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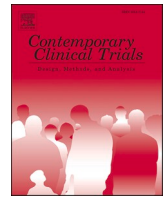
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A self-management plus mind body intervention for adolescents and young adults with type 2 diabetes: Trial design and methodological report

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ABSTRACT

Background: The onset of type 2 diabetes (T2D) is increasingly common in adolescents and young adults (AYAs). Improving self-management skills and the mental health of this population is important, but understudied.

Methods: The goal of this research was to develop a mind-body intervention which could serve as an adjunctive therapy to support AYAs with T2D (INTEND intervention). Toward that end, we used an iterative process, including use of focus groups, advisory board, and cognitive semi-structured interviews with patients, parents of patient and clinical providers, to understand the gaps in the current information provided to AYAs with T2D. Based on the data gathered from the focus groups and interviews, we enhanced an existing self-management intervention for adults with T2D to include an additional mind body intervention for AYAs with T2D. The INTEND intervention will be piloted in a group of AYAs with T2D.

Results: This report describes the methodology and design of the IntervENTion for Early onset type 2 Diabetes (INTEND) study. The details of this single arm pre-post pilot feasibility trial are described.

Discussion: If successful, the INTEND approach has the potential to advance care for vulnerable youth with T2D.

1. Introduction

Youth onset type 2 diabetes (YT2D) is a growing epidemic with significant cost and disease burden. Recent research demonstrated a 7% annual increase in T2D rates in U.S. youth.[1,2] As many as 5000 new cases of T2D are diagnosed in US youth each year, with a growing chronic disease burden. [3]

As with many chronic diseases, T2D that first begins in youth produces more significant lifetime morbidity than when first diagnosed in adulthood and when compared to youth with type 1 diabetes (T1D). [4] YT2D presents with earlier and more severe complications than would be expected from established risk factors, such as BMI, blood pressure and glucose control.[5,6] Both microvascular (retinopathy, neuropathy, nephropathy) and macrovascular (cerebrovascular, cardiac) complications typically occur in adult-onset T2D 15 years after diagnosis but may occur as early as 3–5 years after onset of disease in youth.[7,8] Youth with T2D have a 39-fold risk of end stage kidney disease and dialysis compared to healthy peers, and an increased risk for diabetic

retinopathy which, if left untreated, can ultimately lead to blindness. [9–11] Complications associated with T2D in youth lead to increased hospitalization, decreased quality of life, and, ultimately, may take years from a vulnerable youth's life [11–14].

Youth with chronic illness are significantly more likely to develop anxiety and depression than those individuals without chronic illness [16–18] and those with mental health comorbidity have more health burden and disease complications [19,20]. Both adolescents and young adults with T2D have higher reported rates of anxiety and depression symptoms [21,22]. Fisher et al. (2019) has suggested that standard diabetes care should include mental health when a new diagnosis is made [23]. Mendenhall, et al. further describe the reciprocal impact diabetes and depression have on each other and the impact on both individual patients and the broader health of a community [24,25]. In adults, the interactive relationship diabetes and depressive symptoms have on each other is well documented [26–28]. However, the research in youth remains limited and there is a need to develop strategies to intervene in youth with T2D, in part, because of their higher risk of

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developing depressive symptoms. [1,21,29].

There is a well-developed body of empirical studies in adults with T2D and the positive impact self-management strategies have on glycemic control, disease self-efficacy and measures of anxiety and depression [30–32]. Sajatovic, et al., a member of this team, has developed a self-management intervention for adults with T2D and mental health disorders [33,34]. This intervention, targeted training in illness management (TTIM) has been shown to improve diabetes knowledge, mental health symptoms, and measures of global health [34,35]. There is a growing body of literature regarding improving self-management skills in adolescents with diabetes [36,37]. Results suggest adolescents with confidence and skills to manage T2D have better outcomes than those with less, and that self-management interventions improve quality of life in youth with diabetes [36,37]. However, the bulk of self-management literature in youth remains in those with T1D [36].

There is substantial evidence that mind-body practices, or integrated care therapies, are beneficial in adults with a broad range of chronic illness [38–44]. In children and adolescents, there is also significant evidence for integrated care, especially in hospitalized youth, children with cancer, and in chronic pain affecting children. [45–47] Burgeoning research suggests that mind body practices, such as mindfulness and meditation help reduce symptoms of depression in adolescents with psychiatric illness. [48–52] There is also growing research that the addition of mind-body interventions to self-management improves outcomes in adults with T2D [53–55]. There is evidence to suggest a wide range of mind-body interventions are effective including yoga, tai chi, qigong, and meditation [53,56–59]. Indeed, a recent study found that mindfulness meditation improved glycemic control in adult women with T2D [44]. Furthermore, a recent meta-analysis reported mindfulness meditation improved self-management (e.g., lower HbA1c) in adults with T2D [43]. However, very limited research is available for mind-body interventions for youth with chronic disease such as T2D [60]. This article describes the design and pilot implementation of a self-management plus mind-body intervention (INTEND) for adolescents and young adults with T2D, see Fig. 1 for the 3-phase design of this study.

2. Methods

2.1. Overview

In Phase 1 of this 3-phase project, focus groups were conducted with AYAs (age 15–20) with T2D, their guardians, and healthcare providers to evaluate barriers and facilitators to management of T2D. Findings were used to modify an existing self-management intervention for adults

with T2D and develop an additional mind body component for the intervention for AYAs with T2D. The self-management intervention was based upon TTIM, the diabetes self-management intervention developed by a member of our team [34]. In Phase 2, an advisory board of a subset of AYAs, caregivers and healthcare providers evaluated the developed intervention, suggested modifications and subsequently reviewed the modified INTEND (InterveNTion for Early oNset type 2 Diabetes) intervention. In Phase 3, a pilot feasibility trial of the INTEND intervention will be undertaken to examine feasibility, tolerability and preliminary outcomes in quality of life, anxiety symptoms, depressive symptoms and laboratory measures of severity of T2D, as measured by fasting glucose, lipids and HbA1c in AYAs with T2D. In all 3 phases, individuals 18 years and older provided informed consent over a restricted Zoom platform. Informed consent was captured using REDCap electronic data capture tools at University Hospital of Cleveland [61–63]. Individuals younger than 18 years provided assent with informed consent provided by their legal guardian using a restricted Zoom platform with all parties present. All study procedures and interventions (focus groups/interviews, Advisory Board meetings, peer educator training, and the single arm intervention sessions) in all phases will take place over a secure telehealth platform (e.g. Doxy or UH Zoom). Study data were collected and managed using REDCap [61–63].

2.2. Phase 1: focus groups

Focus groups were led by one of the study PIs and used a semi-structured interview format. Focus group participants included AYAs (age 15–20) with T2D. Because of the focus on the mental health consequences of youth onset T2D, AYA focus group participants had a comorbid diagnosis of an anxiety disorder or major depressive disorder (MDD). The study utilized purposive sampling, targeting adolescents and young adults with type 2 diabetes, their caregivers, and their healthcare providers. Participants were recruited through outreach to the University Hospitals Pediatric Endocrinology, Integrative Medicine, and Behavioral Health Departments at University Hospitals Cleveland Medical Center in Cleveland. Research team utilized flyers and spoke to potential participants, and their guardians, in person, during regular standard of care visits. The sample included: 1) three youth (AYA) participants, three female, with mean age of 17 (range, 16–19), diagnosed with T2D, and MDD or anxiety; 2) three parents of the AYA diagnosed with T2D, and comorbid MDD and/or anxiety, mean age 45 (range, 39–49); and 3) six healthcare professionals including registered nurse, social worker, diabetes educators, psychiatry fellow, endocrinologists, and dieticians, with mean years of practice 17 years (range, 3–23).

Interview questions were guided by empirical findings from the

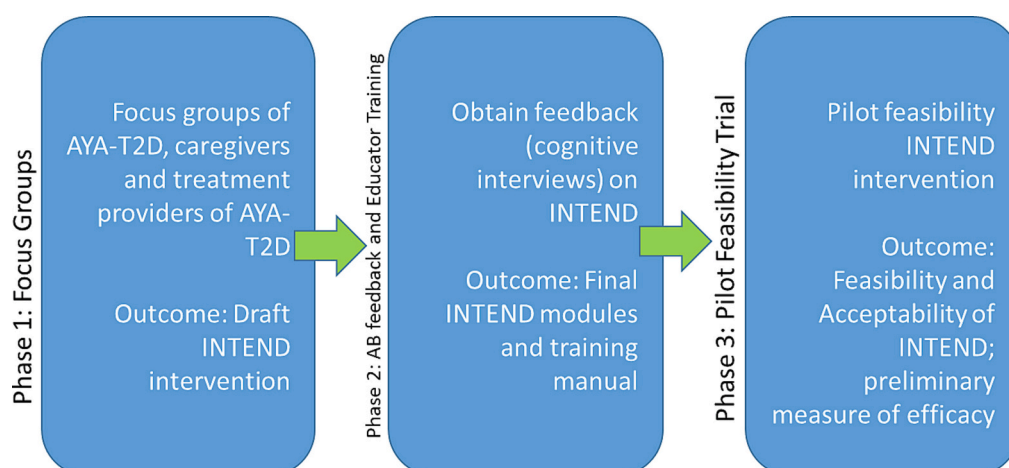


Fig. 1. Three Phase Design for INTEND development.

literature, as well as combined clinical and research experience of the research team. The research team was made up of a pediatric endocrinologist, pediatric endocrinology department clinical research nurse, child and adolescent and adult psychiatrists, a pediatric mind-body physician, clinical and research psychologists, as well as clinical research specialists. The semi-structured interviews encouraged study participants to express their views and elicit valuable insights into personal and social phenomena. Duration of interviews ranged from 30 to 70 min.

Four predominant themes emerged regarding barriers to management of T2D and its symptoms: 1) psycho-emotional barriers, such as bullying, isolation and stigma, 2) social barriers, such as lack of household and community support, 3) medical barriers, including difficulty with healthcare communication, a divide between T1D and T2D (for example, standardized nursing/nutritional/medication support are widely available for T1D and resources available for T2D are much less standardized and widely available), and 4) behavioral barriers, such as difficulty with medication and dietary adherence. In the management of T2D symptoms, facilitators included family members with shared diagnosis, hope and positive body awareness.

2.3. Phase 2: advisory board

Following the focus groups, the study team convened an advisory board intended to provide additional input for intervention refinement. The advisory board was comprised of 2 AYAs with T2D, 2 parents and 3 healthcare providers that care for AYAs with T2D. The intervention was reviewed and feedback was collected from the advisory board and utilized for improvement.

2.4. Qualitative procedures and data analysis

Inductive nature of the qualitative approach to this study allowed for focus to remain on participants' experiences, highlighting their preferences and needs to help inform and shape a better suited healthcare. Focus groups and individual interviews were video and audio recorded, de-identified, and transcribed verbatim. A team of three reviewers and an auditor, all of whom had been trained in qualitative analysis, analyzed the data. A Consensual Qualitative Research (CQR) method was used to then look for themes within the data, allowing for the study of attitudes, beliefs, and personal inner experiences among participants [64]. A coding process focused on identifying specific thematic content until unanimous consensus themes and subthemes was reached among the team [64]. Results of this thematic analysis are presented elsewhere. [65]

3. Overview of INTEND intervention

INTEND is a brief and practical remotely-delivered intervention that includes 6 sessions (spaced out over about 6 weeks) for adolescents and young adults, age 15–20 and 2 sessions for their parents or caregivers, see Table 1 for a full outline of the intervention. Each session includes a self-management portion, modified from TTIM and a specific mind body intervention targeted toward mood and anxiety management [10–34]. The self-management pieces of each session include educational topics related to diabetes, myths and stigma related to T2D and nutrition strategies specific to T2D. In addition, skills are taught at each session included SMART goal setting: (Specific, Measurable, Achievable, Realistic, Timeframe), problem solving, medication mastery and strategies for effective communication with your healthcare provider.

In addition to the self-management pieces, we chose three mind-body interventions (diaphragmatic breathing, inner smile meditation, guided meditation) to help this population address developmentally specific challenges faced by youth with chronic illness [66]. Diaphragmatic breathing was chosen as it is an ancient technique with an increasing, modern evidence base for autonomic and cortisol regulation,

Table 1

Key components of the INTEND intervention.

	Self-management focus	Mind Body Intervention
Session 1	Introduction to Type 2 Diabetes (T2D) Facts and Myths about T2D Stigma of Early Onset T2D Strategies to Cope with Stigma	Introduction to Mind Body Interventions Belly Breathing as first example
Session 2	Challenge of Being an AYA with T2D Stress and T2D Personal Goal Setting (SMART goal setting approach)	Physiology of Mind Body Techniques Review of Diaphragmatic Breathing/Belly breathing. Reflections on practice, group practice, when to use.
Session 3	Problem Solving Skills. Problem Solving using the SMART strategy	Guided Meditation 1 – Intro 1st general guided meditation, “Healing Meditation”
Session 4	Nutritional basics and strategies Problem Solving to Feed Your Body in a Healthy Way	2nd guided meditation – specific guided meditation regarding living with diabetes
Session 5	Understanding Your Medications and Routine to Help with Medication Mastery Troubleshooting Checking Blood Sugar	Introduce Inner Smile Neurobiology Inner Smile Inner Smile Meditation
Session 6	Effective Communication with Healthcare Providers Provider Interaction Role Play	Inner Smile Meditation 2 Diaphragmatic Breathing Guided Meditation.

and may help improve sustained attention, decrease anxiety, and improve mood [67–69]. Inner Smile Meditation, conceptualized as within the category of mindfulness training, is also an ancient strategy for cultivating an attitude of positivity, engaging the neural networks tied to emotional positivity. Emerging evidence shows it to be promising as an evidence-based strategy for mood modulation [70–72]. Guided meditation, in general, presents a vast field that encompasses numerous intentions and formats. We chose to introduce the participants to both general guided meditation, and a specific meditation directed to improving their sense of connection to the large community of other AYAs with T2D, to counter perceptions of isolation and loneliness particularly [73].

Follow-up measures will be collected at week 6 and 12. INTEND is co-led by a clinician educator trained in both diabetes self-management and mind body interventions and a peer educator, someone who has “walked the walk” with early onset T2D. The clinician educator will be someone with either a background in T2D or in mind body interventions. A peer educator will be recruited from the endocrinology department that is led by one of our investigators. The peer educator will be ≥18 years old, be diagnosed with T2D, and be willing and able to engage in several training sessions, collaboration meetings with the team and ongoing collaboration with the clinician educator. The study clinician who developed the INTEND intervention will train both the clinician and peer educator on the self-management and mind body interventions. One of the study clinicians who is a mind body practitioner will train both the clinician educator and peer educator on the specific techniques in the mind body interventions. In this pilot study, fidelity to the intervention will be assessed by the mind-body study clinician observing a portion of the intervention groups.

4. Phase 3: pilot feasibility testing

This 12-week single arm pre-post prospective pilot will implement INTEND in a small group of youth with T2D to assess feasibility, acceptability and collect preliminary outcome data. The project will be operationalized in 3 specific aims: Aim 1: Test the feasibility and acceptability of INTEND in a pilot of AYAs, age 15–20, with T2D ($n = 6$) and their caregivers ($n = 6$); *Hypothesis (Aim 1): The INTEND intervention will be feasible and acceptable for AYAs with T2D as demonstrated by mean attendance to at least 75% of sessions and high study retention (> 80%).*

Aim 2 (exploratory): We will evaluate the impact of the INTEND intervention on youth quality of life and symptoms of anxiety and depression, as measured by diabetes related quality of life and PROMIS measures of anxiety and depression. Aim 3 (exploratory): We will evaluate the impact of the INTEND intervention on laboratory measures of severity of T2D, as measured by fasting glucose, lipids and HbA1c.

4.1. Pilot feasibility: sample

We will recruit up to two peer educators, 5–6 patient participants and 5–6 parent participants for a total of up to 14 individuals will participate in the single arm pilot. Sample size was based on previous studies by this team of modifying evidence based interventions for a new participant population[74,75]. The AYAs will be included if they are age 15–20, have a clinical and verified diagnosis of T2D and an available guardian if under 18. In addition, they will be excluded if they are deemed an acute risk to self or others or are pregnant. Participants will be recruited from the pediatric endocrinology clinic where several of our team members see clinical and research participants. Based on feedback from phase 1 and 2, it was decided to include all 15–20 with T2D and not require a formal mental health diagnosis for inclusion. Symptoms of anxiety and depression, but not formal diagnosis, are common in youth with T2D and feedback from phase 1 and 2 suggested that all youth with T2D could benefit from this intervention [21].

4.2. Pilot feasibility: measurements

All AYA participants will have basic demographic information collected and will have assessments at baseline, week 6 and week 12. The primary outcome will be feasibility and usability, as measured by number of sessions attended, and a patient and clinician acceptability survey, which will be assessed at week 6 and week 12. In addition, the study team will collect basic laboratory data related to T2D from AYAs with T2D at baseline and week 12. In addition, T2D related quality of life will be assessed, and PROMIS measures of anxiety and depression at baseline, week 6 and week 12. See Table 2 for a full schedule of assessments and interventions.

4.3. Pilot feasibility: data analysis

As the primary goal of this pilot study is feasibility and acceptability, only descriptive statistics will be used and change from baseline in the primary and secondary measures using dependent samples paired *t*-tests

Table 2
Schedule of Assessments and Interventions:

	Baseline	Week 1–6	Week 6	Week 12
AYAs				
Demographics	x			
T2D related quality of life [76]	x		x	x
PROMIS measures anxiety depression [77]	x		x	x
Laboratory measures (fasting HbA1c, lipids, glucose)	x			x
Remote Intervention		x		
Feasibility and Acceptability feedback			x	x
Number of AYAs recruited				
Retention (%sessions attended)				
Acceptability				
Retention (% sessions attended)				
Satisfaction - patient and clinician acceptability survey				
Caregivers				
Demographics	x			
Feasibility and Acceptability feedback			x	

to assess pre-post data in the sample that completed the study.

5. Discussion

The study procedures outlined above describe the development and preliminary testing of a novel treatment for self-management in AYAs with T2D, INTEND. INTEND was modified from an evidence based self-management intervention for T2D in adults[33,34] with input from key stakeholders, including youth with T2D, caregivers and medical providers.

To our knowledge, the INTEND intervention is the first of its kind using a mind-body intervention to enhance a self-management program in AYAs with T2D. While the empirical evidence in adults with T2D does support mind-body interventions in adults with T2D[43,44,59], results from this trial will provide the first evidence in youth. This intervention builds upon a small but growing body of literature supporting the efficacy of self-management in adolescents with T2D to improve quality of life [37] and a significant body of literature supporting self-management and mind body interventions in adults with T2D[43,44,78,79].

The results of the Phase 3 pilot trial will provide evidence of whether the proposed INTEND is feasible to enroll and retain AYAs with TSD and provide preliminary quality of life and symptoms of anxiety and depression in youth with T2D. Pending promising findings from this study, the team will seek to conduct a larger scale RCT comparing INTEND to a generalizable comparator. One design consideration for future investigations that has potential to enhance future dissemination potential of the INTEND approach in routine care settings, might be to include both effectiveness and implementation elements. For example, a next project might be operationalized as a Type 1 hybrid effectiveness-implementation design intended to accelerate translation while at the same time providing a valid estimate of potential clinical effectiveness and target engagement evaluation specific to diabetes and whole-health self-management. As noted by Bauer and colleagues [80], in a report discussing conceptual methodologies of effectiveness-implementation trial designs, a Type 1 hybrid could be operationalized that incorporates formal assessment of barriers and facilitators to implementation into the traditional clinical RCT design, in order to speed the process of future scale-up and spread of the intervention. In such designs, model-guided mixed methods analyses are conducted across multiple levels (patient, provider, system, community) that can be used for subsequent intervention adaptation and implementation efforts [81]. A longer-range goal is to test the effectiveness of embedding INTEND into standard (non-research) clinical settings and what strategies are needed for implementation if both the pilot and efficacy RCT show positive results. Ultimately, if successful, the INTEND intervention has the potential to advance care for vulnerable youth with T2D.

6. Strengths and limitations

Strengths: This intervention pilots a novel intervention for an underserved population. In addition, input from stakeholders were involved throughout the development of the intervention. Upon completion of this pilot study, this will provide useful feasibility and preliminary efficacy data.

Limitations: In this small pilot study, there was no control group and this will affect all measures including metrics of recruitment, adherence feasibility and preliminary outcomes. Larger studies, in the future, should include a control group to enhance ability to measure the above outcomes. In addition, the small sample size will limit generalizability and results should be interpreted with caution.

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Declaration of Competing Interest

The authors express no conflicts of interest for the writing this article.

Data availability

Data will be made available on request.

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