. For those in SWEEP, clinical improvements in metabolic outcomes were observed at 3 months (Table 3). Whether providing diabetes education after SWEEP could enhance and sustain potential improvements in metabolic control would be worthy of exploration. A large trial of collaborative care for depression in persons with diabetes that did not include diabetes education found a significant improvement in depression, but no improvement in HbA1c [25]. Although Lustman et al. [20] did not find an improvement in glycemic control immediately following individual CBT for depression at 10 weeks, an improvement was noted by 6 months. It was suggested that this delay in benefit may be due to the need to focus on CBT skills vs. diabetes care. It should be noted, however, that all patients received diabetes education in that study. In the present study, although diabetes education was not provided, glucose monitoring and health behaviors (e.g., physical activity as a method to improve mood) (Table 1 and Fig. 1) were emphasized. Thus, it may be very reasonable to provide diabetes self-management training following completion of depression treatment. Once depression improves, it may be an opportunity to “seize the moment” as patients may be more receptive to education and lifestyle changes. This “window of opportunity” may be the optimal time to offer educational support [85].

There is evidence to suggest that negative emotions, such as anxiety, fear, and depression, can affect learning and performance [86, 87] and that depressed persons need more repetitions to reach mastery and have more difficulty with transfer skills [88]. Research has demonstrated that a good mood has a positive effect on one's attention, ability to learn, and ability to engage in self-management behaviors [89–92]. Thus, treating depression and then targeting diabetes self-management may be the most effective approach to improving health outcomes for women with diabetes and would be a logical step for further study.

Improved health-related quality of life was reported by participants, specifically on the mental and psychological components of life. This is not surprising given that the program was targeted at improvements of this aspect of health. Perhaps with education targeted at diet and physical activity following the treatment of depression, improvements in the physical aspects of life may also be possible.

Limitations

Some of the strengths of the study may also be seen as limitations. For this study, the SWEEP program was administered by the same nurse who was trained in group CBT for depression and supervised by a clinical psychologist. Although the materials for the program (e.g., power-point presentations, homework assignments) can be manualized, the need to receive training on the assessment and use of CBT for depression management would be highly recommended. For clinical translation, the testing of the SWEEP program among nurses who receive CBT training and are oriented to the SWEEP program would be the ideal. Given the number of patients with diabetes that experience depression, it may be reasonable to expect that nurses have training in depression assessment to successfully manage their complex care. Secondly, even though the SWEEP program is highly structured and could be readily implemented (Table 1), a number of techniques are used to improve depression and the other moods (e.g., stress relaxation CD, thought stopping). It should also be recognized that the support women received from each other prior to or during the group

sessions could have contributed to their improvement in depression. In this study, UC was used as the control condition. Thus, perhaps another study where parallel groups (SWEEP program, diabetes education and support, and usual care) are randomized could tease out the contribution of group support in alleviating depression in women with type 2 diabetes. Several studies like this are currently in progress [46, 93]. Finally, since the study was not powered to test for changes in glycemic control, perhaps a larger study to determine the impact of treating depression and its impact on glycemic control is warranted.

Future Research

The challenges that health-care providers face in addressing the emotional issues for persons with type 2 diabetes has recently been reported [94]. Although medication is often a treatment option prescribed for depression and anxiety, some medications can negatively impact glucose levels and also cause weight gain. There is a need to develop treatment options whereby the emotional needs of persons with type 2 diabetes can be met so that successful diabetes self-management can take place.

Vaccarino [95] reported that gender-specific trials should be conducted as men and women may respond differently to psychosocial interventions. Reports identify that sex-based differences need to be considered in developing health programs [96–99]. One study reported that women with diabetes receive higher levels of social support from their health-care team members than men with diabetes, and thus, their treatment plan needs to be different than their male counterparts [98]. Another study reported that women had a higher prevalence of negative emotions and internal control that prevented them from reaching optimal glycemic control and benefit most from diabetes care offering social support, whereas men benefit by getting information regarding their disease management [99]. Most recently, a successful behavioral intervention targeted at Hispanic women with type 2 diabetes was reported [100]. Differences in approaches to treatment for men and women may be necessary to achieve improved metabolic outcomes, particularly for women.

The SWEEP program was developed specifically for women based on focus group data and is the first CBT program to treat dysphoric symptoms in depressed women in a group setting and to demonstrate an improvement in depression. Given that women had requested diabetes self-management information following the CBT intervention, future research to examine whether persons are more responsive to diabetes education and diabetes self-management training following successful treatment for their mood disorders should be conducted with sample sizes that could detect changes in self-care behaviors and metabolic outcomes.

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	Worst Mood			OK/Average			Best Mood			
Monday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Tuesday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Wednesday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Thursday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Friday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Saturday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____
	Worst Mood			OK/Average			Best Mood			
Sunday	1	2	3	4	5	6	7	8	9	**Blood Sugar**
Notes: _____										AM _____ PM_____

Directions: Circle one number for each day. Try to use the range, not just 1, 5, or 9. There is no right answer. Only you know how you feel each day. It will feel more natural as you practice.

Fig. 1.

SWEEP quick mood log. Note: Adapted with permission from Muñoz et al. [50]

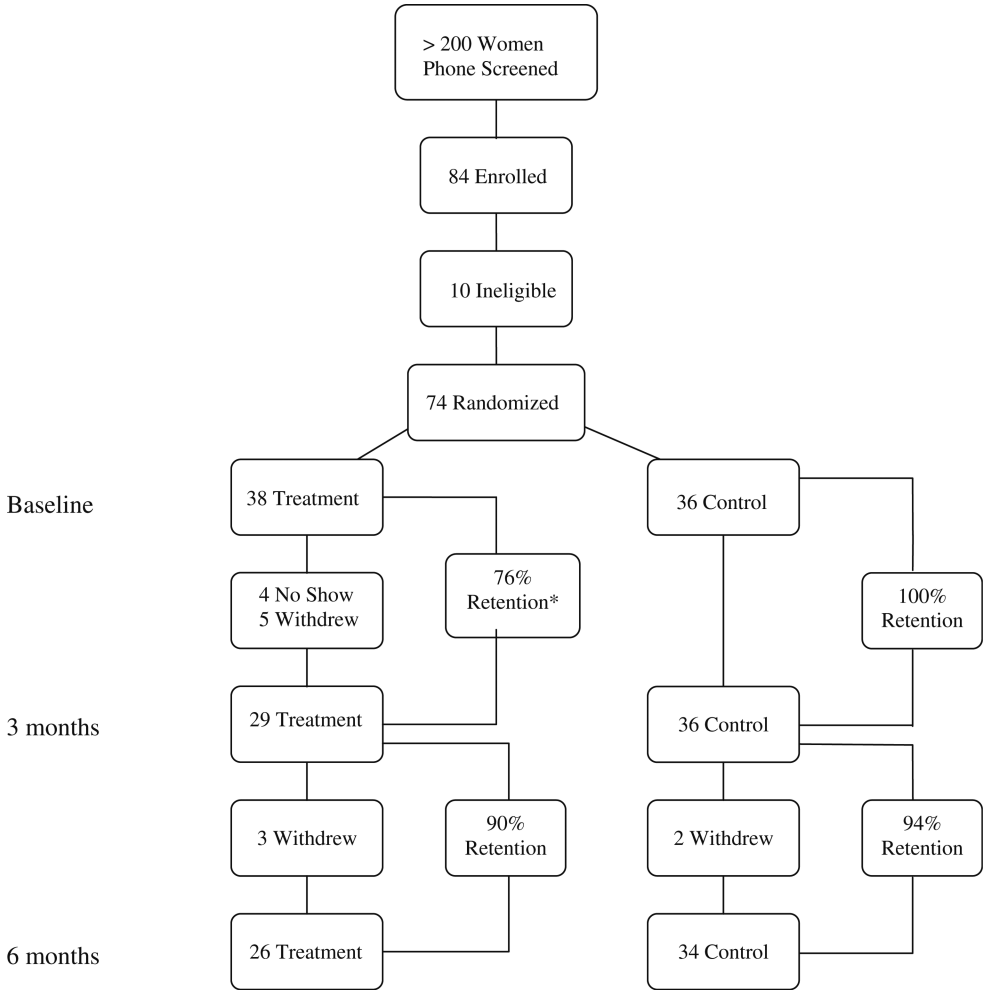

Fig. 2.

Recruitment and retention flow diagram. There were four women who never showed up for the first class or thereafter. For those who did show up (n=34), there was an 85 % retention from baseline to 3 months

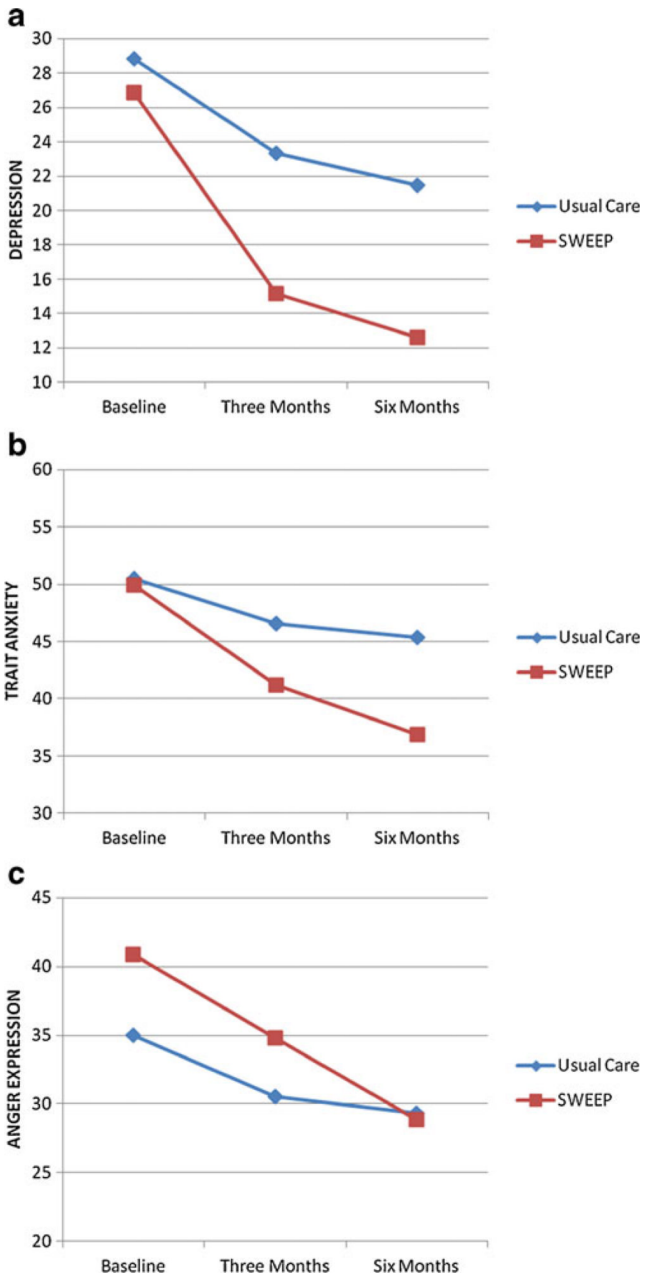

Fig. 3.

a Changes in depression as a function of time and treatment. **b** Changes in trait anxiety as a function of time and treatment. **c** Changes in anger expression as a function of time and treatment

Table 1

Content and personal projects for the SWEEP Program

Session no.	SWEEP content	Weekly projects in class and at home
1	Welcome to SWEEP; understanding how mood affects blood sugar; learning the symptoms of depression, anxiety, anger	SWEEP Journey-Welcome Rose Ceremony (class) Daily quick mood and blood sugar log (home)
2	Recognizing signs of stress, understanding how it affects blood sugar & self-care behaviors	Identify personal stressors (class) Practice stress relaxation CD (home)
3	Learning how depression creates negative thoughts and impacts self-care behaviors, understanding automatic thoughts and using a thought record	Helpful/unhelpful thought assessment (class) Begin thought record: identify the situation, feelings, and thoughts (home)
4	Celebration of halfway point; learning how to think differently and challenge automatic thoughts	Continue thought record and include evidence to support/not support automatic thoughts (home)
5	Identifying other methods to decrease negative thoughts and improve self-care behaviors (thought stopping, distraction, physical activity)	Practice thought stopping (class) Identify and schedule activities (e.g., walking) to decrease negative thoughts (home)
6	Understanding relationships and how they affect mood and self-care behaviors, learning how to communicate effectively	Video clip of poor communication impact on relationships and mood (class) Identify social circle of positive/negative relationships (home)
7	Learning how to respond differently and asking for what you need	Practice listening skills (class) Using “I” statements (home)
8	Putting it all together, reviewing skills learned, relapse of mood and behaviors	Identification of most helpful skills (class) Review “Quick mood and blood sugar logs” to assess for improvements (class)

Participants turn in the “Quick mood and blood sugar log” (Fig. 1) every week

Table 2

Baseline characteristics of participants

Variable	Treatment (*N*=38) Mean (SD)	Control (*N*=36) Mean (SD)
Age (years)	54.8 (8.8)	54.0 (8.4)
Race (%)		
White	63 %	69 %
Black	29 %	25 %
Hispanic	8%	6%
Weight (lbs)	229.1 (64.4)	226.9 (48.7)
Diabetes (years)	10.5 (8.2)	10.0 (6.5)
Mood outcomes		
Depression	27.7 (9.3)	28.9 (9.5)
Trait anxiety	51.6 (9.8)	50.4 (9.2)
State anxiety	45.8 (12.8)	47.9 (11.9)
Anger expression	40.6 (13.2)	34.7 (13.9)
Trait anger	19.8 (4.8)	18.6 (5.7)
State anger	18.7(6.5)	18.1 (5.2)
Glycemic control		
Glucose (mg/dl)	165.3 (71.1)	168.8 (74.9)
HBA1c (%)	7.8 (1.8)	7.9 (2.0)
Quality of life outcomes		
Life satisfaction		
Quality of life	15.0 (5.2)	15.5 (5.0)
Functional status		
Mental health	36.6 (10.0)	37.2 (10.9)
Physical health	38.0 (10.5)	41.4 (9.4)

There were no statistically significant differences between treatment and control groups for those randomized (38 vs. 36) and those who participated (34 vs. 36).

Table 3

Observed means and standard deviations (SD) of outcome measures per time point and group

Variables	SWEEP			Usual care		
Time	**Baseline (*n*=38) Mean (SD)**	**3 months (*n*=29) Mean (SD)**	**6 months (*n*=26) Mean (SD)**	**Baseline (*n*=36) Mean (SD)**	**3 months (*n*=36) Mean (SD)**	**6 months (*n*=34) Mean (SD)**
Mood outcomes						
Depression	27.7 (9.3)	15.2 (7.9)	12.6 (8.0)	28.9 (9.5)	23.1 (11.4)	21.5 (10.2)
Trait anxiety	51.6 (9.8)	40.9 (10.1)	36.9 (10.1)	50.4 (9.2)	46.1 (12.3)	45.3 (12.0)
State anxiety	45.8 (12.8)	38.8 (11.1)	35.7 (12.4)	47.9 (11.9)	43.2 (12.2)	43.6 (12.6)
Anger expression	40.6 (13.2)	34.9 (12.2)	28.9 (13.7)	34.7 (13.9)	30.3 (13.9)	29.6 (14.9)
Trait anger	19.8 (4.8)	17.1 (3.8)	16.4 (4.8)	18.6 (5.7)	17.5 (6.3)	16.1 (5.2)
State anger	18.7 (6.5)	17.8 (4.3)	16.9 (3.1)	18.1 (5.2)	17.9 (5.4)	18.2 (7.2)
Glycemic control						
Fasting glucose(mg/dl)	165.3 (71.1)	144.6 (44.0)	141.5 (47.3)	168.8 (74.9)	187.0 (78.9)	167.6 (77.6)
HBA1c (%)	7.8 (1.8)	7.4 (1.3)	7.4 (1.3)	7.9 (2.0)	7.8 (1.8)	7.8 (1.6)
Quality of life outcomes						
Life satisfaction						
Overall	15.0 (5.2)	18.2 (4.5)	19.7 (4.3)	15.5 (5.0)	17.1 (4.4)	17.5 (5.5)
Health	13.5 (5.4)	17.1 (4.6)	18.5 (5.0)	14.1 (5.5)	16.0 (4.7)	16.5 (5.8)
Psychological	15.2 (6.7)	19.1 (6.0)	21.5 (4.9)	14.6 (6.9)	16.9 (6.6)	17.2 (7.7)
Family	18.4 (6.9)	19.4 (6.4)	20.1 (6.2)	18.0 (6.6)	18.9 (6.1)	18.5 (6.7)
Socioeconomic	15.7 (6.2)	18.5 (5.0)	20.4 (4.8)	17.6 (5.5)	18.1 (5.0)	19.1 (5.7)
Functional status						
Mental	36.6 (9.9)	47.4 (10.8)	49.4 (8.5)	37.2 (10.9)	43.0 (9.8)	42.8 (12.4)
Physical	38.0 (10.5)	37.3 (13.6)	38.1 (12.9)	41.4 (9.4)	40.1 (9.7)	39.8 (9.7)