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Integrative, mindfulness group therapy in adolescents with diabetes

Submission date	Recruitment status	[_] Prospectively registered
03/01/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/01/2026	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/11/2026	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Mrs Ashley Lekach

ORCID ID
https://orcid.org/0009-0008-1792-0221

Contact details
325 Clinton Ave, 14 E
Brooklyn
United States of America
11205
+18504455631
ASL9041@nyp.org

Additional identifiers

The DAISY Foundation HE Grant No.
HEG-2024-1142

Study information

Scientific Title

A pilot study of an 8-week, group-based, chakra-informed kundalini yoga intervention for adolescents and young adults with diabetes: feasibility, youth outcomes, and caregiver distress

Study objectives
The purpose of this prospective pilot-based intervention is to evaluate the feasibility, safety, and efficacy of an integrative multi-modal, small-group, wellness intervention for adolescents aged 12-21, diagnosed with Type I and II diabetes. This research will explore integrative therapies' potential to improve blood sugar control, stress and inflammation in children and young adults living with diabetes.

Ethics approval required
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Ethics approval(s)
Approved 03/04/2024, NewYork-Presbyterian Brooklyn Methodist Hospital Institutional Review Committee (NewYork-Presbyterian Brooklyn Methodist Hospital, 506 6th Street, Brooklyn, 11215-9008, United States of America; +1 718/780-5575; pcfullar@nyp.org), ref: 2174522

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Diabetes, Diabetes related distress, Depression, Anxiety, Perceived Stress, Glycemic control, Caregiver related diabetes distress

Interventions
The 8-week intervention includes a series of therapeutic sessions in small groups (3-5 people) utilizing integrative therapy for about 1.5-2 hours. Sessions will be held in a private room on the hospital campus, facilitated by the Primary Investigator, an FNP and Certified Yoga instructor. The format for each session will follow a theme and start with a meditation or prompt, followed by journaling & reflection, group sharing & affirmation, and kinesthetics, specifically, yoga postures. Participants will be given care kits: yoga mat, blocks, strap, water bottle, journal, and pen. In addition to the 8-week intervention, the study participants will complete study

procedures as shown below for intervals of baseline, week 8 and 3 months:
Research surveys: PSS-10, DDS-17 & PDDS-18
Routine visit surveys: Social Determinant of Health, General Anxiety Disorders (GAD-7), and Patient Health Questionnaire (PHQ-9) extracted from the electronic medical record
Biometrics: Body Mass Index, weight, waist circumference
Vitals: Oxygen saturation, heart rate, respiratory rate, and blood pressure
Devices: Continuous Glucose Monitor (CGM)
Laboratory tests: Cortisol, CRP, IL-6, TNF-a, adiponectin, leptin, adiponectin-leptin ratio, HbA1c, vitamin D, TSH, fT4, Creatinine/albumin ratio, lipid profile.

Intervention Schedule:

• Baseline (preliminary labs, biometrics, surveys: SDOH, PHQ9, GAD, DDS-17, PDDS18, PSS-10, CGM within 2+ weeks of intervention, consent).
• Week 1: Root: Security, Grounding, Stability
• Week 2: Sacral: Passion, Creativity
• Week 3: Solar Plexus: Personal, Power, Confidence
• Week 4: Heart: Love, Kindness, Harmony
• Week 5: Throat: Truth, Honesty, Self-Expression
• Week 6: Third Eye: Intuition, Insight, Perception
• Week 7: Crown: Elevating Connections
• Week 8: Closing Ceremony (Reflection/Feedback Survey)
• Upon completion of the program repeat: Labs, biometrics, surveys: DDS-17, PDDS-18, PSS-10, GAD, PHQ9, CGM not exceeding 1-2 weeks
• Schedule 3-month post-intervention endocrine follow-up clinic visit. Obtain final labs, biometrics, surveys: DDS-17, PDDS-18, PSS-10, GAD, PHQ9, CGM 3-month summary

Intervention Type
Behavioural

Primary outcome(s)
1. Diabetes related distress measured using the Diabetes Distress Scale 17item (DDS-17) at baseline (pre), on completion of the program (post), and 3-month follow up

2. Parental diabetes related distress measured using the ParentalDetermined Disease Steps (18item (PDDS-20) at baseline (pre), on completion of the program (post), and 3-month follow up

3. Depression measured using the Patient Health Questionnaire 9item (PHQ-9) at baseline (pre), on completion of the program (post), and 3-month follow up

Key secondary outcome(s)

Completion date
01/11/2025

Eligibility

Key inclusion criteria
1. For the intervention, adolescents aged 12-21 years, all genders, have a minimum of 1 year DM history and type 1 or type 2 diabetes as defined by the American Diabetes Association. Participants who are proficient in English, at a minimum of 3rd grade reading level (for the

purpose of consent/assent).
2. Caregiver(s) will be invited to participate in the SDOH (once during consent) and the PDSS survey at pre,-post, and at the 3 month follow up visit with endocrinology. A caregiver is considered any member of the family that directly interacts with daily diabetes management.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 Years

Upper age limit
21 Years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Adolescents less than 12 years of age
2. Non-English speaking
3. Less than 1 year history of type 1 and type 2 diabetes as defined by the American Diabetes Association

Date of first enrolment
01/07/2024

Date of final enrolment
05/08/2024

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
DAISY Foundation

ROR
https://ror.org/052fbzq52

Funder(s)

Funder type

Funder Name
DAISY Foundation

Alternative Name(s)
DAISY, The DAISY Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/03/2026	25/11/2026	Yes	No