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Helping Albertans with diabetes: a pharmacist-led care program in community pharmacies

Submission date
05/10/2025

Recruitment status
Recruiting

Registration date
06/10/2025

Overall study status
Ongoing

Last Edited
06/10/2025

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

Type 2 diabetes is common in Alberta and many people don't reach targets for A1C, blood pressure, and cholesterol. This study will test whether a structured, pharmacist-led care pathway using a simple computer decision-support tool and shared decision-making helps adults with poorly controlled type 2 diabetes lower A1C and improve heart-health risk. The main aim is to compare change in A1C over 6 months between the new pathway and usual care. Secondary aims include changes in calculated cardiovascular (CV) risk, blood pressure, LDL-cholesterol, completion of routine diabetes checks, vaccinations, patient satisfaction, and the extent of shared decision-making.

Who can participate?

Adults (aged 18+ years) in Alberta with type 2 diabetes whose A1C is above target (>7%). People with type 1 or gestational diabetes, those already at their personal A1C target, pregnant individuals, or people unable to consent/attend follow-ups are not eligible.

What does the study involve?

After consent and a baseline questionnaire, participants are randomly assigned to one of two groups:

Intervention group: Ongoing pharmacist care using a step-by-step tool based on Canadian guidelines. It calculates personal cardiovascular risk (EPI·RxISK™), sets individualized targets, suggests medication/lifestyle options, and books follow-ups every 6 weeks for 6 months. Pharmacists can adjust or prescribe medicines and order labs within their scope, and they share plans with the participant's primary care team.

Control group: Their pharmacist gathers current diabetes information and gives them a letter with their A1C to take to their family doctor or nurse practitioner. They get a brief lifestyle visit at 3 months and a final visit at 6 months. After the study, they're offered the full pharmacist pathway.

What are the possible benefits and risks of participating?

Possible benefits: Closer follow-up, clearer treatment plan, potential improvements in A1C and

overall CV risk, and help staying on track with screenings and vaccinations.
Possible risks: More frequent visits and blood tests may cause inconvenience, brief anxiety, needle discomfort, or (rarely) infection from blood draws. Participants can withdraw at any time.

Where is the study run from?
In community pharmacies (including pharmacist-led clinics) across Alberta, Canada.

When is the study starting and how long is it expected to run for?
January 2025 to December 2026

Who is funding the study?
University of Alberta via the Shoppers Drug Mart Research Primary Care Grant.

Who is the main contact?
Dr Stephanie Gysel, sgysel@ualberta.ca

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Implementation and evaluation of a pharmacist-led diabetes care pathway in Alberta community pharmacies (D-PATH)

Acronym
D-PATH

Study objectives
Primary Objective:
To determine the effect of a pharmacist-led diabetes care pathway on participants' glycemic control in individuals with poorly controlled type 2 diabetes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/03/2025, University of Alberta Health Research Ethics Board (11312-89 Ave NW, Edmonton, T6G 2N2, Canada; +1 (0)7804920459; arise@ualberta.ca), ref: Pro00145395

Study design
Multicenter interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions

Participants in the intervention arm will receive the care using a shared decision-making pharmacist care pathway approach designed to guide type 2 diabetes management to achieve target A1C levels and reduce the risk of diabetes-related complications. The pharmacist care pathway is modelled after the Canadian Diabetes Association Guidelines. This pathway (tool) will be built into a computer web-based program and include step-by-step, algorithm-guided patient assessment to achieve target A1C levels and reduce the risk of diabetes-related complications. This tool will also calculate the participant's estimated CV risk.

The participant and pharmacist will be guided by the care pathway to review the participant's current type 2 diabetes management and diabetes-related complication risk factors and engage in shared decision-making to guide further management of diabetes. The care pathway will suggest individualized follow-up plans, guideline-driven targets (e.g., A1C or blood pressure or serum lipid concentration targets) and treatments (including lifestyle modifications and medications). The pharmacist and participant will be prompted to reach an agreed diabetes management plan and book a follow-up appointment in 6 weeks' time.

Follow-up appointments will continue every 6 weeks for 6 months. Participants' treatment regimen may be adapted by initiating new prescriptions medications or adjusting the dosage or frequency of prescription medications or ordering laboratory tests. All the aforementioned activities are within the scope of practice for pharmacists in Alberta (https://www.pharmacists.ca/advocacy/scope-of-practice/). As such, pharmacists can perform them as part of the routine care they are providing to their patients.

Control group:
The control group will involve facilitated relay of information to participants' family physician or nurse practitioner. Participants in the control group will have their pharmacist collect information informing the patient's current diabetes control. Participants will then be given a letter that contains their A1C value, and they will be advised to present it to their family physician or nurse practitioner. No specific suggestions for diabetes management will be detailed in the letter. In the case where the patient does not have a family physician or nurse practitioner, they will be referred to a physician walk-in clinic. Note, this may result in confounding of the control group. A follow-up appointment will be booked for all participants in the control group at 3 months to discuss dietary and lifestyle interventions in the management of type 2 diabetes to maintain participant interest in the study and again at 6 months' time for a final visit.

During the 6-month follow-up appointment, participants will have their diabetes management reassessed. At the end of the study period (after the 6-month follow-up appointment), all the participants in the control group will be offered to receive care using the shared decision-making pharmacist care pathway approach designed to guide the type 2 diabetes management process (received by participants in the intervention arm).

Randomization:
Individual patients will be the unit of randomization.
Study participants will be randomized on a 1:1 ratio to the intervention or control groups using a variable blocked randomization.
Randomization will be conducted using a centralized randomization service by EPICORE to ensure allocation concealment.

Intervention Type
Other

Primary outcome(s)
Glycemic control measured using A1C at baseline and at 6 months

Key secondary outcome(s))
1. Cardiovascular risk measured using the EPIRISK calculator at baseline and at 6 months
2. Blood pressure measured using a standardized blood pressure monitor at baseline and at 6 months
3. LDL measured using a standardized lipid panel at baseline and at 6 months
4. Number of patients completing influenza and pneumococcal immunization measured by assessment of patient records at 6 months
5. Number of patients who completed annual foot exams, eye exams, and kidney function screening measured by assessment of patient records at 6 months
6. Number of patients who have appropriate vascular protection in place measured by assessment of patient records at 6 months
7. Types of interventions provided by the pharmacists including education on lifestyle factors (tobacco cessation, diet, exercise), prescribing or changing the dose of medications, education on new or changed medications, education on adherence to medications and/or lifestyle recommendations measured by assessment of patient records at 6 months
8. The percentage of individuals who attended their scheduled laboratory assessments measured by assessment of patient records at 6 months
9. The percentage of individuals who use continuous glycose monitoring devices as part of their type 2 diabetes management measured by assessment of patient records at 6 months
10. Patient satisfaction as measured by the diabetes treatment satisfaction questionnaire standard and change at baseline and at 6 months
11. Extent to which shared decision making was achieved in the intervention as measured by the validated Shared Decision Making 9-item Questionnaire (SDM-Q-9) tool at 6 months

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Individuals aged 18 years or older
2. Individuals with type 2 diabetes, further assessed to rule out latent autoimmune diabetes in adults (LADA) or maturity onset diabetes of the young (MODY) by asking patients: “Do you have diabetes that does not require the use of insulin, or did not require the ongoing consistent use of insulin immediately after diagnosis for more than 6 months after diagnosis” AND “Did you develop diabetes as a result of damage to the pancreas such as acute/chronic pancreatitis, or pancreatic surgery?”
3. Individuals with type 2 diabetes not reaching HbA1c target of ≤7.0%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals with type 1 diabetes, gestational diabetes, or other forms of diabetes that are not type 2 diabetes
2. Pregnant individuals
3. Individuals at their HbA1c target (HbA1c ≤7.0%) or those with a limited life expectancy, frailty, or lack hypoglycemic awareness (i.e., those with an A1c target >7.0%)
4. Individuals unable to provide consent or who are unwilling to attend follow-up visits

Date of first enrolment
13/10/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta
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Sponsor information

Organisation
University of Alberta

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type

Government

Funder Name
Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta

Alternative Name(s)
Faculty of Pharmacy and Pharmaceutical Sciences, Ualberta, Faculty of Pharmacy and Pharmaceutical Sciences, U of A

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Stephanie Gysel (sgysel@ualberta.ca).

Anonymised individual participant data (IPD) that support the findings of this study will be made available, along with relevant supporting documentation (e.g., data dictionary, protocol, and statistical analysis plan) by request. No information that could directly identify participants will be shared.

The anonymised dataset will become available by request approximately 12 months after publication of the main trial results. Data will remain available for a minimum of 5 years after publication, in accordance with University of Alberta and EPICORE Centre data-retention policies.

Access may be granted to researchers wishing to conduct secondary analyses that are consistent with the aims of the original study—such as investigations into diabetes management, pharmacist-led care models, or health-services outcomes. Data will not be shared for commercial use or any analyses unrelated to these research themes.

Requests for access should be made in writing to the EPICORE Centre, University of Alberta (the study's data management centre). Researchers must submit:
1. A brief proposal outlining the intended analysis
2. Evidence of institutional ethics approval (if applicable) and
3. A signed data-use agreement.
Requests will be reviewed by the study investigators and EPICORE's data access committee before data release. Approved users will receive de-identified data through a secure, password-protected file transfer system.

Written informed consent will be obtained from all participants before enrollment. The consent process will include clear information about study procedures, data collection, possible risks and benefits, and how participant data will be stored, anonymised, and potentially shared for future ethically-approved research.

Before any data are shared outside the research team:
All personal identifiers (e.g., names, addresses, contact details, health card numbers, dates of birth) will be removed.
Participants will be assigned a unique study identification number.
The key linking study IDs to personal identifiers will be stored separately in a secure, password-protected database accessible only to authorised EPICORE staff.
Data will be checked for indirect identifiers (e.g., small subgroups or rare conditions) to ensure no risk of re-identification.
Only anonymised datasets will be used for analysis and any external sharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/10/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes