The Diabetes Body Project: Multi-site trial of a virtually delivered eating disorder prevention program for young females with type 1 diabetes

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON53556

Source
ToetsingOnline

Brief title
Diabetes Body Project

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Eating disorders and disturbances

Synonym
Diabetes Mellitus Type 1, type 1 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Oslo University Hospital
Source(s) of monetary or material Support: JDRF / Oslo University Hospital

Intervention

Keyword: eating disorders, prevention, RCT, type 1 diabetes

Outcome measures

Primary outcome

Eating disorder behaviors, eating disorder symptoms, and future eating disorder

onset over 2-years follow-up.

Secondary outcome

Diabetes distress, diabetes illness perceptions, quality of life, glycemic

control, diabetes ketoacidoses and hospitalizations

Study description

Background summary

Young females with type 1 diabetes (T1D) show a 60% lifetime incidence of eating disorders, which is 462% greater than in young females without T1D. Eating disorder behaviors (e.g., dietary restriction, insulin omission) and symptoms (e.g., binge eating, vomiting for weight loss) increase risk for poor glycemic control and consequent morbidity and mortality from T1D. Theoretically, T1D amplifies pursuit of the thin appearance ideal, body dissatisfaction, dietary restriction, and negative affect, which are established risk factors for eating disorders because insulin treatment causes weight gain, strict dietary control is necessary for T1D management, and T1D contributes to negative affect (e.g., depression and anxiety). Thus, developing and evaluating interventions that prevent eating disorder symptoms/behaviors and eating disorder onset in this ultra-high-risk population is a key public health priority.

Study objective

We aim to investigate the efficacy of a novel eating disorder prevention

program, the Diabetes Body Project, specifically targeting young females T1D. Firstly, we will test the hypothesis that Diabetes Body Project will produce significantly greater reductions in eating disorder behaviors, eating disorder symptoms, and future eating disorder onset among young people with T1D over 2-year follow-up than educational controls (primary outcomes). Further, we will test the hypothesis that Diabetes Body Project participants will show greater improvements in diabetes distress, diabetes illness perceptions, and quality of life over 2-year follow-up than educational controls (secondary outcomes). Moreover, we will test the hypothesis that Diabetes Body Project participants will show greater improvements in glycemic control (HbA1c and time-in-range; TIR), and reduction in episodes of diabetic ketoacidosis, and hospitalization over 2-year follow-up than educational controls.

Study design

This is an international, multi-site collaboration, inviting young females with T1D in Oslo (Norway), Amsterdam (the Netherlands), Boston (USA), and San Francisco (USA) to participate in a randomized controlled trial including two body acceptance interventions: The Diabetes Body Project and educational video*s.

Intervention

Diabetes Body Project: 6 weekly 1-hour virtual group sessions

Study burden and risks

All participants will complete questionnaires online 5 times over the 2 years. This will take approximately 30 minutes per measurement point. In addition diagnostic interviews will be conducted by telephone which take about 30 minutes as well. To assess HbA1c, participants will receive a test kit at home and be asked to draw blood by a finger prick, comparable with their regular blood glucose tests. Participants in the Diabetes Body Project group will participate in six 1-hour group sessions (weekly). Participants in the educational control group will be asked to watch 6 hours of educational video*s. Both groups might benefit in terms of body acceptance and eating behaviours as it has been shown that the educational videos are effective although probably not as effective as the Diabetes Body Project.
Based on experiences from more than 20 years of standard Body Project research, potential risk to participants are considered minimal and unlikely. In terms of the Diabetes Body Project, a pilot was conducted at Oslo University Hospital. No adverse effects were recorded. However, a couple of participants withdrew from the study stating that during the course of the group meetings, they had realized that they had more challenges related to body image than they were previously aware of, which made group meetings difficult. In those cases, we had a conversation with them and agreed that they should talk to their diabetes

clinician about this individually. For the remaining participants, qualitative interviews post Diabetes Body Project participation revealed that they had increased awareness and more tools to deal with body pressures and body image concerns. This finding is also supported by our quantitative pilot data, showing significant improvements in ED risk factors and symptoms. Based on this, we are confident that benefits outweighs the potential risks for research participants and others.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

type 1 diabetes; diagnosed at least 1 year ago; age 14-35 years

Exclusion criteria

DKA with hospitalization in the last year; hospitalization for eating disorder in the past year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05399446
CCMO	NL81681.029.22