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Reorganizing the approach to diabetes through the application of registries

Submission date	Recruitment status	☐ Prospectively registered
05/10/2016	No longer recruiting	☒ Protocol
Registration date	Overall study status	☐ Statistical analysis plan
07/10/2016	Completed	☒ Results
Last Edited	Condition category	☐ Individual participant data
05/05/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a lifelong condition where the pancreas doesn't produce enough insulin or the body's cells don't react to insulin, causing a person's blood sugar level to become too high. It is well known that type 2 diabetes impacts Indigenous/First Nations people across the world, including Canada. Overall, the rate of type 2 diabetes in First Nations communities is 3-5 times higher than the general Canadian population. Healthcare for people with type 2 diabetes is becoming more of a team effort with patients not only seeing physicians, but nurses, dieticians, pharmacists and other healthcare providers. It's important that clinical information is tracked, shared, reviewed and individualized. Most people living in First Nations communities are isolated, with limited access to regular healthcare and specialist services. Most healthcare is delivered by nurses and community health workers, making team-based care challenging and expensive. Often it is up to the patients to navigate and seek the best care. This gap in services, along with other challenges like physician/nursing shortages, cultural barriers and living in remote communities, leads to high rates of diabetes complications, like dialysis, blindness, and shorter life expectancy. RADAR is a project focused on caring for people with type 2 diabetes living on First Nation reserves in Alberta. RADAR combines information systems (for tracking and registering patients) and a care coordinator. The aim of this study is to assess the effectiveness of RADAR at improving the quality of clinical care of First Nations people living with type 2 diabetes on reserve.

Who can participate?
Patients aged 18 or over with type 2 diabetes who have recently (within last 1-2 years) received care from the First Nations health facility

What does the study involve?
RADAR works behind the scenes, and patients may not even know about it. It provides a service to local nurses and community health workers to help them manage their type 2 diabetes patients. It improves care and ensures that it is provided in the best available manner. RADAR is introduced sequentially to the participating communities in consecutive 4-6 month periods, based on the communities 'readiness'. The care coordinator works with local healthcare workers to identify patients with type 2 diabetes and register them into the CARE platform, a secure system that helps record, track and assess people with diabetes in the community. The care

coordinator works with local healthcare workers to manage patients with type 2 diabetes. Success is measured through improvements in A1c (a blood sugar test), blood pressure and cholesterol. Other areas of diabetes care are also looked at, like foot and eye examinations, receipt of vaccinations, smoking cessation counselling, and the proportion of patients linked to a health services provider.

What are the possible benefits and risks of participating?
If RADAR can better organize care, there may be savings to the healthcare system. The largest benefits will be seen by patients through the improvement of care for their diabetes. Community health workers will have greater knowledge of diabetes and its care, helping to provide the best care to patients. There are no risks to patients. All activities are the same as those for regular diabetes clinical care. The only potential harms are related to privacy of health information. All data provided to the research team will be non-identifiable. As a result, any such risk is minimal.

Where is the study run from?
1. Bigstone Health Commission (Canada)
2. Aakom Kiiyi Health (Canada)
3. Saddle Lake Cree Nation (Canada)

When is the study starting and how long is it expected to run for?
January 2015 to September 2020

Who is funding the study?
1. Alberta Innovates Health Solutions (AIHS) (Canada)
2. Canadian Institutes for Health Research (CIHR) (Canada)
3. Lawson Health Research Institute (Canada)

Who is the main contact?
Dr Dean Eurich

Contact information

Type(s)
Scientific

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Protocol serial number
Pro00048714

Study information

Scientific Title
Reorganizing the Approach to Diabetes through the Application of Registries: a non-randomized cross-over trial

Acronym
RADAR

Study objectives
Our primary objective is to implement and assess the effectiveness of an integrated population based electronic health record (EHR)/registry system specifically designed for First Nations communities (Community Assessment Response and Empowerment [CARE] platform), coupled with dedicated support from a centralized care coordinator (CC) to systematically organize proactive diabetes care in the communities to improve diabetes-related outcomes. Thus, RADAR is the combination of the CARE platform and the CC support. We hypothesize that RADAR will result in an overall improvement in the quality of clinical care of First Nations people living with type 2 diabetes on reserve, as measured by evidence-based outcomes (A1c, BP, cholesterol) and quality of care indicators (e.g., foot and eye examinations). We believe that RADAR will help promote timely management of people with type 2 diabetes and increase diabetes knowledge and management practices among local healthcare workers. In addition, managers can use the EHR/registry to track diabetes trends, determine the effectiveness of diabetes programs, and assist in resource planning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Alberta Health Research Ethics Board, 17/08/2015, ref: Pro00048714

Primary study design
Interventional

Study design
Modified stepped wedge controlled trial design

Study type(s)
Other

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

Interventions
This is a modified stepped-wedge controlled implementation trial. It's a cross-over design, whereby each community serves as its own control before 'switching' to the intervention at

different time points. In essence, RADAR will be implemented sequentially to the communities in consecutive 4-6 month periods, based on the communities 'readiness'. By the end of the evaluation period, RADAR will have been implemented in all the communities.

The RADAR model incorporates two distinct elements: a custom EHR, integrated with a population-based diabetes registry and analytics platform – CARE platform; and, a centralized care coordinator (CC). The CARE platform was designed by OKAKI Health Intelligence Inc. to meet the specific requirements of nursing-driven health programs currently being delivered on reserve in Canadian First Nations communities.

The CC is a First Nations registered nurse and certified diabetes educator with significant experience with care on reserve. The CC will work remotely with the local healthcare workers on reserve to improve quality of care for people with diabetes, facilitated through shared use of the CARE platform and web conferencing technologies. The CC supports systematic review of patients and case conferencing activities to support and prioritize care, problem-solves system or patient-level care issues, and provides education to local healthcare workers. In addition, the CC acts as a bridge between the First Nations communities and other service providers to help coordinate patient care on and off reserve. Together, both RADAR elements address the 5Rs in organizing diabetes care, that is, recognize, register, relay, recall, and resource, in the First Nations context. In addition, managers and researchers can use the analysis of population-level data for epidemiological assessments, quality-improvement, and decision-making.

Specifically, during the baseline phase, the CC will work with local healthcare workers to identify patients with type 2 diabetes and register them into the CARE platform, but not make any management recommendations. All patients will be registered into the CARE platform, including their demographic and clinical data (e.g. A1c, blood pressure, lipids, eye exams, foot care), where available. Patient information to populate the baseline data will be obtained from all potential sources (e.g., medical records, patient interviews, Alberta's provincial EHR for laboratory results (Netcare)). All available data up to 18 months prior to the end of the baseline period will be used to populate CARE, as patient encounters with the health system may not be consistent.

During the intervention phase, the CC will work with local healthcare workers to proactively manage patients with type 2 diabetes, including monitoring and recall of patients, relaying clinical information and coordinating care, facilitated through the shared use of the CARE platform.

At the end of the intervention (minimum 1 year, depending on the community), clinical data (e.g., A1c, blood pressure, lipids, eye exams, foot care) will be extracted from the CARE platform. All relative changes will be analyzed using the last known recorded value.

The intervention will last approximately 1 year, depending on the community's capacity. Towards the end of the intervention phase, the Care Coordinator will gradually diminish support and transfer responsibilities.

Intervention Type

Other

Primary outcome(s)

1. A1c
2. Blood pressure
3. Cholesterol

Data collected for regular clinical care is used to assess the primary and secondary outcomes.

There is no additional data collected from patients specific to the RADAR study. It may be considered a type of chart review. Timepoints: baseline, end of Intervention (minimum 1 year, depending on the community).

Key secondary outcome(s)

1. The proportion of clinical measures and tasks completed in accordance with Canadian Diabetes Association Clinical Practice guidelines (e.g., A1c, BP, cholesterol, foot and eye examination, receipt of vaccinations, smoking cessation counseling)
2. The number of patients registered in CARE
3. The proportion of patients linked to a health services provider

Data collected for regular clinical care is used to assess the primary and secondary outcomes. There is no additional data collected from patients specific to the RADAR study. It may be considered a type of chart review. Timepoints: baseline, end of Intervention (minimum 1 year, depending on the community).

Completion date

30/09/2025

Eligibility

Key inclusion criteria

1. Patients >18 years of age diagnosed with type 2 diabetes
2. Recently (within last 1-2 years) received care from the First Nations health facility
3. Provided verbal consent for First Nations health care workers to manage their diabetes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients with type 1 diabetes
2. Patients <18 years of age
3. Those who are subsequently discovered not to have type 2 diabetes (and were not initially in the baseline period)
4. Those refusing care within the First Nations health facility; patients with type 2 diabetes identified after the conclusion of the baseline phase of the project

Date of first enrolment

01/01/2015

Date of final enrolment
30/08/2023

Locations

Countries of recruitment
Canada

Study participating centre
Bigstone Health Commission
Canada
T0G 2K0

Study participating centre
Aakom Kiiyi Health
Canada
T0K 0H0

Study participating centre
Saddle Lake Cree Nation
Canada
T0A 3T0

Study participating centre
Cold Lake First Nations
Canada
T9M 1P4

Study participating centre
Stoney Nakoda First Nation
Canada
T0J 3W0

Study participating centre
Tsuu T'ina Nation
Canada
T2W 6H6

Study participating centre
Kainai Nation
Canada
T0L 1Y0

Sponsor information

Organisation
University of Alberta

ROR
https://ror.org/0160cpw27

Organisation
Alliance for Canadian Health Outcomes Research in Diabetes (ACHORD)

Funder(s)

Funder type
Industry

Funder Name
Alberta Innovates - Health Solutions

Alternative Name(s)
AIHS

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Canada

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Lawson Health Research Institute

Alternative Name(s)
Lawson

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

The data used to evaluate the primary and secondary outcomes are clinical measures routinely collected for clinical care. The data used for evaluation is non-identifying health information, provided by the custodian to the research team for the purpose of research. All patient level data remains with the communities and custodians. A single copy of the de-identified data will be stored on a password protected, encrypted, and secured university server maintained by the Academic Information and Communication Technologies (AICT) group at the University of Alberta. However, as we are not the data custodians, we cannot share any patient data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative results	04/02/2020	07/02/2020	Yes	No

Results article	qualitative results	03/05/2021	05/05/2021	Yes	No
Protocol article	protocol	06/02/2017		Yes	No