ISRCTN71990442 https://doi.org/10.1186/ISRCTN71990442

A clinical trial designed to understand if participation in a clinical program developed specifically to support emerging adults with type 1 diabetes leads to improved diabetes outcomes

Submission date
18/11/2025

Recruitment status
Recruiting

Registration date
21/11/2025

Overall study status
Ongoing

Last Edited
20/11/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many emerging adults with type 1 diabetes find it difficult to maintain their blood sugar levels within the recommended range most of the time. This can increase their risk for serious short- and long-term diabetes-related health problems. Managing diabetes becomes especially difficult during the transition from pediatric care to adult care when emerging adults are expected to manage their condition on their own.

The Achieving Health in Emerging Adults with Diabetes (AHEAD) Program was developed to support emerging adults with their transition to independence. It focuses on helping them build the skills, motivation, and confidence needed to manage their diabetes independently. The program is based on the self-determination theory and best practices for supporting successful healthcare transitions.

This study will test the effectiveness of the AHEAD Program.

Who can participate?
Emerging adults between the ages of 16-19 who have had type 1 diabetes for more than one year, a recent A1C ≥7.0%, can complete written surveys, and can receive care at Seattle Children' s Diabetes Clinics for the next 2 years.

What does the study involve?
Participants are randomly allocated into Usual Care or AHEAD. Participants will have 6 clinic visits and complete surveys around the time of their clinic visits. Usual Care participants will continue to receive the diabetes care they currently receive every three months. AHEAD participants will receive support from a team of diabetes providers who have expertise in supporting emerging adults living with diabetes.

What are the possible benefits and risks of participating?
The findings from this study may help us understand how to best support emerging adults with type 1 diabetes. By taking part in this study, there are no risks of physical injury or harm.

Where is the study run from?
University of British Columbia (Canada) and Seattle Children's Hospital (United States of America)

When is the study starting and how long is it expected to run for?
December 2025 to August 2029

Who is funding the study?
BreakthroughT1D

Who is the main contact?
Dr. Faisal Malik, faisal.malik@bcchr.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Faisal Malik

ORCID ID
https://orcid.org/0000-0002-2543-4214

Contact details
4480 Oak Street
Vancouver
Canada
V6H 3V4
604-875-2117
faisal.malik@bcchr.ca

Additional identifiers

Protocol serial number
4-SRA-2024-1580-M-B

Study information

Scientific Title
Achieving Health in Emerging Adults with Diabetes (AHEAD) Program: In emerging adults with type 1 diabetes, does the AHEAD Program when compared to usual care improve glycemia, diabetes distress, and health care transition readiness?

Acronym

AHEAD Program

Study objectives
1. Determine the AHEAD Program's effectiveness in improving diabetes outcomes in a pragmatic randomized controlled trial.
HYPOTHESIS: The AHEAD Program will be associated with improved glycemia, reduced diabetes distress, and higher health care transition readiness compared to usual care.

2. Evaluate the impact of the AHEAD Program on self-determination theory constructs and their potential mediating role in improving diabetes outcomes.
HYPOTHESIS 1: The AHEAD Program will improve autonomy, competence, and relatedness compared to usual care.
HYPOTHESIS 2: Self-determination theory constructs will mediate the effect of the AHEAD Program on glycemia.

3. To evaluate the costs and cost-effectiveness of the AHEAD Program.
HYPOTHESIS: The AHEAD Program will be cost-effective relative to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/02/2025, Seattle Children's Institutional Review Board (MS 818-RI PO Box 5371, Seattle, 98145, United States of America; +1 206-987-7804; IRB@seattlechildrens.org), ref: STUDY00005176

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes in emerging adults

Interventions

This is a pragmatic randomized controlled trial that will use a hybrid type 1 effectiveness-implementation study design. This study is a single-centre.

Participants will be recruited through referrals or direct approach from Seattle Children's diabetes clinics. After providing informed consent, participants will be randomized in a 1:1 ratio to either the Usual Care arm or the AHEAD arm. Randomization is performed using a computer-generated sequence within the REDCap randomization module.

Participants in each arm will attend six diabetes clinic visits, scheduled approximately every three months. Before each clinic visit, participants will complete brief electronic surveys. Glycemia data will be collected as part of diabetes clinic visit.

Usual Care participants will continue to receive diabetes care from their current medical team. AHEAD participants will continue to come to their usual medical facility for diabetes care but instead of receiving care from their current medical team, they will be seen by a new team of AHEAD providers during their clinic visit. The AHEAD team consists of providers who specialize in the care of emerging adults with diabetes and who focus on preparing and supporting participants with independence with their diabetes management.

Total participant involvement is approximately 18 months, ending after completion of their sixth clinic visit and final surveys. Some participants may be in the study for longer than 18 months if they are unable to schedule clinic visits every 3 months because of participant scheduling conflicts or medical team capacity constraints.

Intervention Type
Mixed

Primary outcome(s)
1. Glycemia measured using hemoglobin A1c levels collected via point-of-care (in-person clinic visit) or dried blood spot (telemedicine visit) testing at 3, 6, 9, 12, 15, and 18 months

Glycemia measured using hemoglobin A1c levels approximately every 3 months.

Key secondary outcome(s))
1. Time in range (70-180 mg/dL) will be measured using continuous glucose monitor sensor glucose values at 3, 6, 9, 12, 15, and 18 months
2. Time below range (<70 mg/dL) will be measured using continuous glucose monitor sensor glucose values at 3, 6, 9, 12, 15, and 18 months
3. Time above range (>180 mg/dL) will be measured using continuous glucose monitor sensor glucose values at 3, 6, 9, 12, 15, and 18 months
4. Diabetes distress measured using Problem Areas in Diabetes - Teen and Parent of Teen Version approximately at 3, 6, 9, 12, 15, and 18 months
5. Depression measured using Patient Health Questionnaire – 9 at 3, 6, 9, 12, 15, and 18 months
6. Social needs measured using social needs/determinants of health questionnaire at 3, 6, 9, 12, 15, and 18 months
7. Health care transition readiness and competence measured using Readiness Assessment of Emerging Adults with Type 1 Diabetes tool and Transition Readiness Assessment Questionnaire at 3, 6, 9, 12, 15, and 18 months
8. Disordered eating measured using Disordered Eating Problem Survey – Revised at 3, 6, 9, 12, 15, and 18 months
9. Anxiety measured using Generalized Anxiety Disorder – 7 survey at 3, 6, 9, 12, 15, and 18

months
10. Diabetes self-management measured using Self-Care Inventory-Updated questionnaire at 3, 6, 9, 12, 15, and 18 months
11. Diabetes family conflict measured using Diabetes Family Conflict Scale at 3, 6, 9, 12, 15, and 18 months
12. Autonomy measured using Treatment Self-Regulation Questionnaire at 3, 6, 9, 12, 15, and 18 months
13. Relatedness measured using Health Care Climate Questionnaire at 3, 6, 9, 12, 15, and 18 months

Completion date
31/08/2029

Eligibility

Key inclusion criteria
1. 16-19 years-old
2. Have had type 1 diabetes≥ 12 months
3. Had a recent A1C ≥7.0%
4. Currently receive outpatient diabetes care at a Seattle Children's Hospital Diabetes Clinic located in Bellevue, Everett, Federal Way, or Seattle
5. Are able to complete written surveys
6. Will be able to receive clinical care in WA state for the next 2 years

Participant type(s)
Carer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
19 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have had a pilot program AHEAD clinic visit
2. Most recent Usual Care diabetes visit was with a current AHEAD provider.

Date of first enrolment

01/12/2025

Date of final enrolment
01/06/2027

Locations

Countries of recruitment
United States of America

Study participating centre
Seattle Children's Hostipal
4800 Sand Point Way NE
Seattle
United States of America
98105

Sponsor information

Organisation
University of British Columbia

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Not defined

Funder Name
Breakthrough T1D

Alternative Name(s)
Juvenile Diabetes Foundation, Juvenile Diabetes Research Foundation, JDF, JDRF

Funding Body Type
Government 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
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (OpenScience Framework: https://osf.io/). Shared data generated from this project will be available no later than the time of publication of the analyses examining the study's primary aims. The duration of preservation and sharing of the data will be a minimum of 10 years after the funding period.

To address privacy and confidentiality concerns, sharing of data generated will be limited to de-identified data at the aggregate level and access, distribution, and reuse of the data be controlled by the study investigators.

IPD sharing plan summary
Stored in publicly available repository