ISRCTN13459962 https://doi.org/10.1186/ISRCTN13459962

Transition of youth with type 1 diabetes from pediatric to adult diabetes care with a transition coordinator using communication technologies

Submission date
20/01/2020

Recruitment status
No longer recruiting

Registration date
22/01/2020

Overall study status
Completed

Last Edited
14/01/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The transition from pediatric to adult diabetes care is associated with high rates of medical follow-up dropout. Young adults with type 1 diabetes may be difficult to engage through traditional modes of communication. This study aims to address this care gap by using a technology-enhanced transition coordinator, a liaison between patients and healthcare services, to facilitate seamless care during the transition period.

Who can participate?
Youth with type 1 diabetes aged 17 or 18

What does the study involve?
A transition coordinator connects with young adults with type 1 diabetes using communication technologies commonly used by this age group, including texting, email and social media. The researchers assess the impact of a technology-enhanced transition coordinator by comparing a group of young adults with diabetes who had access to this service to a group who did not.

What are the possible benefits and risks of participating?
It is hoped that this intervention will reduce the number of young adults with diabetes who fall out of medical follow-up. This study will provide crucial information that will help improve care practices for this vulnerable population. The possible risk to consider is the threat to privacy and confidentiality with new communication technologies. In order to contain this risk, the researchers will be working closely with the Privacy Office to ensure that they take all measures possible to protect patients' privacy.

Where is the study run from?
Alberta Children's Hospital (Canada)

When is the study starting and how long is it expected to run for?
January 2013 to March 2019

Who is funding the study?
The Lawson Foundation (Canada)

Who is the main contact?
Dr Sonia Butalia
sbutalia@ucalgary.ca

Contact information

Type(s)
Scientific

Contact name
Dr Sonia Butalia

Contact details
1820 Richmond Road SW
Calgary
Canada
T2T 5C7
+1 (0)4039558327
sbutalia@ucalgary.ca

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Transition of youth with type 1 diabetes with a technology-enhanced transition coordinator

Study objectives
It is hypothesized that the technology-enhanced transition coordinator will reduce loss to follow up in youth with type 1 diabetes transitioning from pediatric to adult diabetes care.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 17/11/2014, Conjoint Health Research Ethics Board (CHREB) (Research Services Office, 2500 University Drive, NW, Calgary AB T2N 1N4, Canada; Tel: +1 (403) 220-2297; Email: chreb@ucalgary.ca), ID #REB14-1158

Study design
Multi-center open-label non-randomized multicentre clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
The usual care group was a historical group not exposed to the transition coordinator for a period equivalent to the intervention prior to the start of the intervention. The intervention group had the transition coordinator role established as “standard of care for all patients” attending pediatric clinics for the period of the intervention.

Both usual care and intervention groups received routine diabetes and transition care as per national diabetes guidelines. Usual care included regular appointments with their pediatric diabetes care team (endocrinologist, diabetes nurse, dietician and on an as needed with a psychologist and/or a social worker) and transition discussions starting at age 14. The intervention group was provided additional support by way of a non-medical transition coordinator during the transition and transfer from pediatric to adult diabetes care. The transition coordinator role included the: use of text messaging or email communication (as per participant’s preference) every 2 months and as needed by participants, communication with pediatric and adult diabetes teams regarding emergency visits or hospitalizations, and supporting participants (i.e. completion of forms, finding a family doctor, psychosocial resources). The intervention group were also encouraged to use a transition website and were invited to join a private Facebook® page moderated by the transition coordinator. The transition coordinator met in person with individuals at least 6 months prior to referral to adult diabetes care and continued their support for 12 months past the transfer date. Both usual care and intervention groups had routine adult diabetes care which included their endocrinologist and as needed visits with a diabetes educator and/or a dietician. Follow up was for 18 months post transfer for both study arms.

Intervention Type
Other

Primary outcome measure
Proportion of participants that did not attend at least one routine clinic visit in adult diabetes care within 1 year after transfer

Secondary outcome measures
Measured at 12 and 18 months post-transfer:
1. Diabetes-related clinical outcomes (i.e., hemoglobin A1c, albumin:creatinine ratio (ACR), number of A1c's, number of ACRs, emergency department visits and hospitalizations for diabetic ketoacidosis)
2. Quality of life measured using Diabetes Self-Efficacy questionnaire, Problem Areas in Diabetes questionnaire, Diabetes Quality of life for Youth questionnaire, and a program satisfaction questionnaire

Overall study start date
01/01/2013

Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. Diagnosis of type 1 diabetes according to the American Diabetes Association for at least the last 6 months
2. Aged 17 to 18 years
3. Had been seen by their pediatric endocrinologist in the last 12 months
4. In the last year of pediatric care and transitioning to an adult care site in the city within the next year
5. A Personal Health Number (PHN) for data linkage

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
142

Total final enrolment
303

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/01/2013

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
Canada

Study participating centre
Alberta Children's Hospital
28 Oki Drive NW
Calgary
Canada
T3B 6A8

Study participating centre
Diabetes Centre
1820 Richmond Road SW
Calgary
Canada
T2T 5C7

Study participating centre
Peter Lougheed Hospital
3500 26 Avenue NE
Calgary
Canada
T1Y 6J4

Study participating centre
Associate's Clinic
401-9 Avenue SW
Calgary
Canada
T2P 3C5

Sponsor information

Organisation
University of Calgary

Sponsor details
2500 University Drive NW
Calgary
Canada
T2N 1N4
+1 (0)403 220 5110
sbutalia@ucalgary.ca

Sponsor type
University/education

Website
https://www.ucalgary.ca/

Funder(s)

Funder type
Charity

Funder Name
Lawson Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
Canada

Results and Publications

Publication and dissemination plan

The researchers plan to publish the study protocol and statistical analysis. The trial (including focus groups that informed the intervention) results will be disseminated through presentations, conferences and peer-reviewed journals.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sonia Butalia (sbutalia@ucalgary.ca). The data will be in anonymized form and in numerical format. The data will become available within 2-4 weeks of request and sent electronically with password protection and encryption. The data will be available for the analyses conducted in this study and for up to five years post study completion. The ethical and legal restrictions are as per the researchers' Institution (The University of Calgary; www.ucalgary.ca and its ethics board for human research, the Conjoint Health Research Ethics Board).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2021	14/01/2021	Yes	No