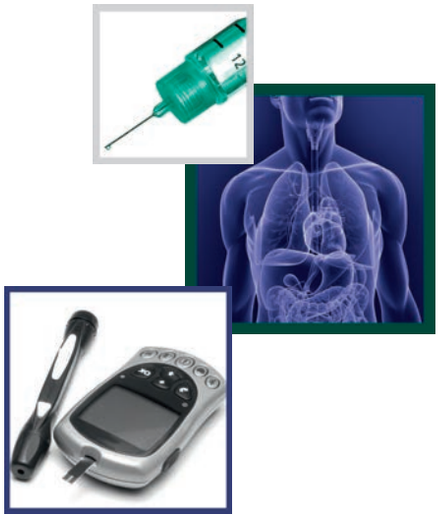
RESEARCH ARTICLE



Cognitive–behavioral therapy for adolescents with Type 1 diabetes and subclinical depressive symptoms

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Practice Points

- Adolescents with Type 1 diabetes and depressive symptoms are at an increased risk of poorer self-management and glycemic control.
- Cognitive–behavioral therapy (CBT) has been shown to effectively reduce depressive symptoms in adults with Type 1 and 2 diabetes and healthy adolescents.
- Nine adolescents (aged 13–18 years) with Type 1 diabetes and subclinical depressive symptoms participated in a 12-session individual CBT intervention.
- Adolescents in this study demonstrated a decrease in depressive symptoms following CBT.
- Adolescents also reported improvements in diabetes self-management following intervention completion.
- CBT may be an effective intervention for reducing depressive symptoms in adolescents with Type 1 diabetes.
- Improvements in depressive symptoms may also result in improvements in diabetes self-management and, subsequently, HbA1c.
- Randomized controlled trials examining the impact of CBT on depressive symptoms and diabetes self-management for adolescents with Type 1 diabetes are warranted.
- Future research should include an examination of potential mediating factors and cost–effectiveness.

SUMMARY **Aims:** The purpose of this study was to adapt and pilot an evidence-based individual cognitive–behavioral therapy (CBT) intervention to reduce depressive symptoms in adolescents with Type 1 diabetes and subclinical depressive symptoms, a group at increased risk of poor self-management and glycemic control. **Materials & methods:** Nine adolescents (aged 13–18 years) participated in a 12-session individual CBT intervention. Participants and their caregivers completed measures of depressive symptoms and diabetes

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management pre- and post-intervention. Blood glucose monitoring frequency and HbA1c were obtained via chart review. **Results:** Paired-samples t-tests indicated improvements in depressive symptoms, measured by adolescent (t[8] = 5.38; p = 0.0004; Cohen's d = 1.59) and caregiver report (t[8] = 2.50; p = 0.04; Cohen's d = 0.66) and diabetes self-management, measured by adolescent report (t[8] = -3.24; p = 0.01; Cohen's d = -0.98) following intervention completion. **Conclusion:** CBT is a promising intervention for adolescents with Type 1 diabetes and subclinical depressive symptoms.

Type 1 diabetes and its management serve as risk factors for the development of depressive symptoms [1,2]. Estimates of elevated depressive symptoms in adolescents with Type 1 diabetes approach 25% [3–6]. When present, depressive symptoms place adolescents with Type 1 diabetes at higher risk for poorer self-management [7–9] and glycemic control [5,10,11], and, subsequently, higher risk of complications [9] and hospitalizations [6]. Therefore, the combination of depressive symptoms and Type 1 diabetes presents a significant concern for the patients, their families, and the providers caring for them [9].

It has been hypothesized that the relationship between depressive symptoms and self-management behaviors may be accounted for by the negative attributions, diminished ability to concentrate, and lower self-efficacy associated with depressive symptoms [12]. When depressed, adolescents with Type 1 diabetes may have negative attributions, such as 'this is not going to help me feel better' or 'what's the point?', which prevent them from initiating tasks for self-management. Furthermore, background depressive symptoms may lead individuals to lack the energy, motivation, or concentration required to carry out self-management tasks [12]. When diabetes management is compromised by depressive symptoms, glycemic control subsequently suffers [13].

Cognitive–behavioral therapy for reduction of depressive symptoms

For these reasons, interventions targeting depressive symptoms in this population are greatly needed. Studies of adults with Type 1 diabetes [14] and Type 2 diabetes [15] have begun to suggest that cognitive–behavioral therapy (CBT) effectively reduces depressive symptoms and improves diabetes self-management [16]. Currently, however, limited evidence exists regarding the efficacy of interventions for adolescents with Type 1 diabetes and depression [17]. The only study examining CBT for depression in adolescents with Type 1 diabetes found a reduction in self-reported depressive symptoms in Puerto Rican adolescents completing group CBT [18]. Treatment for medically well adolescents with depression, however, has been closely examined, and psychotherapies, including cognitive change components (i.e., altering unrealistic, negative cognitions), have received some of the strongest support. Results of a recent meta-analysis of psychotherapies for the treatment of depression in adolescents indicated that psychotherapies, including cognitive-change components, demonstrated an effect size of 0.35 [19]. One of the most well-known interventions for depression including cognitive-change components is the manualized treatment created by the Treatment for Adolescents with Depression (TADS) team [20]. This skills-oriented intervention was developed based on the theory that depressive thought patterns and a lack of positively reinforcing behaviors cause or maintain depression [20].

While CBT is an effective intervention for many individuals, the TADS team also found that as many as half of adolescents do not respond to treatment [20]. Adolescents with higher levels of depressive symptoms and a longer duration of depressive symptoms are less likely to respond to CBT [21,22]. In an attempt to further increase the efficacy of treatments for pediatric depression, many recent intervention efforts have targeted adolescents with subclinical levels of depression and adolescents who exhibit risk factors (i.e., parental depression) for depression. Results of these studies are promising and indicate that cognitive–behavioral interventions effectively reduce depressive symptoms in adolescents with subclinical levels of depressive symptoms [23,24] and suggest that if adolescents with subclinical depressive symptoms are targeted, it may be possible to prevent some of the negative consequences associated with clinical depressive symptoms. For adolescents with Type 1 diabetes, this may mean the prevention of diabetes-related complications (i.e., decreased blood glucose monitoring [BGM] frequency and increased HbA1c) associated with depressive symptoms. To our knowledge, however, no interventions have specifically targeted individuals with Type 1 diabetes and lower, subclinical levels of depressive symptoms [25].

Therefore, the purpose of this study was to adapt and pilot an evidence-based individual cognitive–behavioral intervention to reduce depressive symptoms in adolescents with Type 1 diabetes and subclinical (no current diagnosis of a depressive disorder) depressive symptoms. The first aim was to examine the feasibility of implementing a cognitive–behavioral intervention for adolescents with Type 1 diabetes and subclinical depressive symptoms in an outpatient behavioral medicine clinic. The second aim was to examine the impact of CBT on depressive symptoms in a sample of adolescents with Type 1 diabetes. The third aim was to examine the impact of CBT on diabetes-related outcomes, self-management and glycemic control. It was hypothesized that adolescents who completed the intervention would demonstrate statistically significant improvement in depressive symptoms, self-management behaviors, and glycemic control post-intervention.

Materials & methods

Participants

Adolescents (aged 13–18 years) and their caregivers were recruited from a pediatric diabetes clinic at Cincinnati Children's Hospital Medical Center (OH, USA). The electronic medical record was used to identify adolescents with a diagnosis of Type 1 diabetes according to American Diabetes Association criteria [26]. The participant flow diagram is presented in **Figure 1**.

We randomly selected a quarter of these individuals (n = 219) and provided them with recruitment materials via letter or phone call, or in person in the clinic. Twenty four adolescents (11%) and their caregivers agreed to complete screening measures to determine eligibility for the study. Sixteen of the 24 adolescents met inclusion criteria (a diagnosis of Type 1 diabetes, daily insulin dosing ≥0.5 units per kilogram, evidence of depressive symptoms in subclinical range, Children's Depression Inventory [CDI] raw score of 5–13). The other eight participants did not endorse depressive symptoms in the subclinical range (CDI raw score <5). Exclusion criteria included the presence of a major mental or developmental disorder, an additional chronic medical disease or condition other than celiac disease or thyroid disorders (given the high comorbidity of these conditions with Type 1 diabetes [27,28]), and current enrollment in psychotherapy targeting depressive symptoms.

Of the participants who met inclusion criteria, 13 (81%) agreed to participate in the study. One adolescent was not able to be contacted to complete the baseline assessment after agreeing to participate, and thus did not receive treatment. Two participants left treatment after the first two sessions and one participant did not return for the follow-up assessment following the intervention. These four participants were not included in this study, resulting in a final sample of nine adolescents (56% of the participants who met inclusion criteria) who completed treatment and both assessments.

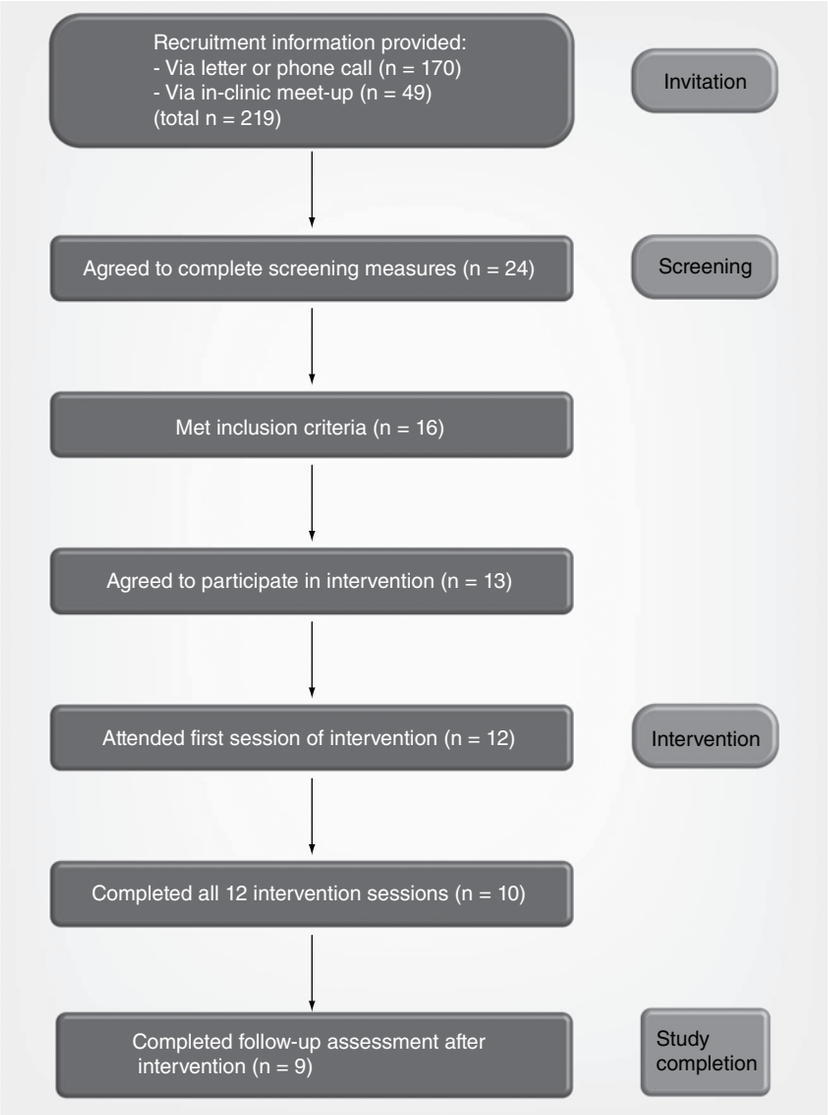

Figure 1. Flow diagram for all invited and enrolled participants.

Procedures

All study procedures were approved by the relevant Institutional Review Board. Adolescents

were provided US$25.00 for completion of the pretreatment assessment and $50.00 for the completion of the post-treatment assessment. Caregivers were compensated $10.00 at each assessment for their time and travel.

Screening

After obtaining parental consent and written adolescent assent, screening measures (CDI [29] and Adolescent Symptom Inventory-4 [ASI-4] [30]) were administered. The CDI and ASI-4 were chosen as screening instruments given their brief nature, good reliability and validity, and ability to assess the inclusion and exclusion variables of interest. Adolescents who evidenced subclinical depressive symptoms on the CDI (total raw score of 5–13) and did not have a major mental disorder as indicated by the ASI-4 were eligible to participate. Referral information was provided to participants interested in receiving mental health services who did not meet inclusion criteria.

Intervention

The intervention consisted of the delivery of a diabetes-specific adaptation of the first 12 sessions of the TADS cognitive-behavior therapy manual [20]. Each 60-min session consisted of three 20-min components. During the first 20 min of the session, the therapist reviewed the previously assigned homework with the adolescent, obtained an update on mood and current stressors, and reviewed the agenda. During the second 20 min of the session, adolescents were taught a skill related to the topic of the session. Skills include: goal-setting; mood monitoring; increasing pleasant activities; problem solving; recognizing and challenging automatic thoughts; and relaxation (i.e., deep breathing, progressive muscle relaxation and guided imagery). During the final 20 min of the session, unresolved stressors raised in the first 20 min of the session were discussed and the homework assignment was planned. The complete TADS manual is freely accessible online [101]. To address the unique stressors faced by adolescents with Type 1 diabetes, the TADS manual was adapted to include the following diabetes-specific topics: diabetes-specific negative thoughts; diabetes burnout; and negative effects related to BGM.

The intervention was delivered by one of three therapists (one psychology postdoctoral fellow and two doctoral students each with a master's degree in clinical psychology). All had experience delivering CBT and working with adolescents with Type 1 diabetes. To facilitate cross-clinician consistency, all therapists were trained by the principal investigator and attended regular group supervision with the principal investigator.

Assessment

Enrolled participants and their caregivers completed assessment measures prior to study entry and directly following participation in the intervention. Adolescents completed the Children's Depression Rating Scale-Revised (CDRS-R) and Diabetes Self-Management Profile (DSMP)-for flexible regimens. Caregivers completed the CDI-Parent Version (CDI-P) and DSMP-for flexible regimens. Chart reviews were completed to obtain BGM frequency and glycemic control. Pre- and post-intervention assessments were conducted by a research assistant not involved in the delivery of the intervention.

Measures

Screening measures

Children's Depression Inventory

The CDI, a 27-item self-report instrument, was used to determine eligibility [29]. Adolescents rated items representing the manifestation of depression in children and adolescents as 'no symptom', 'mild symptom' or 'distinct symptom'. Items were reverse scored as necessary and summed to create a total score, with higher scores representing higher levels of depressive symptoms. The CDI has demonstrated reasonably high levels of internal consistency and validity in adolescents [31]. For the purposes of this study, the presence of subclinical depressive symptoms was defined as a total raw score of 5–13 on the CDI.

Adolescent Symptom Inventory-4

The ASI-4 was also used to determine eligibility [30]. Caregivers completed this 120-item checklist based on the Diagnostic and Statistics Manual of Mental Disorders, Fourth Edition diagnostic criteria for multiple psychological disorders. If caregiver responses suggested significant psychological difficulties other than depression, the adolescent was not eligible for this study.

Demographic & clinical variables

Family information survey

Caregivers completed a demographic survey assessing their child's age, gender, ethnicity and age at diagnosis of Type 1 diabetes. In addition, caregivers provided information regarding their family's composition, socioeconomic status and insurance status.

Physiologic variables

Method of insulin therapy (injections vs continuous subcutaneous insulin infusion) and daily insulin dose were obtained via chart review. A research assistant recorded the relevant variables from the medical record of the closest clinic visit prior to the pre-intervention assessment. Inter-rater reliability of record review for this study was ≥95%.

Intervention assessment

Feasibility

Feasibility of implementing this intervention in the outpatient behavioral medicine clinic of the pediatric hospital where participants receive their diabetes care was assessed. Measures of feasibility included attendance, participant retention and session length. These variables were recorded by the interventionist at each session.

Diabetes-related outcomes

BGM frequency

BGM frequency was obtained via meter download. Data from the previous 14 days were averaged to create a daily frequency of BGM.

Diabetes Self-Management Profile

The DSMP is a structured interview that assesses multiple aspects of diabetes self-management, including insulin administration, BGM, dietary intake and physical activity. The DSMP was administered individually to both the caregiver and adolescent. Responses were summed to create a total score, with higher scores representing more meticulous self-management [32]. Moderate internal consistency has been demonstrated in previous literature [32].

Glycemic control

Glycemic control was analyzed via blood assay (DCA 2000, Bayer Inc., NY, USA) and obtained from medical records. The HbA1c level used as the pre-intervention value was obtained by averaging the two values from clinic visits closest to the time the intervention started. Similarly, a post-intervention HbA1c level was obtained by averaging HbA1c values at the two clinic visits following the completion of the intervention.

Psychological functioning

Children's Depression Rating Scale-Revised

The CDRS-R is a rating scale completed from responses provided in a semi-structured interview conducted with the adolescent. The total t-score was used for the purposes of these analyses. Higher t-scores represent an increased likelihood that a depressive disorder will be confirmed in a comprehensive diagnostic evaluation (40–54 'unlikely', 55–64 'might be'; 65–74 'likely'; 75–84 'very likely'; >85 'almost certain'). The CDRS-R has demonstrated good reliability and validity in previous samples of adolescents [33].

CDI-Parent Version

The caregivers' reports of adolescent depressive symptoms were examined using the CDI-P. Caregivers rated 17 items suggesting the manifestation of depression in their adolescent on a 4-point Likert scale. Items were reverse scored in accordance with published guidelines [29] and summed to create a total score. Higher scores represent higher levels of depressive symptoms. The CDI-P is a reliable and valid measure [29].

■ Data analysis

Descriptive statistics including measures of central tendency and variability were calculated. The internal consistency of each measure was calculated using Cronbach's α-coefficient. Paired samples t-tests were used to compare pre- and post-intervention mean scores on outcome measures. Effect sizes were examined using Cohen's d.

Results

■ Descriptive statistics

Descriptive statistics are presented in **Table 1**. At the pre-intervention assessment, participants were between 13 and 18 years of age (mean: 15.77; standard deviation: 1.44). The majority of the participants were male (67%) and Caucasian (78%). The average diabetes duration was 4.11 years (standard deviation: 2.95 years), and the majority of participants (67%) were currently using an insulin pump for delivery. Over two-thirds (67%) of adolescents lived in two-caregiver households and had private insurance (78%). The median family income was $30,001–50,000.

■ Feasibility

Of the 12 adolescents who began the intervention, nine (75%) attended all weekly intervention sessions and assessments. All interventionists completed each of the 12 treatment sessions within the allotted 60-min window.

■ Depressive symptoms

Results of the t-test examining the semi-structured interview (CDRS-R) indicate that adolescents reported significantly fewer symptoms of

Table 1. Demographic and clinical characteristics prior to intervention.

Variable	n (%)	Range
Clinical variables		
Diabetes duration (years); M (SD)	4.11 (2.95)	1.30–9.45
Insulin delivery by pump; n (%)	6 (67)	–
Demographic variables		
Age (years); M (SD)	15.77 (1.44)	13.90–18.26
Male gender; n (%)	6 (67)	–
Minority status; n (%)	2 (22)	–
Caregiver (married); n (%)	6 (67)	–
Private insurance; n (%)	7 (78)	–

M: Mean; SD: Standard deviation.

depression post-intervention than pre-intervention, t(8) = 5.38; p = 0.0004; Cohen's d = 1.59 (Table 2). Parents also reported that their adolescents were experiencing significantly fewer symptoms of depression following participation in the intervention, t(8) = 2.50; p = 0.04; Cohen's d = 0.66.

Diabetes-related outcomes

According to adolescents, their self-management levels were higher following the intervention than prior to the intervention, t(8) = -3.24; p = 0.01; Cohen's d = -0.98. Additional measures of diabetes management, including caregiver-reported self-management and blood glucose monitor download, did not differ significantly between pre- and post-intervention. Glycemic control post-intervention was not significantly different than glycemic control prior to the intervention. While two of the nine participants demonstrated decreases in HbA1c (average decrease 0.8), most had rising values across the course of the HbA1c assessments (spanning over a year in most cases).

Discussion

The results of this pilot study show that individual CBT may be a feasible and effective nonpharmacologic treatment for reducing depressive symptoms in adolescents with Type 1 diabetes and subclinical symptoms of depression. By the end of treatment, eight of the nine participants endorsed levels of depressive symptoms on the CDRS-R indicating that 'a depressive disorder is unlikely to be confirmed in further evaluation' [34]. This improvement in depressive symptoms is consistent with decreases in depressive symptoms demonstrated in previous studies of group CBT for adolescents with Type 1 diabetes [18], individual CBT for adults with Type 2 diabetes [15], and web-based CBT for adults with Type 1 and Type 2 diabetes [35].

Participants also reported an improvement in diabetes self-management following intervention completion. Eight of nine participants reported improvements in self-management following the intervention, and the total mean score of participants was similar to a 'highly adaptive' subgroup of individuals described in previous research [36]. To our knowledge, this is the first study of a CBT intervention for depression to also evidence improvement in self-management [15,18,35]. While this pilot study did not examine mechanisms of change, by targeting depressive symptoms,

Table 2. Results of paired-samples t-tests.

Variable	Pre-treatment; mean (SD)	Post-treatment; mean (SD)	t	p-value	Cohen's d
CDRS-R	54.89 (4.43)	47.44 (4.90)	5.38	0.0004	1.59
CDI-P	15.58 (10.36)	9.81 (6.73)	2.50	0.0400	0.66
DSMP adolescent	55.89 (10.31)	66.00 (10.32)	-3.24	0.0100	-0.98
DSMP caregiver	56.44 (6.71)	61.33 (12.23)	-1.90	0.0900	-0.50
BGM frequency	4.33 (2.50)	3.44 (1.51)	1.18	0.2700	0.43
HbA1c (%)	8.00 (1.47)	9.30 (2.09)	-2.29	0.0500	-0.72

BGM: Blood glucose monitoring; CDI-P: Children's Depression Inventory-Parent Version; CDRS-R: Children's Depression Rating Scale-Revised; DSMP: Diabetes Self-Management Profile; SD: Standard deviation.

this intervention may have decreased negative attributions, improved concentration and improved self-efficacy. Improvements in any of these variables could have led to improvements in diabetes self-management. It may also be that learning new skills for problem solving and a general approach to handling stressful situations or adversity may have translated to diabetes-specific problem solving in daily management. Despite improvements in overall diabetes self-management, BGM frequency did not change over the course of the intervention. This may be attributed to the fact that adolescents in this sample were generally well-controlled and checked their blood glucose frequently prior to intervention. As a result, potential improvements in glycemic control or BGM frequency specifically may have been relatively small in this sample. Second, while BGM frequency was addressed as relevant to the content of the session (e.g., improving communication with parents about BGM frequency), this outcome was not a primary target of the intervention.

Despite the previously documented relationship between self-management and HbA1c [37], participants in this study did not evidence improvements in HbA1c as hypothesized. In fact, HbA1c levels rose for the majortiy of participants (78%). This increase in HbA1c may be attributed to several factors. First, as HbA1c was collected via chart review from clinic visits closest to pre- and post-intervention, imprecise measurement may have limited our ability to detect a change. Second, the normative increases that occur in HbA1c with development may have made overshadowed any improvements in HbA1c resulting from improvements in self-management [38].

The important implications of this pilot study should be interpreted within the context of several limitations. First, the lack of a control group limits the ability to understand changes in depression, self-management and HbA1c in the context of development. Second, the small sample size and demographic homogeneity limits the generalizability of findings, the ability to examine mechanisms of change and the ability to control for potential confounding variables (i.e., thyroid dysfunction). Third, our post-intervention assessment occurred directly following intervention completion and additional long-term follow-up data were not collected.

Future perspective

The promising results of this pilot study, coupled with the increases in depression, self-management difficulties and HbA1c that occur during adolescence, illustrate that testing the effectiveness and cost–effectiveness of this intervention in a randomized-controlled trial is worthwhile. Future studies should include larger samples of adolescents, further investigate factors that mediate changes in depressive symptoms and self-management, and examine outcomes at longer follow-up intervals.

This pilot study expands on the current literature as it is the first examination of the impact of individual CBT on subclinical depressive symptoms and diabetes-related outcomes in adolescents with Type 1 diabetes. This study showed that the TADS CBT manual, originally created for treatment of depression in medically well youth, may be an effective treatment for depression reduction in adolescents with Type 1 diabetes and subclinical depressive symptoms [20]. Improvements in diabetes self-management were also documented, providing further support for the relationship between mental health and diabetes-related outcomes. This promising intervention may be a viable avenue for depression treatment and prevention in an at-risk group of adolescents. Future research efforts should include randomized controlled trials investigating mechanisms of change and long-term outcomes.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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