ISRCTN63277390 https://doi.org/10.1186/ISRCTN63277390

Testing solutions for improvement of primary care for people with diabetes

Submission date
16/01/2025

Recruitment status
Not yet recruiting

Registration date
19/02/2025

Overall study status
Ongoing

Last Edited
20/08/2025

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
This study aims to improve primary health care in Mendoza, Argentina, especially for people with type 2 diabetes. Strong primary health care is crucial for effective health systems, but the COVID-19 pandemic has highlighted weaknesses and inequities, particularly in less-resourced areas. Argentina faces increasing rates of chronic conditions like diabetes and has an ineffective and inequitable health system. The Quality Evidence for Health System Transformation (QuEST) initiative was launched to generate evidence for improving health systems. The Institute for Clinical Effectiveness and Health Policy (IECS) is working with the Ministry of Health of Mendoza to assess health service gaps, test solutions, and generate evidence to transform the health system.

Who can participate?
Adults residing in Mendoza who have been diagnosed with type 2 diabetes for at least one year can participate. Participants must be 18 years or older and assist selected primary health care (PHC) centres.

What does the study involve?
The study involves three phases. In Phase I, the selected interventions will be refined through a pilot test at three facilities. In Phase II, a cluster-randomised controlled trial will be conducted, enrolling 12 departments in Mendoza Province, with six departments randomly assigned to the intervention arm for a 12-month period. Participants' disease control, engagement with primary health care, and patient-reported outcomes will be assessed using routine clinical records and a patient cohort. Phase III will involve analysis and coordination with the Ministry of Health to disseminate findings and inform policy.

What are the possible benefits and risks of participating?
Participants may benefit from improved primary health care services and better management of their diabetes. The study aims to promote integrated and continuous services that are accessible at low cost. There may be minimal risks associated with participating, such as the time required for assessments and surveys.

Where is the study run from?
The study is run from the Institute for Clinical Effectiveness and Health Policy (IECS) in collaboration with the Ministry of Health of Mendoza, Argentina

When is the study starting and how long is it expected to run for?
November 2023 to November 2027

Who is funding the study?
The study is funded by the Instituto de Efectividad Clínica y Sanitaria (IECS) in Argentina

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR158215

Study information

Scientific Title
Testing co-produced solutions for service delivery redesign of primary care for people with diabetes

Acronym
SARA-D

Study objectives
Research Question: Will a co-produced redesigned care model based in primary care improve health system outcomes in people with diabetes?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/08/2024, Consejo Provincial de Evaluación ética en investigación en Salud (Provincial Health Research Ethics Review Board) of Mendoza Province, Argentina (San Martín and Rondeau, Second Floor, Mendoza, 5500, Argentina; +542614234425; dicyt@mendoza.gov.ar), ref: 149/2024

Study design
Efficient parallel-arm cluster randomized controlled hybrid type 1 trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Other

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Diabetes

Interventions
As this is a cluster RCT, the intervention package targets a group of primary health centres located in 6 randomly selected departments, and it will be implemented for 15 months.

The intervention package aims to improve diabetes care at the primary healthcare level through a multifaceted approach that integrates patient-centred care, technology, education, and systemic coordination. At its core, the package prioritizes accessibility and continuity of care by introducing Protected Appointments, which allocate dedicated time slots for diabetes management and ensure patients receive care, including evaluations, glucose control, medication reviews, nutritional counselling, and complication monitoring. To enhance patient tracking and management, the package includes the creation of a Diabetes Patient Registry, which digitally records patient information. This registry ensures accurate monitoring and follow-up. Using WhatsApp for Communication leverages a widely accessible platform to send

appointment reminders, educational messages, and follow-ups, improving patient engagement and adherence. Patient and Family Workshops and Family Support Workshops are designed to equip patients and their families with the knowledge and skills needed for effective diabetes management. These workshops cover topics such as glucose monitoring, healthy eating, exercise, emotional well-being, and emergency management, using interactive materials and community collaboration to deliver impactful sessions. To bridge gaps in specialist care, the package introduces telemedicine, enabling primary care physicians to seek second opinions from specialists via teleconsultations. Finally, the package emphasizes Coordination Between Levels of Care, establishing clear referral protocols and digital systems to streamline communication between primary, secondary, and tertiary care levels.

Randomization process:
A balanced randomization procedure will be implemented to ensure that the intervention and control clusters are comparable in terms of baseline HbA1c levels, sociodemographic variables, and cluster size. Randomization will take place after the baseline data collection period to maintain allocation concealment and minimize selection bias. The randomization process will be programmed and conducted using R software.

Updated 20/08/2025:
Randomization process:
A balanced randomisation procedure will be used to ensure that the intervention and control clusters are balanced with baseline HbA1C levels, sociodemographic variables (income and education), and cluster size. We will randomise following the baseline data collection period

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measures as of 20/08/2025:
1. Composite outcome measured using routine clinical records. It will be measured at least once during the baseline period and at least once during the intervention period:
1.1. Glycaemic control (HbA1c <8%)
1.2. Blood pressure control (<140/90 mmHg)
1.3. Use of statins (statin prescription) -limited to patients ≥40 years

Previous primary outcome measures:
1. Composite outcome measured using routine clinical records. It will be measured at least once during the baseline period and at least once during the intervention period:
1.1. Glycaemic control (HbA1c <8%)
1.2. Blood pressure control (<140/90 mmHg)
1.3. Use of statins (statin prescription) -limited to patients ≥40 years
2. User-reported Quality of Care (QoC) measured at least once during the baseline period and every 2 or 3 months during the intervention period

Secondary outcome measures
Measured using E-Cohort Survey at least once during the baseline period and every 2 or 3 months during the intervention period (unless noted otherwise):
1. Primary care engagement is measured by the percentage of visits conducted at the primary healthcare level reported by participants
2. System competence is measured by the compliance with the full set of selected diabetes prevention recommendations from national guidelines

3. Patient confidence in the health system is measured by the combination of health security, endorsement of the current system, and trajectory
4. Inequities assessment is measured by exploring gender, migration status, education, and income as potential variables related to underperformance in primary outcomes
5. Patient empowerment is measured using the Diabetes Empowerment Scale
6. Direct costs related to diabetes care are estimated from the costs assessed including medications, diagnostic tests, procedures, medical supplies, and visits to health professionals using data from the Accounting Department, Ministry of Health at least once during the baseline period and at least once during the intervention period

Overall study start date
01/11/2023

Completion date
30/11/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/08/2025:
1. Adults residing in Mendoza who have been diagnosed with type 2 diabetes for at least 1 year
2. 18 years of age or older
3. Diagnosis of type 2 diabetes for at least 1 year
4. Residents of Mendoza Province
5. Assisting selected public PHC centres

Previous inclusion criteria:
1. Adults residing in Mendoza with exclusive public insurance coverage who have been diagnosed with type 2 diabetes for at least 1 year
2. 18 years of age or older with exclusive public insurance coverage
3. Diagnosis of type 2 diabetes for at least 1 year
4. Residents of Mendoza Province
5. Assisting selected PHC centres

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Both

Target number of participants

652

Key exclusion criteria
Less than 18 years old

Date of first enrolment
01/09/2025

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
Argentina

Study participating centre
Ministry of Health of Mendoza Province
Av. Peltier 351
Mendoza
Argentina
5500

Sponsor information

Organisation
Instituto de Efectividad Clínica y Sanitaria

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Sponsor type
Charity

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ROR
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Funder(s)

Funder type
Charity

Funder Name
Instituto de Efectividad Clínica y Sanitaria

Results and Publications

Publication and dissemination plan
Dissemination activities and outputs will include: writing and submitting main manuscripts for publication, disseminating the findings at scientific societies, writing reports specifically designed for policy makers to enable them to implement the strategy in other regions of the country, and tailored outputs for patients, clinicians and researchers. We will also use conferences and other events to disseminate our findings. IECS and Mendoza MOH Communication teams will contribute to disseminate our work in social media, websites and journals
Involving policy and decision makers, and the people's opinion at early stages will help facilitate the dissemination of findings. Regarding impact, we anticipate that improvement in disease management as well as patient experience must have clinical benefits as well as positive economic benefits for the health system, related to reduced usage of secondary level and tertiary level facilities, out of pocket
costs for patients and reduced number of clinical events related to T2DM.

Intention to publish date
30/11/2028

Individual participant data (IPD) sharing plan
The participant-level data from our trial is stored in REDCap, a secure web-based application designed for managing clinical research data. The stored data includes demographic information, baseline and follow-up clinical measurements, and relevant study variables. Access to the data can be requested through a formal application process, which involves submitting a request to the principal investigator for each user.
The data will be available after the study's primary results have been published. Informed consent will be obtained from all participants, including consent for data storage and potential sharing for research purposes. To ensure participant confidentiality, all data are anonymized prior to sharing, with personal identifiers removed and replaced by unique study-specific IDs. Access is subject to ethical and legal restrictions to protect participant privacy.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	in Spanish version 1.1	19/06/2024	18/02/2025	No		Yes