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Complement Ther Med. Author manuscript; available in PMC 2018 June 01.

Published in final edited form as:

Complement Ther Med. 2017 June ; 32: 66–74. doi:10.1016/j.ctim.2017.04.003.

Pilot Randomized Controlled Trial of a Mindfulness-Based Group Intervention in Adolescent Girls at Risk for Type 2 Diabetes with Depressive Symptoms

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Abstract

Objective—(1) Evaluate feasibility and acceptability of a mindfulness-based group in adolescent girls at-risk for type 2 diabetes (T2D) with depressive symptoms, and (2) compare efficacy of a mindfulness-based versus cognitive-behavioral group for decreasing depressive symptoms and improving insulin resistance.

Design and setting—Parallel-group, randomized controlled pilot trial conducted at a university.

Participants—Thirty-three girls 12-17y with overweight/obesity, family history of diabetes, and elevated depressive symptoms were randomized to a six-week mindfulness-based (n=17) or cognitive-behavioral program (n=16).

Interventions—Both interventions included six, one-hour weekly group sessions. The mindfulness-based program included guided mindfulness awareness practices. The cognitive-behavioral program involved cognitive restructuring and behavioral activation.

Main outcome measures—Adolescents were evaluated at baseline, post-intervention, and six-months. Feasibility/acceptability were measured by attendance and program ratings. Depressive

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ClinicalTrials.gov identifier: NCT02218138 clinicaltrials.gov

Conflict of interest: All authors report no conflicts of interest.

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symptoms were assessed by validated survey. Insulin resistance was determined from fasting insulin and glucose, and dual energy x-ray absorptiometry was used to assess body composition.

Results—Most adolescents attended ≥80% sessions (mindfulness:92% versus cognitive-behavioral:87%, p=1.00). Acceptability ratings were strong. At post-treatment and six-months, adolescents in the mindfulness condition had greater decreases in depressive symptoms than adolescents in the cognitive-behavioral condition (ps<.05). Compared to the cognitive-behavioral condition, adolescents in the mindfulness-based intervention also had greater decreases in insulin resistance and fasting insulin at post-treatment, adjusting for fat mass and other covariates (ps<.05).

Conclusions—A mindfulness-based intervention shows feasibility and acceptability in girls at-risk for T2D with depressive symptoms. Compared to a cognitive-behavioral program, after the intervention, adolescents who received mindfulness showed greater reductions in depressive symptoms and better insulin resistance.

Keywords

Adolescents; Depression; Insulin Resistance; Mindfulness; Type 2 Diabetes

1. Introduction

Type 2 diabetes (T2D) is a chronic disease that causes serious health problems.[1] T2D affects 40-50% of U.S. adults, with the highest estimates in historically disadvantaged racial/ethnic groups.[2] Racial/ethnic and socioeconomic health disparities are particularly apparent in youth-onset T2D, which is sharply on the rise.[3] Youth-onset T2D is twice as common in adolescent girls[3] and has been associated with an aggressive disease course, making effective prevention a high priority.[4]

Adolescent girls considered at-risk for developing T2D are overweight/obese (body mass index [BMI]≥85th percentile) and/or have a T2D family history.[5] Further, they often experience high psychosocial stress.[6] One out of five girls, in community samples, have elevated depressive symptoms,[7] with higher estimates (25-75%) in Black and Hispanic girls.[7] Starting at approximately 13 years of age, females develop higher rates of early-life and chronic depressive disorders as compared to males, a health disparity that persists throughout the lifespan.[8] In observational studies of youth and adults, depressive symptoms relate to worsening or maintenance of insulin resistance over time,[9–11] a key physiological precursor to T2D.[12] Likewise, depressive symptoms predict the development of youth- and adult-onset T2D,[13,14] accounting for obesity. While the explanatory mechanisms are poorly understood, it has been hypothesized that depressive symptoms promote stress-related behaviors and alter stress physiology, which in turn advance insulin resistance, independent of positive energy balance.[15]

Given the high psychosocial stress in adolescent girls at-risk for T2D, we anticipated that mindfulness-based stress reduction might be beneficial for decreasing depressive symptoms and ameliorating insulin resistance in this group. Mindfulness-based clinical interventions are designed to increase dispositional (stable) mindfulness, the propensity to bring voluntary

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attention to the present moment with a non-judgmental, accepting attitude.[16] In adults with type 2 or type 1 diabetes, mindfulness-based interventions decrease depressive and anxiety symptoms up to one-year later.[17-20] In some cases, mindfulness-based interventions have resulted in improved glycemic control[21,22] or blood pressure,[17,21,23] but other studies failed to find effects.[18-20] From a conceptual framework, mindfulness-based training theoretically may lead to improvements in metabolic and cardiovascular health through enhancing self-regulation.[24] Mindfulness-based practices are designed to foster awareness and attention to thoughts, emotions, and actions, promoting more effective self-regulation over a variety of factors critical for health, including stress response and lifestyle behaviors.[24]

Intervening with mindfulness during adolescence, prior to the onset of T2D, has not been evaluated for decreasing depressive symptoms and improving insulin resistance. Yet, adolescence is a sensitive, highly neuroplastic period for self-regulation, making it an optimal window in the lifespan for interventions designed to foster self-regulatory skills.[25] A series of randomized controlled trials (RCTs) demonstrated that breath awareness training lowered blood pressure compared to an active control in adolescents, including those at-risk for hypertension.[26] In other RCTs, mindfulness-based interventions demonstrated efficacy for decreasing depressive and anxiety symptoms in adolescents at-risk for, and with, diverse mental and behavioral health problems.[27-29] Despite support for feasibility and acceptability of mindfulness-based training among adolescents,[27-29] feasibility, acceptability, and potential utility of a mindfulness-based intervention for prevention of worsening insulin resistance in adolescents at-risk for T2D have not been evaluated. The purpose of this study was to determine feasibility and acceptability of a brief, mindfulness-based group program in adolescent girls at-risk for T2D. We focused on adolescent girls because of their higher risk, as compared to boys, for elevated depressive symptoms and youth-onset T2D.[3,8] Further, we sought to estimate the comparative efficacy of a mindfulness-based program relative to a cognitive-behavioral intervention. We selected a cognitive-behavioral intervention as the comparison condition, because cognitive-behavioral interventions demonstrate efficacy for decreasing depressive symptoms and preventing major depressive disorder (MDD) in adolescents.[30] In adults with T2D and MDD, cognitive-behavioral therapy has been shown to lessen depression, increase adherence, and improve glycemic control.[31]

2. Methods

2.1. Study population

The investigators developed materials to invite adolescent participation in a brief group intervention to lower T2D risk. Participants were recruited through flyers to schools and physicians, community postings, advertisements on e-mail listservs, and direct mailings to local-area homes. Inclusion criteria were: (i) female, (ii) age 12-17y, (iii) overweight/obesity (BMI≥85th percentile), (iv) parent-reported T2D, prediabetes, or gestational diabetes in ≥1 first-or second-degree relative, (v) good general health, and (vi) mild-to-moderate depressive symptoms (≥16 on the 20-item Center for Epidemiologic Studies-Depression Scale [CES-D]).[32] Exclusion criteria were: (i) major psychiatric disorder (e.g., MDD), (ii) major medical problem including T2D (fasting glucose level>126 mg/dL), (iii) medication use affecting

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insulin resistance or mood (e.g., insulin sensitizers, anti-depressants, stimulants), (iv) structured weight loss or psychotherapy, and (v) pregnancy.

Parents/guardians and adolescents provided written consent and assent, respectively. The Institutional Review Board of Colorado State University (CSU) approved all procedures. Adolescents were compensated for their time.

2.2. Study design

This study was a parallel-group, pilot RCT. Assessments were conducted in the Human Performance/Clinical Research Laboratory at CSU in Fort Collins, Colorado. Intervention sessions took place from March 2014-August 2015 in CSU's Center for Family and Couple Therapy. After a phone screen, prospective participants and parents/guardians attended an outpatient visit to determine eligibility, provide informed assent/consent, and collect baseline assessments. Following the collection of baseline assessments, eligible participants were randomized to either a six-week mindfulness-based or six-week cognitive-behavioral program. Randomization, stratified by age and race/ethnicity, was generated by an electronic program with permuted blocks, and participants were notified by telephone of their group assignment. Three cohorts were run in parallel, on separate days, during after-school or weekend hours, with 3-8 girls/group.

2.3. Mindfulness-based intervention

The mindfulness-based group intervention was based upon an adolescent mindfulness curriculum, Learning to BREATHE.[33] Adolescents met for six, one-hour sessions, once per week. In a preliminary study, Learning to BREATHE decreased depressive symptoms compared to an attention-matched comparison group in adolescents with academic problems.[28] Based upon mindfulness-based stress reduction,[34] Learning to BREATHE was created for adolescents by using developmentally appropriate interactive activities and guided discussions to teach standard mindfulness skills. Example mindfulness awareness activities include breath awareness, body scanning, mindful eating, sitting meditation, loving kindness practice, and mindful movement (yoga). Brief (~10 minutes/day) homework was assigned to help adolescents practice skills and apply them to daily life. Adolescents were given meditation audio-recordings, a yoga mat, meditation cushion, homework log, and worksheets. The group was led by a clinical psychologist and co-facilitated by one of two graduate students in marriage and family therapy. The psychologist attended a two-day training on Learning to BREATHE with the developer (PB). All facilitators received supervision on audio-recorded sessions and had an ongoing mindfulness practice.

2.4. Cognitive-behavioral intervention

Structurally equivalent to the Learning to BREATHE program, the cognitive-behavioral group was a manualized depression prevention, the Blues Program, consisting of one-hour sessions, once per week, for six weeks.[35,36] The program has demonstrated efficacy in decreasing depressive symptoms and reducing MDD incidence in adolescents compared to assessment-only and active controls, from six-months to two years following participation.[35,36] Sessions are interactive, activity-based, and include motivational enhancement. Content includes psycho-education, cognitive restructuring, pleasant

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activities, self-reinforcement, and coping skills. At all sessions, adolescents are assigned homework (e.g., daily mood journal, scheduling pleasant activities). They were provided with a homework log and worksheets. The groups were co-facilitated by the same clinical psychologist who led the mindfulness-based group to control for facilitator effects, and was co-facilitated by a counseling psychology graduate student. Our team has demonstrated adherence and competence in this program's administration.[37]

2.5. Outcomes overview

Attendance and facilitator/adolescent-rated homework completion were assessed throughout the intervention. Adolescents rated program acceptability at post-treatment, scheduled ~2 weeks after the intervention. All other measurements were collected at baseline, repeated at post-treatment, and again six-months after the intervention began. Phlebotomists were blinded to group allocation. Assessors of body measurements and psychosocial adjustment were not consistently blinded.

2.6. Feasibility/acceptability

We calculated total sessions attended, and evaluated ≥80% attendance (≥5 sessions). Facilitators rated if adolescents completed homework (yes/no) at the end of each session. Adolescents completed a daily electronic journal, accessible from a smart phone, tablet, or computer, after sessions one and four. Adolescents were instructed to complete the journal once/day for seven days before bed; they received a daily text reminder at ~9:00pm. Adolescents reported (yes/no) if they had completed homework that day. They also rated the helpfulness of the homework from *1=not at all* to *5=extremely*. At post-treatment, participants completed an adapted program acceptability questionnaire.[38] Seven items, rated on a five-point Likert scale, evaluated perceived comfort, support from facilitators and group members, and health benefits.

2.7. Measures

2.7.1. Mindfulness—Dispositional mindfulness was measured using the 15-item *Mindful Attention Awareness Scale (MAAS)*.[39] Participants read statements describing episodes of mindlessness (e.g. “I find myself doing things without paying attention”) and reported how frequently they typically had each experience from *1=almost always* to *6=almost never*. A mean score was calculated, with higher scores reflecting greater mindfulness. The MAAS has adequate test-retest reliability, high internal consistency, and multiple forms of validity in late adolescents and young adults.[39] Findings also support its reliability and validity in diverse adolescent samples.[40,41]

2.7.2. Depressive/anxiety symptoms and perceived stress—The CES-D was used to determine inclusion (total score≥16) and to provide a continuous measure of depressive symptoms.[32] The CES-D has good psychometric properties and has been used extensively in adolescents.[42] To evaluate a psychiatric disorder that would warrant study exclusion, the reliable and valid Schedule for Affective Disorders and Schizophrenia for School-Age Children (K-SADS)[43,44] was administered to adolescents by a trained interviewer. The K-SADS health history section was administered to parents to assess diabetes family history and an adolescent medical problem that would necessitate exclusion. Participants completed

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the psychometrically sound, 20-item State-Trait Inventory for Children-Trait Version.[45] The total score is calculated as the sum of all items (range: 20-60). Global perceived stress was assessed with the 14-item Perceived Stress Scale, which has demonstrated reliability and validity in late adolescents.[46] The total, sum score ranges from 14-70.

2.7.3. Insulin resistance—After a 10-hour overnight fast, participants provided fasting venous blood samples for determination of serum insulin and glucose concentrations. Insulin assays were performed by the University of Colorado, Denver's Clinical and Translational Research Center core laboratory. Serum insulin was analyzed with radioimmunoassay (Millipore, Billerica, Massachusetts). Glucose was determined immediately using an automated device (2300 STAT Plus Glucose Lactate Analyser, YSI Inc., Yellow Springs, Ohio). Insulin resistance was estimated using the homeostasis model assessment of insulin resistance (HOMA-IR), calculated as: (fasting insulin [μU/mL] × fasting glucose [mmol/L])/ 22.5.

2.7.4. Body composition/puberty—Participants removed their shoes and outer clothing to be weighed, in the fasted state, to the nearest 0.1 kg using a calibrated scale. Height was determined with a calibrated wall stadiometer from the average of three measurements recorded to the nearest millimeter. BMI and BMIz were calculated according to CDC 2000 standards.[47] Total fat and fat free mass (kg) were derived from dual-energy x-ray absorptiometry (DEXA; Hologic, DiscoveryW, QDR Series, Bedford, MA, USA). Breast development was assessed using self-reported Tanner stage.[48]

2.8. Analytic plan

Analyses were performed using SPSS 24.0 (IBM Corp, 2016). Outliers (3% of all data points) were adjusted to 1.5 times the interquartile range below or above the 25th or 75th percentile,[49] resulting in satisfactory skew and kurtosis. We selected this approach *a priori* because it minimizes outliers' influence on the characteristics of the distribution, minimally changes the distribution overall, and avoids problems with eliminating outliers altogether.[49] Independent t-tests and χ^2 evaluated baseline differences between adolescents in the mindfulness-based versus cognitive-behavioral conditions. Median session attendance and percent attending ≥80% sessions were compared between conditions with non-parametric and χ^2, respectively. Independent t-tests and χ^2 compared acceptability and homework completion. Differences between conditions (mindfulness vs. cognitive-behavioral) in baseline to post-intervention and baseline to six-month changes in psychosocial and metabolic outcomes were tested with ANCOVA. Covariates were baseline age, weight status, puberty, race/ethnicity, the respective baseline level of each outcome, baseline fat mass, and post-treatment or six-month change in fat mass from baseline. For these analyses, missing data were handled with multiple imputation using pooled estimates from 20 imputed data sets. The imputation model included group condition and attendance, race/ethnicity, baseline age, weight status, and lean mass, baseline and post-treatment/six-month changes in BMI, fat mass, mindfulness, depressive/anxiety symptoms, perceived stress, insulin resistance, and fasting insulin/glucose. Findings with multiply imputed data were very similar to findings obtained from complete data; thus, only the former are shown.

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Effects were considered significant at $p<.05$. Given the pilot nature of the study, we also describe trend-level associations, $p<.10$. Effect sizes were estimated with Cohen's *d*, interpreted as small (0.2), medium (0.5), or large (0.8).

3. Results

3.1. Participant flow/characteristics

Of 143 families contacted, we conducted screening visits with 38 (27%; Figure 1). Of those, 33 (87%) were eligible and randomized to the mindfulness-based ($n=17$) or cognitive-behavioral conditions ($n=16$). Adolescents on average (SD) were 15.01y (1.68) in the mindfulness condition and 14.97y (1.75) in the cognitive-behavioral condition ($p=.95$). By design, race/ethnicity did not differ ($\chi^2=.49$, $p=.78$). Most adolescents were non-Hispanic White (mindfulness versus cognitive-behavioral: 70.6% versus 68.8%); the remaining participants were Hispanic (23.5% versus 18.8%) or Native American/American Indian (5.9% versus 12.5%).

Table 1 displays descriptive characteristics by condition. There tended to be more adolescents with obesity in the mindfulness (70.6%) than in the cognitive-behavioral intervention (37.5%, $p=.08$). Conditions did not significantly differ on any other baseline characteristic ($ps>.10$).

3.2. Attendance/homework

Four adolescents in the mindfulness-based and one in the cognitive-behavioral condition withdrew after randomization, but before the intervention started: one moved out of state and the others reported scheduling conflicts. Median attendance was six sessions in mindfulness and five sessions in the cognitive-behavioral intervention, $p=.06$. Percentage who attended ≥80% sessions was similar (92% versus 87%, $p=1.00$).

Based upon facilitator ratings, most adolescents completed homework at session two (mindfulness versus cognitive-behavioral: 77% versus 87%, $p=.64$), session three (77% versus 93%, $p=.31$), and session 5 (85% versus 60%, $p=.22$). At session four, more adolescents in the mindfulness intervention completed homework (100%) compared to the cognitive-behavioral condition (67%, $p=.04$). At session six, more adolescents in the cognitive-behavioral condition were perceived by facilitators to complete homework (100%) compared to adolescents in mindfulness (31%, $p<.001$). For descriptive purposes, Figure 2 displays facilitator ratings across cohorts. There was a pattern of increased homework completion across mindfulness cohorts. We adapted the manual, following cohort one, to more clearly assign and review homework.

Of adolescents who attended ≥1 session, 11 (84.6%) in the mindfulness and 14 (93.3%) in the cognitive-behavioral condition reported homework completion on an electronic journal after session one ($p=.58$). Adolescents in the mindfulness condition completed ratings a median of 6.5/7 days; adolescents in the cognitive-behavioral condition completed ratings 5/7 days ($p=.69$). Based on adolescents' ratings, homework completion after session one was 82.6% in the mindfulness-based and 79.1% in the cognitive-behavioral condition ($p=.75$).

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Adolescents reported that homework was moderately helpful (2.62 (1.00) versus 2.83 (.84), p=.48).

Following session four, 9 (69.2%) adolescents in the mindfulness-based intervention and 11 (73.3%) in the cognitive-behavioral intervention reported homework completion (p=1.00). Median days completed did not differ between mindfulness (4 days) and cognitive-behavioral conditions (4 days; p=1.00). Based on daily ratings, homework completion after session four was 81.9% in mindfulness and 92.3% in the cognitive-behavioral condition (p=.24). Adolescents reported that homework after session four was moderately helpful (2.71 (1.00) versus 2.95 (.97), p=.61).

Those adolescents who did or did not complete journal ratings after sessions one and four did not differ on any baseline characteristic (ps>.19).

3.3. Acceptability

There were no differences in acceptability ratings between conditions (ps>.10; Table 2). Adolescents perceived strong support from facilitators, highly related to other group members, and viewed their mood as improved following both conditions. One hundred percent in mindfulness and 93% in the cognitive-behavioral condition stated the group addressed their concerns (p=1.00); 92% in mindfulness and 100% in the cognitive-behavioral condition perceived the group would be helpful to others like them (p=.48).

3.4. Mindfulness/psychological outcomes

A summary of results from multiple imputation is presented in Table 3. Accounting for all pre-specified covariates, mindfulness increased in both conditions with no between-group differences in changes from baseline to post-intervention (Cohen's d=.41) or six-month follow-up (d=.06; ps>.29; Figure 3a). Depressive symptoms decreased more in the mindfulness condition at post-treatment (d=.56), and this difference persisted at six months (d=.69; Figure 3b). Three adolescents in the cognitive-behavioral condition developed criteria for MDD during the follow-up, and no adolescents did so in mindfulness (p=.24). Accounting for all covariates, anxiety symptoms and perceived stress decreased, with no between-group differences (ps>.13; Figures 3c/d).

3.5. Insulin resistance

Accounting for all covariates, adolescents in the mindfulness-based intervention had greater reductions from baseline to post-treatment in insulin resistance compared to the cognitive-behavioral intervention (d=.93, p=.02; Figure 4a). Six-month change in insulin resistance did not differ (d=.30; p=.48).

Compared to the cognitive-behavioral intervention, adolescents randomized to mindfulness had greater decreases in fasting insulin at post-treatment (d=.78; p=.04; Figure 4b). There were no differences in fasting insulin at six-months (d=.31; p=.34) or fasting glucose at post-treatment (d=.30; p=.34) or six-months (d=.40; p=.21; Figure 4c).

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4. Discussion

This RCT piloted the feasibility and acceptability of a mindfulness-based group program in adolescent girls at-risk for T2D with depressive symptoms. Further, we sought to estimate the effects of the mindfulness intervention on decreasing depressive symptoms and improving insulin resistance compared to a cognitive-behavioral depression prevention program. Across a variety of indices, we found support for feasibility and acceptability, including potential distinct advantages of mindfulness over the cognitive-behavioral program.

First, regarding intervention implementation, mindfulness program attendance was strong and equal to the cognitive-behavioral program. Participants rated the climate and facilitators positively and perceived that the programs benefited their health. In the mindfulness-based intervention, homework completion was generally high, suggesting that adolescents were frequently practicing mindfulness skills in their daily lives. Over 80% who participated in mindfulness reported daily home practice, and 77% or more were perceived by facilitators to be completing homework. Of note, homework included formal mindfulness awareness practice (e.g., guided meditation audio-recordings), but also mindfulness in daily life (e.g., a mindful breathe or quick body scan). Homework completion was lower between sessions five and six; only 33% in mindfulness completed homework according to facilitators. When analyzed by cohort, we determined that this was largely driven by the initial cohort. In subsequent cohorts, we saw improved homework completion at this interval and throughout the program by providing more specific instructions and querying about assigned homework at the outset of sessions. High rates of homework completion are promising, given some data in adults suggesting that daily mindfulness practice may be related to greater benefits during mindfulness-based stress reduction.[50]

The second aim was to estimate the comparative efficacy of the mindfulness-based intervention for decreasing depression and reducing insulin resistance. More significant decreases in depressive symptoms were observed after mindfulness-based treatment than cognitive-behavioral treatment, and this effect was sustained six-months later. No adolescent in mindfulness developed MDD within six-months, and only a few in the cognitive-behavioral intervention became clinically depressed. Alternatively, we observed improvements in anxiety symptoms and perceived stress in both conditions, with no between-group differences, suggesting that mindfulness may be just as efficacious for addressing elevated anxiety symptoms and stress in girls at-risk for T2D. These findings are consistent with previous RCTs, which observed significant reductions in depressive symptoms following mindfulness-based interventions among clinical and psychologically at-risk adolescents.[27-29] While very few studies have directly compared mindfulness and cognitive-behavioral interventions, and none to our knowledge in adolescents, some data suggest that mindfulness-based interventions more effectively address depressive symptoms in adults with more severe baseline depressive symptomatology.[51,52] In addition, we observed a greater decrease in insulin resistance and fasting insulin directly after the mindfulness-based program. The comparative effect sizes for these differences were moderate. These findings raise the possibility that mindfulness training offers unique benefits for decreasing depressive symptoms and improving hyperinsulinemia and insulin

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resistance, early detectable precursors to T2D, in adolescents at-risk for T2D. Some previous research has found that mindfulness-based stress reduction improves glycemic control in adults with diabetes,[21,22] although results have been mixed.[18-20]

This study cannot determine the possible explanatory mechanisms for the acute intervention effects on depressive symptoms and insulin resistance. Theoretically, the major distinction between mindfulness-based and cognitive-behavioral approaches is mindfulness training's systematic cultivation of attention to the body. Breath awareness, attention to where/how unpleasant emotions and stress manifest in the body, and how to use mindfulness to work with unpleasant feelings and physical sensations are unique elements of mindfulness training.[53] Such attention may cultivate greater sensitivity to interoceptive stress-related cues, translating into less depressive symptoms, improved stress-related physiology and, in turn, ameliorating insulin resistance.[54] Nonetheless, it is noteworthy that dispositional mindfulness improved after mindfulness-based and cognitive-behavioral training. Dispositional mindfulness, as assessed with the MAAS, evaluates attention to thoughts and feelings, a focus of both programs. In future studies, it would be beneficial to include objective mindfulness measures and to evaluate stress physiology as a potential mechanism.

The current pilot RCT was intended to evaluate feasibility and acceptability. The study was not powered to evaluate comparative effects of mindfulness versus cognitive-behavioral interventions on psychological or insulin outcomes. Any observed effects must be considered preliminary because of the inherent imprecision in small data samples.[55] Other limitations include the use of fasting measures of insulin resistance, as opposed to more validated oral glucose tolerance or hyperinsulinemic-euglycemic clamp-derived assessments. Due to resources, puberty was self-reported as opposed to being determined from physical examination. Likewise, assessors of body measurements and psychosocial adjustment were not consistently blinded to group allocation. While a study strength was homework evaluation using facilitator and participant reports, not all adolescents completed journals, which may have resulted in overestimation of homework completion. In the future, offering graded incentives for journal completion may increase compliance. Generalizability is limited to girls jointly at-risk for T2D and depression. Characteristic of Northern Colorado, the sample was primarily White, with limited representation of diverse racial/ethnic groups.

Study strengths include the RCT design evaluating a novel intervention approach. A major advantage of the active control comparison condition is that the observed benefits to depression and insulin were in contrast to a supported intervention. To our knowledge, this is the first study to compare a mindfulness-based program in adolescents to an active intervention comparison. Additional strengths include the use of well-validated and multi-modal measures, good retention through six-months, and the innovative, coordinated prevention of two major public healthcare problems, T2D and depression. Results support feasibility and acceptability of mindfulness training in adolescents at-risk for T2D with depressive symptoms, raise the possibility of unique benefits to psychological health and insulin resistance, and warrant the adequately-powered evaluation of a mindfulness-based intervention for T2D prevention in adolescents with depressive symptoms.

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Acknowledgments

Funding: This study was supported by R00HD069516 from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development with supplemental support from the Colorado School of Public Health.

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Highlights

- A mindfulness-based group was feasible and acceptable to adolescent girls at-risk for type 2 diabetes with depressive symptoms
- Adolescents in the mindfulness-based group had greater decreases in depressive symptoms than adolescents in the cognitive-behavioral group at post-treatment and six-months
- Adolescents in the mindfulness-based group had greater decreases in insulin resistance and fasting insulin at post-treatment than adolescents in the cognitive-behavioral group

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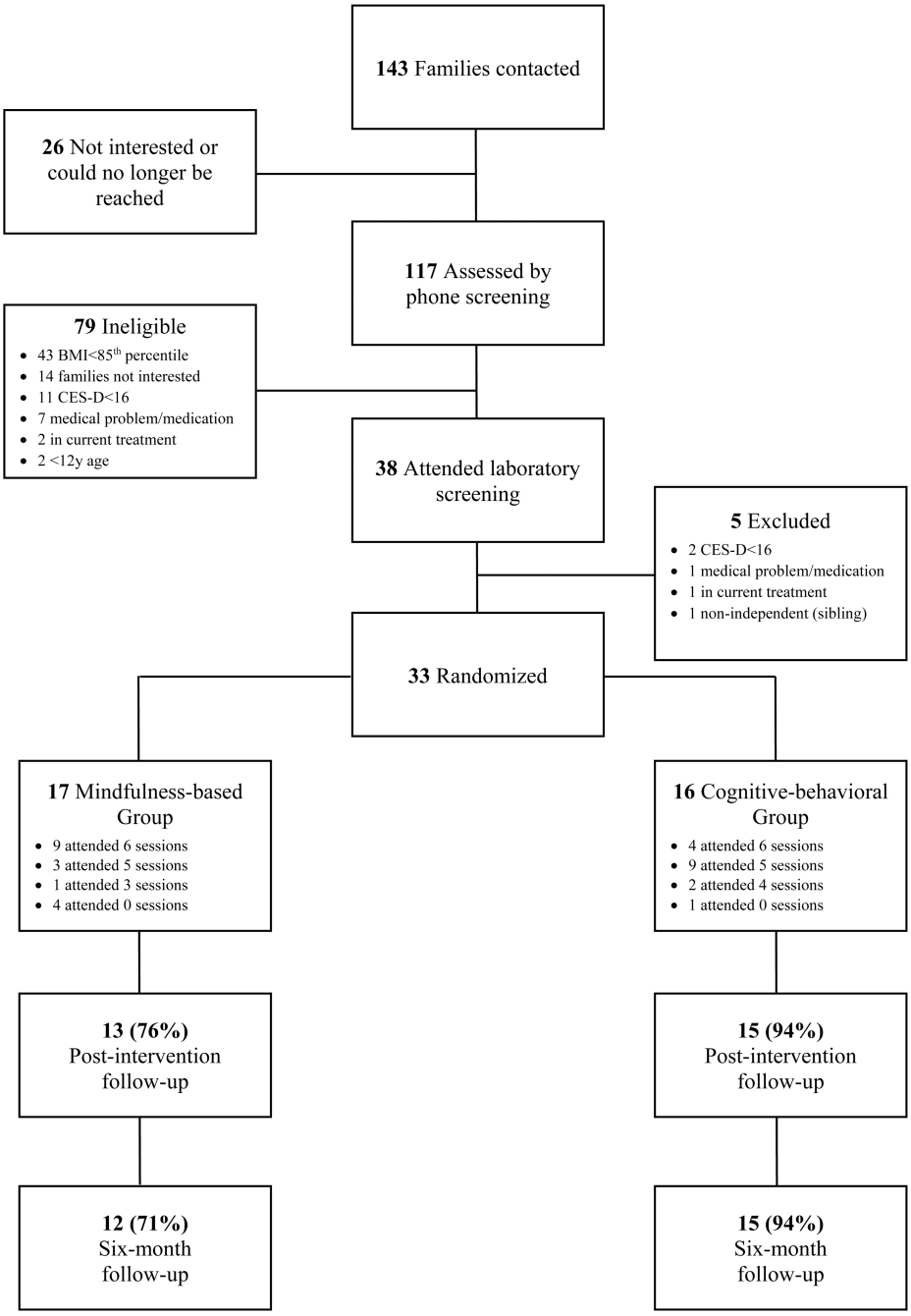

Figure 1. Study flow

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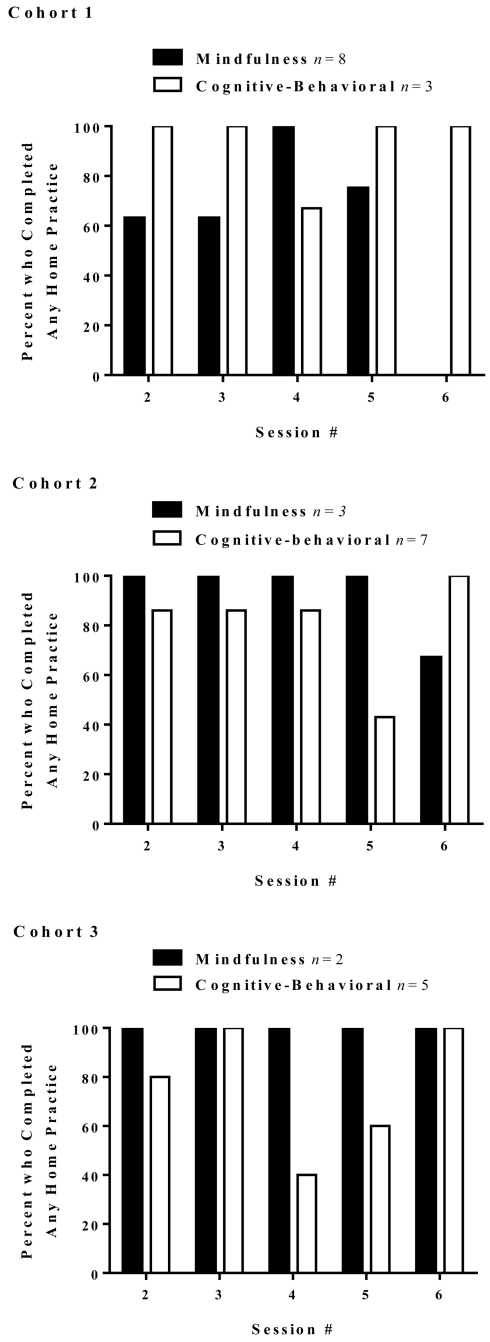

Figure 2. Homework completion by each cohort of mindfulness-based and cognitive-behavioral groups based upon facilitator ratings

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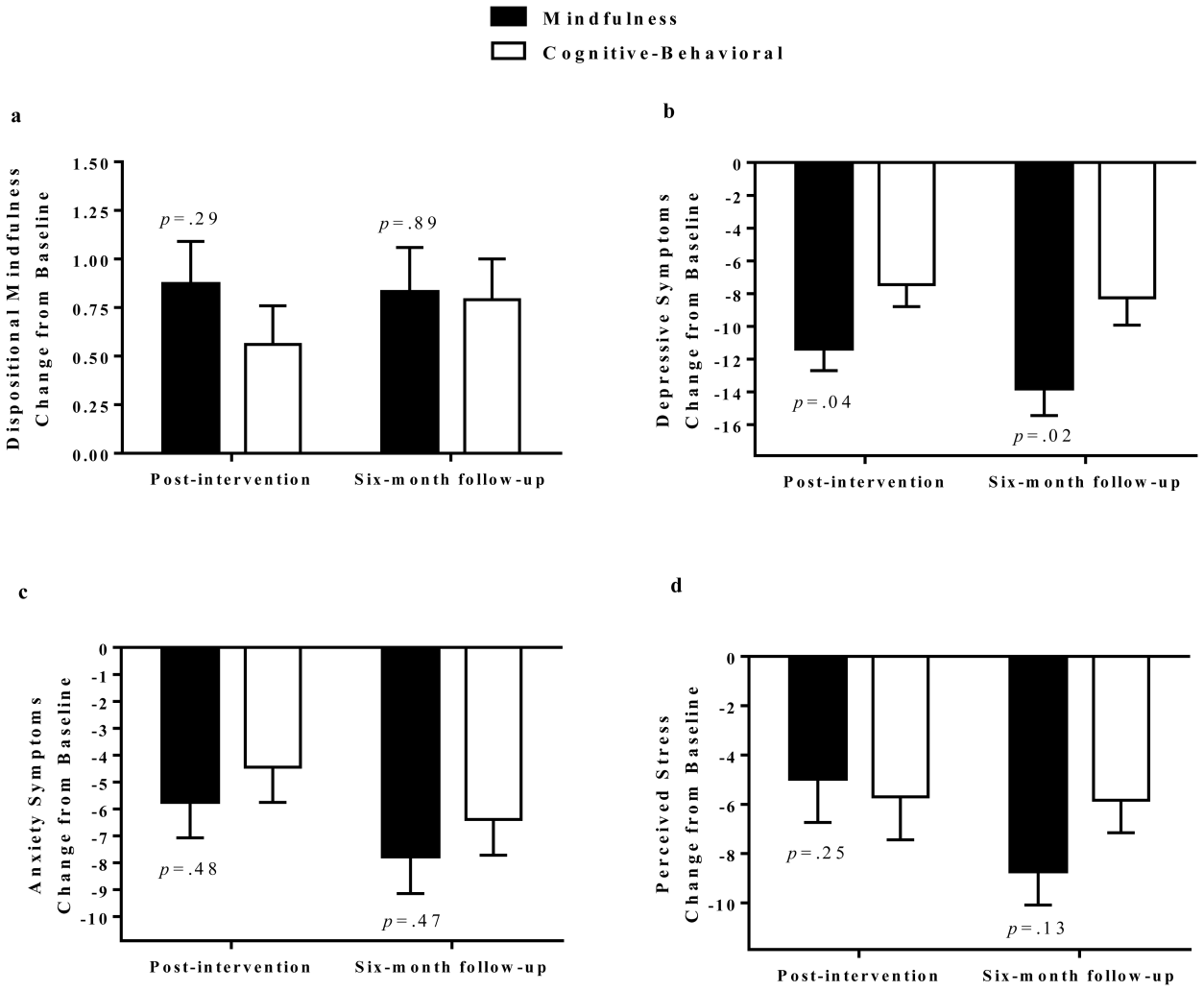

Figure 3.

Changes in (a) dispositional mindfulness, (b) depressive symptoms, (c) anxiety symptoms, and (d) perceived stress by mindfulness-based group (n=17) and cognitive-behavioral group (n=16). Estimates are derived from multiply imputed data and are accounting for baseline level of the outcome, baseline age, baseline puberty, baseline obesity, race/ethnicity, and baseline fat mass and change in fat mass.

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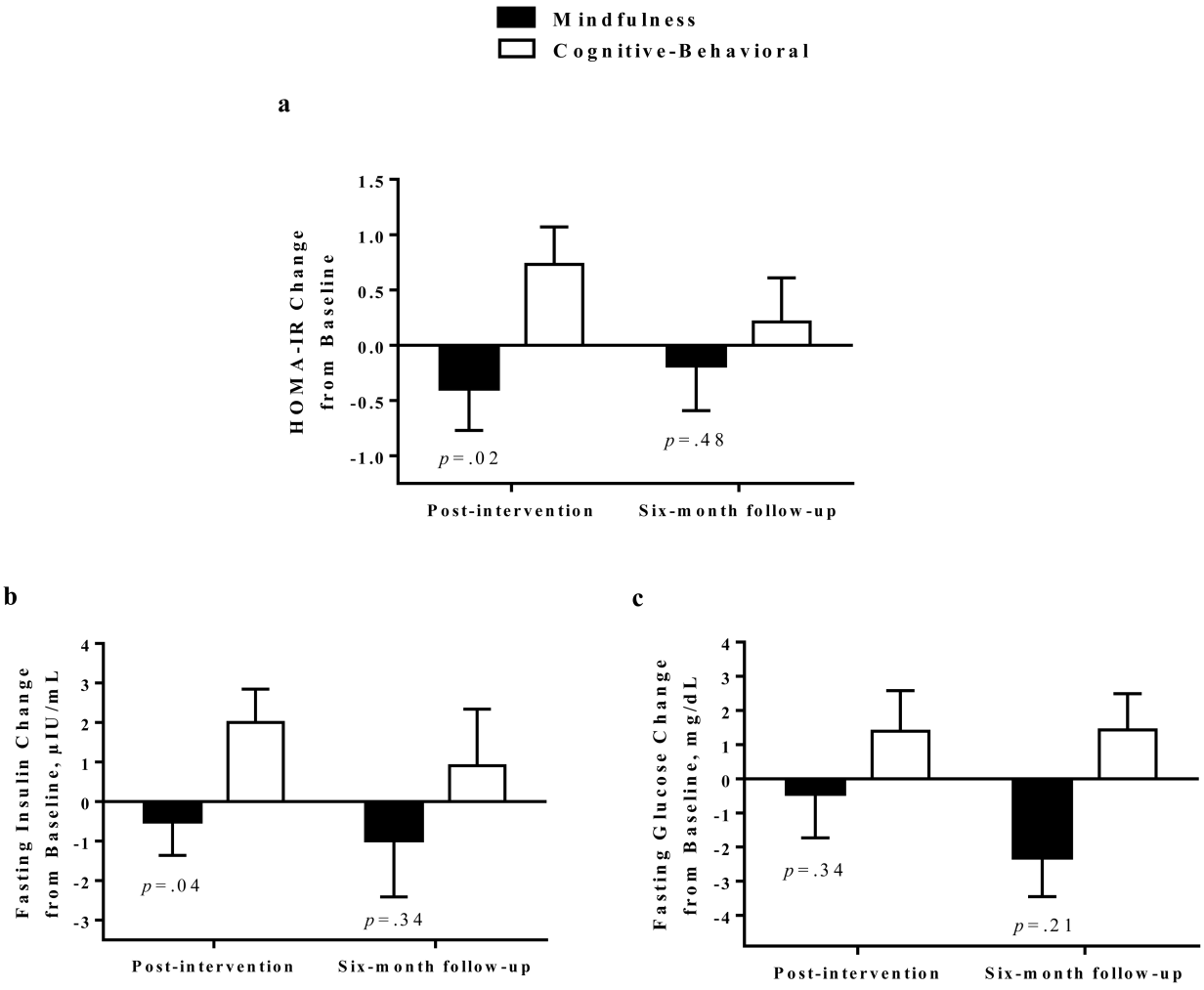

Figure 4.

Changes in (a) homeostasis model assessment of insulin resistance (HOMA-IR), (b) fasting insulin, and (c) fasting glucose by mindfulness-based group (n=17) and cognitive-behavioral group (n=16). Estimates are derived from multiply imputed data and are accounting for baseline level of the outcome, baseline age, baseline puberty, baseline obesity, race/ethnicity, and baseline fat mass and change in fat mass.

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Table 1

Descriptive characteristics of adolescents who participated in the mindfulness-based group and cognitive-behavioral group at baseline, post-intervention, and six-month follow-up

	Mindfulness-based Group			Cognitive-behavioral Group		
	Baseline	**Post-intervention**	**Six-month Follow-up**	**Baseline**	**Post-intervention**	**Six-month Follow-up**
Age, y	15.01 (1.68)	--	--	14.97 (1.75)	--	--
BMI, kg/m^2	30.48 (5.21)	30.78 (5.14)	31.19 (6.02)	29.19 (6.95)	29.75 (6.60)	29.14 (6.87)
BMI, percentile	94.94 (3.45)	95.92 (2.36)	94.83 (3.93)	92.75 (4.65)	93.67 (5.12)	90.60 (8.10)
Body fat mass, %	45.06 (5.59)	44.76 (5.14)	45.22 (5.05)	42.86 (5.10)	41.76 (5.17)	41.64 (5.24)
Body lean mass, kg	43.02 (8.55)	43.01 (7.41)	43.54 (8.72)	41.93 (8.53)	44.13 (8.59)	43.45 (8.10)
Mindfulness	3.47 (.93)	4.29 (.83)	4.44 (.88)	3.33 (.83)	3.85 (.88)	4.14 (.82)
Depressive symptoms	26.87 (6.01)	16.31 (4.71)	13.50 (7.95)	23.30 (6.21)	17.93 (7.79)	15.73 (7.63)
Anxiety symptoms	44.00 (6.95)	39.92 (6.86)	37.00 (8.29)	42.63 (5.33)	39.80 (7.34)	36.87 (7.11)
Perceived stress	46.29 (5.85)	41.46 (7.56)	38.00 (8.09)	44.63 (5.10)	39.00 (7.18)	39.73 (6.30)
Fasting insulin, uIU/mL	14.19 (7.32)	11.27 (4.92)	12.55 (6.70)	11.83 (7.75)	15.64 (13.96)	12.09 (8.97)
Fasting glucose, mg/dL	78.79 (6.21)	75.58 (11.56)	77.11 (6.95)	76.63 (6.51)	78.46 (9.50)	79.24 (4.77)
Insulin resistance	2.82 (1.41)	2.13 (1.08)	2.40 (1.29)	2.19 (1.36)	3.21 (3.45)	2.31 (1.70)

Values displayed are unadjusted means (standard deviations). Dispositional mindfulness was assessed with the average total score of the Mindful Attention Awareness Scale (MAAS); Depressive symptoms were assessed with the total summed score of the Center for Epidemiologic Studies-Depression Scale (CES-D); Anxiety symptoms were assessed with the total summed score of the State Trait Anxiety Inventory for Children-Trait Version (STAI-C); Perceived stress was assessed with the total summed score of the Perceived Stress Scale (PSS); Insulin resistance was calculated as the homeostasis-model assessment of insulin resistance (HOMA-IR).

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Table 2

Program acceptability ratings of adolescents who participated in the mindfulness-based group and cognitive-behavioral group

Item	Mindfulness-based Group	Cognitive-behavioral Group	*p*
	Mean (SD)		
Felt comfortable to open up	2.92 (1.19)	3.60 (.91)	.10
Group leaders were helpful	4.31 (.63)	4.27 (.88)	.89
Felt supported by group leaders	4.31 (.63)	4.33 (.62)	.91
Enjoyed coming to sessions	3.77 (.73)	3.53 (.64)	.37
Related to other group members	4.15 (.80)	4.13 (.64)	.94
Mood improved compared to before group	4.23 (1.01)	4.07 (.59)	.61
Feel healthier compared to before group	3.69 (.48)	3.80 (.56)	.59
	% (*n*)		
Addressed my concerns (yes)	100 (13)	93 (14)	1.00
Group would help others like me (yes)	92 (12)	100 (14)	.48

Continuous items were rated on a Likert scale from 1 to 5, with 1 representing the poorest response and 5 representing the most positive response; *n*=13 in the mindfulness-based group and *n*=15 in the cognitive-behavioral group completed program acceptability ratings.

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Table 3

Summary of group condition effects on changes in post-treatment and six-month outcomes from baseline

	Post-Treatment Change				Six-Month Change			
	Mindfulness	**Cognitive-behavioral**	**Group Effect‡**	***p***	**Mindfulness**	**Cognitive-behavioral**	**Group Effect‡**	***p***
Mindfulness	.87 (.22)	.56 (.20)	-.27, .89	.29	.83 (.23)	.79 (.21)	-.56, .65	.89
Depressive symptoms	-11.34 (1.36)	-7.45 (1.35)	-7.63, -.16	.04	-13.77 (1.68)	-8.25 (1.67)	-10.14, -.91	.02
Anxiety symptoms	-5.73 (1.34)	-4.45 (1.30)	-4.83, 2.27	.48	-7.75 (1.39)	-6.39 (1.33)	-5.03, 2.32	.47
Perceived stress	-4.95 (1.79)	-5.70 (1.74)	-4.05, 5.54	.76	-8.71 (1.38)	-5.84 (1.31)	-6.52, .79	.13
Fasting insulin, uIU/mL	-.50 (.86)	2.00 (.85)	-4.85, -.16	.04	-.97 (1.44)	.91 (1.43)	-5.70, 1.95	.34
Fasting glucose, mg/dL	1.11 (1.73)	1.13 (1.61)	-6.81, 2.33	.34	.51 (1.29)	2.72 (1.20)	-5.66, 1.25	.21
Insulin resistance	-.39 (.38)	.73 (.34)	-2.09, -.15	.02	-.18 (.41)	.21 (.40)	-1.47, .69	.48

‡95% CI for mindfulness-based group versus cognitive-behavioral group difference. Values displayed for mindfulness and cognitive-behavioral group conditions are means (standard errors) derived from multiply imputed data. All estimates are adjusted for baseline age, weight status, puberty, race/ethnicity, the respective baseline level of each outcome, baseline fat mass, and post-treatment or six-month change in fat mass from baseline. Dispositional mindfulness was assessed with the average total score of the Mindful Attention Awareness Scale (MAAS); Depressive symptoms were assessed with the total summed score of the Center for Epidemiologic Studies-Depression Scale (CES-D); Anxiety symptoms were assessed with the total summed score of the State Trait Anxiety Inventory for Children-Trait Version (STAI-C); Perceived stress was assessed with the total summed score of the Perceived Stress Scale (PSS); Insulin resistance was calculated as the homeostasis-model assessment of insulin resistance (HOMA-IR).