A mindfulness-based intervention for adolescents with prediabetes or type 2 diabetes

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IRB Protocol # 21496

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Table of Contents:

Abbreviations

BMI	**Body mass index**
CBT	**Cognitive behavioral therapy**
HbA1c	**Glycemic control**
L2B	**Learning 2 Breathe**
MBI	**Mindfulness-based intervention**
T2D	**Type 2 diabetes**

1.0 Background and Rationale

The obesity epidemic is associated with an increase in youth-onset type 2 diabetes (T2D), [1] as well as its precursor condition, prediabetes. [2] Approximately, 20% of youth, ages 12-18 years old, have prediabetes. [3,4] If prediabetes progresses to T2D, glycemic control is often more difficult to achieve in youth as compared to adults. [3,4] Poor glycemic control is associated with diabetes-related complications and decreased life expectancy. [3,5] This is especially troubling as obesity and T2D disproportionately affect youth from marginalized and minority race/ethnicity backgrounds who often face additional stressors and barriers to diabetes care. [6-8] Effective patient-centered, holistic treatments are needed for youth with prediabetes or T2D. [7,9]

Mindfulness-based interventions (MBI) may offer additional benefits to traditional health care for youth living with prediabetes or T2D. Mindfulness refers to non-judgmental, focused attention on the present moment. [10] MBIs teach skills to increase present moment attention and adopt a nonjudgmental attitude towards one's experience which can foster healthy stress coping behaviors and greater self-regulation; [11] both of which are associated with improved diabetes self-care behaviors. [12,13] MBIs were introduced to the clinical population in the 1970's and have been translated for a variety of populations and health conditions including diabetes.

A systematic review and meta-analysis of eight RCTs investigated the effect of MBIs on glycemic control (HbA1c) and psychological outcomes (depression, stress, diabetes-related distress, anxiety) in adults with diabetes. [14] The authors found that MBIs had a moderate effect size on decreasing depression and stress, and changes were greatest in individuals with higher baseline psychological symptoms. [14] MBIs were associated with small reductions in HbA1c and diabetes-related distress, but MBIs did not have a consistent effect on anxiety. [14] A longer follow up time (>6 months post baseline) was associated with greater improvements in HbA1c. [14]

Few studies have examined the role of MBIs in adolescents for diabetes prevention and management. Ellis et. al. (2019) conducted a RCT to evaluate the efficacy of a MBI in urban adolescents with poorly controlled type 1 diabetes. Adolescents with a high stress reactivity score at baseline in the MBI group experienced the greatest decreases in HbA1c at 6 months (0.70%) compared to those in the cognitive behavioral therapy (CBT) group (0.35%) and diabetes support group (0.53%).[15] For adolescents with elevated levels of stress, MBI may be beneficial for improving glycemic control. [15]

A RCT compared the effectiveness of a six-week MBI vs a CBT group on depression and insulin resistance in adolescent girls with risk factors for T2D. [16] Depressive symptoms, perceived stress, insulin resistance, and adiposity were measured at baseline, post-intervention, and 6 months. [16] Adolescents in the MBI group had greater decreases in depressive symptoms compared to CBT group at post-treatment and 6 months. [16] The MBI group also had improvements in insulin resistance compared to the CBT group, after controlling for adiposity. [16]

MBIs may be a promising complementary approach for T2D prevention and treatment in youth, and thus, warrant further investigation.

2.0 Specific Aims

We propose a MBI for adolescents with prediabetes or T2D. Specific aims of this proposal include:

Aim 1: Pilot test the feasibility and acceptability of a mindfulness-based intervention in adolescents with prediabetes or type 2 diabetes.

Aim 2: Explore secondary physical and mental health outcomes of the study cohorts.

Primary outcomes will assess participant adherence to the study protocol and satisfaction with the intervention. Secondary outcomes will preliminarily assess the effect of the intervention on clinical care measures (e.g., HbA1c, BMI) and patient-centered outcomes including quality of life. We will identify factors that support or interfere with the uptake and sustained use of the intervention in the diabetes care context to assist in future multi-site, pragmatic, or implementation science trials. We hypothesize that offering mindfulness-based skills will result in improved outcomes and thus would lead to change in clinical practice to incorporate such teachings.

3.0 Inclusion/Exclusion Criteria

Adolescents between the ages of 12-18 years old who are referred for treatment of prediabetes or T2D are eligible for this study. Participants will have normal cognition and will be English speaking as the group is offered in English. Adolescents are not eligible to participate if they have diagnosed cognitive disability that would prevent participation in a group or if they are unable to attend the MBI group sessions.

Criteria for inclusion:

- Age 12-18 years
- Referred to clinic for treatment of prediabetes or type 2 diabetes
- English speaking

Criteria for exclusion:

- Diagnosed cognitive disabilities
- Inability to attend visits due to individual schedules

4.0 Enrollment

We aim to recruit 50 individuals with the goal of at least 20 participants to complete the study (two groups of 10 participants).

Recruitment Sites: Diabetes care providers see patients in an outpatient setting at Riley Specialty Care at IU Health Methodist in Indianapolis, Indiana. Additional outreach clinics available for participant recruitment include Riley Specialty Care at Riley Outpatient Center, IU North, Bloomington, Fort Wayne, and South Bend.

Recruitment Procedures: Eligible patients will be recruited in one of the following ways: 1) health care providers will identify eligible adolescents during clinic visits, 2) a letter will be mailed to patients referred for prediabetes or type 2 diabetes who have been seen in one of our clinics within the last 12 months, or 3) a member of the research team will call eligible patients. The letter and phone call scripts are provided in separate documents.

Consent Procedures: When a family indicates interest, a member of the research team will initiate contact with the parent or guardian at the end of a clinic visit (if time allows) or by phone. The team member will describe the study, assess eligibility, and answer questions. If the adolescent (and guardian) is willing to participate in the study, the consent process and baseline questionnaires will be completed virtually. The consent process will be based in REDCap. If a family declines participation, they will be asked if they would like to complete the study declination form. This will help to understand reason for disinterest in a MBI.

5.0 Study Procedures

Following enrollment, participants will complete baseline surveys and begin attending the 12-week MBI. Participants will complete surveys following completion of the MBI and at the 12-month follow up. Participants will receive compensation for completing surveys and attending the MBI.

Data Collection

Process Measures: Intervention fidelity will be assessed with a checklist of session content to ensure that the facilitator is delivering the intervention as intended. Facilitators will follow the manualized curriculum and scripts for mindfulness skills practice.

Feasibility and Acceptability Measures: Feasibility and acceptability measures include study participation rate, time to recruit, attendance, study retention rate, study completion rate, data completion, and program acceptability.

Participant Measures: Participants will be emailed a link to complete surveys in REDCap. Surveys will be completed at baseline (B), following completion of the MBI at 12-weeks (T1), and at the 12 month follow up (T2). Participants may complete follow-up surveys (12-weeks and 12 months) up to 1 month after the designated time point. A guided interview will also be performed at 12-weeks to receive feedback about the participants' experiences in the study.

Clinical data (HbA1c, BMI, and BMI z-score) will be collected at baseline and at each standard clinical prediabetes or diabetes appointment up to 12 months after the intervention.

Table 1. Study Measures

Feasibility and Acceptability Measures	
Measure	***Definition***
Study Participation Rate	Number of participants who consented to take part in the study divided by the number of patients approached. We will also document reasons for refusal to participate in the study.
Time to Recruit	Time required to attain the needed sample for each recruitment wave
Attendance	Attendance at each intervention session will be recorded.
Study Retention Rate	Number of participants in a study arm who remain in the study and maintain communication with study staff (regardless of session attendance) divided by the number of participants enrolled in the study.
Study Completion Rate	Number of participants who complete all assessments divided by the number of participants enrolled in the study arm.
Data Completeness	Percentage of questionnaires/study measures completed.
Program Acceptability	Acceptability of the intervention to participants as measured by agreement (on a 5-point likert scale) with different satisfaction measures.
Clinical Measures	

Hemoglobin A1c (HbA1c) Body Mass Index (BMI) BMI z-score **When collecting clinical data from prediabetes or diabetes appointments, research team will document any changes to medications that impact glycemia and/or BMI.*
Participant-Centered Measures
Demographics Patient-Reported Outcomes Measurement System Emotional Distress-Depression-Pediatric Item Bank (PROMIS) Screen for Childhood Anxiety Related Emotional Disorders (SCARED-5) Perceived Stress Scale (PSS-10) Peds QL Generic Core Scales Mindful Attention Awareness Scale (MAAS) – Adolescents Difficulties in Emotion Regulation Scale (DERS) L2B Program Questionnaires Post-study guided interview: 1. What did you like about participating in this study? 2. What did you dislike about participating in this study? 3. What were your expectations from participating in this study? 4. Were those expectations met?

Intervention:

The MBI will be conducted in a virtual group setting by Zoom, with a target size of 8-12 participants. Groups may vary in size based on session attendance.

Mindfulness-based intervention. The MBI will follow the Learning to BREATHE (L2B) curriculum. L2B is a manualized 12-week curriculum that teaches a variety of mindfulness skills including breath awareness, body scanning, mindful eating, sitting meditation, loving kindness practice, and mindful movement. Weekly group sessions will last 45-60 minutes. Participants will be invited to engage in daily practice of mindfulness skills (home practice).

Table 2. Learning 2 Breathe Curriculum

Session	Mindfulness Theme	Mindfulness Topic	Mindfulness Practice
1	Listen! Your body is trying to tell you something.	Define mindfulness	Body scan (short version)
2	Listen! Your body is trying to tell you something.	Mindfulness vs automatic pilot	Body scan (long version)
3	Thoughts are just thoughts.	What thoughts are like A common way to handle certain thoughts	Mindfulness of thoughts
4	Thoughts are just thoughts.	How thoughts affect us	Mindfulness of thoughts

5	Surf the wave of your emotions.	Universality of emotions Emotions and the mind-body connection	Find the feeling (short version)
6	Surf the wave of your emotions.	A common way to handle certain emotions	Surfing the waves of emotions plus gratitude
7	Attention to body, thoughts, and feelings is good stress management.	Basic concepts about stress Universality of stress	Mindful movement
8	Attention to body, thoughts, and feelings is good stress management.	Effects of chronic stress	Mindful movement
9	Learn to be kind to yourself and others	Basic concepts about the brain Practicing mental habits Ways we practice kindness or meanness to ourselves	Loving kindness meditation
10	Learn to be kind to yourself and others	Cultivating well-being	Person just like me
11	Habits for a healthy mind.	Program take-away	Participant choice
12	Habits for a healthy mind.	Closing Ritual	Compassion practice

Compensation:

We will offer $10, $25, and $40 gift cards for the completion of study surveys at baseline (B), the completion of the intervention (T1), and 12 months following the intervention (T2), respectively. We will offer a $10 gift card per group session for attendance. Participants can earn up to $195 in total. This is reasonable because the study encourages the practice of the skills outside of the group sessions.

Study Personnel Responsibilities and Training:

Tamara S. Hannon MD is the PI for this study. Her responsibilities include conceptualizing and designing the study, overseeing the recruitment process, supervising data collection and analysis, as well as critically reviewing and editing the future manuscript.

Julie Pike MPH RDN CDCES is the intervention facilitator. She is a certified diabetes care and education specialist as well as a certified facilitator with The Center for Mind-Body Medicine. She completed the Learning 2 BREATHE training with L2B developer and clinical psychologist Patricia C. Broderick. Her

responsibilities include completing the IRB-approval process, recruiting, and consenting participants, performing data collection and statistical analysis, and manuscript preparation.

Kathryn Haberlin-Pittz MPH CHES is the intervention facilitator. She is a certified health and education specialist. She completed the Learning 2 BREATHE training with L2B developer and clinical psychologist Patricia C. Broderick. Her responsibilities include completing the IRB-approval process, recruiting, and consenting participants, performing data collection, and assisting with further data management needs.

Luz Machuca CHES will serve as the research coordinator and data manager. She is a certified health and education specialist. Her responsibilities include building REDCap data bases, recruiting and consenting participants, performing data collection, sending study visit reminders to participants, and assisting with further data management needs.

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Adverse events will be monitored by the PI and co-investigators. As the participants will be receiving clinical diabetes care and the intervention does not involve a medical intervention or change in medical diabetes therapy, physical adverse events related to the study are not expected. Potential adverse events that could occur include breach of subject confidentiality, loss of privacy in the group setting, discomfort with taking the surveys, and discomfort with the mindfulness skills exercises. Confidentiality will be respected and kept secure as described in section 9.0. Participants will be advised that they do not have to take a survey or answer a question if it causes them discomfort. Participants will be advised that they do not have to participate a particular mindfulness exercise if it causes them discomfort. The group covers topics on thoughts and feelings. If a group member discloses suicidal ideation, the facilitator will administer the Ask Suicide Risk Screening Questions (ASQ) directly after the group session in a one-on one setting to identify the appropriate triage steps. If there is an immediate threat to the participant's safety as indicated by the ASQ, they will be referred to the emergency room for evaluation. The research team will report suicide ideation to the participant's parent or guardian as well as the diabetes social worker. Each event will be handled individually. Adverse events or unanticipated problems involving risk to the participants or others will be reported according to IRB standard operating procedures. If the adverse event represents an unanticipated problem and requires changes to the research protocol, the informed consent process or document, or other corrective actions to protect the safety, welfare, or rights of subjects or others, it will be reported to the IRB using the Prompt Reporting Form within five business days of the investigator becoming aware of the event.

7.0 Study Withdrawal/Discontinuation

The research team will terminate the involvement of a given participant in the research study if they request to stop participating. The criteria which would result in removal from the study are if they request to withdraw from the study or if there has been no communication with the participant in the first two weeks of the study.

8.0 Statistical Considerations

Anticipated statistics for this study will be a combination of descriptive statistics and quantitative statistics. For our primary outcomes, we will examine retention and acceptance, as assessed by overall program attendance, program acceptability, and qualitative interviews. Descriptive statistics will include sex, ethnicity, and survey results at B, T1, and T2.

This study includes a post-intervention group guided interview at 12-weeks. The facilitator will ask the group for feedback about the intervention with the following questions: 1) What did you like about participating in this study? 2) What did you dislike about participating in this study? 3) What were your expectations from participating in this study? 4) Were those expectations met?

A paired t test will be used to compare variables of an individual at baseline and at the end of the study (pre/post), including HbA1c, BMI, BMI z-score, and survey results.

This is a pilot feasibility study, therefore there are no data currently available to accurately calculate power. There are no similar studies to substitute such data.

9.0 Privacy/Confidentiality Issues

Research material obtained from living human subjects will include medical records, with medical information collected by the PI/research team during screening and study visits, as well as data collected from surveys.

Data will be stored in IU REDCap, a secure web platform used to support academic research and is compliant with local and federal regulations for data security and integrity. Access to the study data will be restricted to study personnel.

Any paper records containing identifying information will be kept in locked files accessible only to study staff and unlocked only while a study staff member is physically present. All computer records will require password access; computer workstations will be locked when unattended.

10.0 Follow-up and Record Retention

Timeline

	Year 1				Year 2			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Participant Recruitment								
Intervention								
Data Collection								
Statistical Analysis								
Manuscript Preparation								
Publication and Dissemination								

The duration of record retention will be at least seven years after the study has ended, with the probability of indefinite archiving of study records and data.

11.0 Data Safety Monitoring Plan

Oversight for the conduct of the study will be provided by the study PI Dr. Tamara Hannon. While adverse events are not anticipated, a process has been established for continuous review of data and patient safety. The PI and study team will conduct at least quarterly review meetings of the data. Other members will be included in these meetings at the discretion of the PI. Quarterly meeting summaries will include the number of patients recruited, rate of recruitment refusal, and subject attrition. In addition, the research team will report (1) all causes of mortality and (2) morbidity (including hospitalizations, ER visits, and other injuries/problems resulting from the study protocol). Any adverse events occurring will be documented and reported to the IRB according to the local regulations. Cumulative adverse events and study progress summary will be communicated to the IRB at the time of continuing review.

Several measures will be taken to protect patient confidentiality. Paper records will be minimized by completing the consenting process and surveys directly in the IU REDCap system, a password-protected database with limited access. If a participant requests paper forms, all identifying information collected on paper forms will be entered into IU REDCap. Once identifying information are entered into the "identification database", paper forms will be stored in a locked file cabinet. Data provided by participants verbally, or through written responses to questionnaires and surveys will be stored in individual files, identified by each participant's study code number with one file for each participant. These files will be stored in a locked file cabinet and access to them will be restricted to study personnel only. All data provided by participants will be entered into the IU REDCap database that is separate from the identification database. Data records will be destroyed through shredding seven years after completion of the study.

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