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The intelligent Diabetes Platform - iDiabetes

Submission date	Recruitment status	[X] Prospectively registered
29/02/2024	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/03/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The intelligent Diabetes platform will add precision approaches using computer algorithms and biomarkers to improve outcomes for patients with diabetes. This study will compare three groups across GP practices in NHS Tayside:
1. Usual care - no input from iDiabetes
2. iDiabetes - promoting current guideline care
3. iDiabetesPlus -'Enhanced phenotyping' of patients using additional clinical tests undertaken on routine blood samples, including tests of heart function (BNP and hsTroponin) and for liver fat and fibrosis (scarring), as well as tests for insulin production and resistance. The researchers will also include DNA tests to allow the use of 'genetic risk scores' to flag people at increased risk of heart disease.

Who can participate?
Patients aged 18 years and over with diabetes

What does the study involve?
Over 15 months patients will take part in iDiabetes at their annual diabetes reviews. The researchers will use the clinical data routinely collected at this review, along with test results for the iDiabetesPlus group, to make personalised recommendations for treatment and further investigations such as ECHO and Fibroscan. Clinical staff will access this information via the iDiabetes platform and will discuss all recommendations with the patient. iDiabetes only recommends; patients and their healthcare team will decide together what is best for them. The platform will monitor patients and continue to make recommendations over about 2 years. Long-term outcomes are assessed through linked data over 15 years. By comparing the groups over time this study will assess if the iDiabetes platform is effective and cost-efficient, enabling the rollout of precision diabetes care beyond Tayside. This will be a collaborative approach between researchers, clinical staff, NHS, SCI-Diabetes and MyWay Digital Health. Interviews will be undertaken with patients and staff to explore their views and experiences of those receiving and delivering iDiabetes. The iDiabetes platform must also represent value for money to the healthcare system. To assess this, a health economic evaluation will be conducted.

What are the possible benefits and risks of participating?
Patients may benefit from the iDiabetes intervention as this will encourage their physicians to treat their diabetes in a timely manner either based on international diabetes treatment

guidelines or based on their individual characteristics and health needs.
There are no real risks to patients as they are attending routine appointments. Any treatment recommendations made are all approved within routine care. They are recommendations only and will be discussed between the patient and the healthcare team to determine the best choice for the individual patient.

Where is the study run from?
University of Dundee (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2027

Who is funding the study?
1. Chief Scientist Office, Scottish Government (UK)
2. Tayside Health Fund (UK)

Who is the main contact?
1. Prof. Ewan Pearson, e.z.pearson@dundee.ac.uk
2. Stephanie McKenzie, smckenzie001@dundee.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318454

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

IRAS 318454, CPMS 55424

Study information

Scientific Title
The iDiabetes Platform: enhanced phenotyping of patients with diabetes for precision diagnosis, prognosis and treatment

Acronym
iDiabetes

Study objectives
Implementation of a precision medicine platform will improve outcomes of patients with diabetes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/04/2023, East of Scotland Research Ethics Service (EoSRES) EOSREC1 (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, United Kingdom; +44 (0)1382 383878; tay.eosres@nhs.scot), ref: 23/ES/0008

Study design
Cluster-randomized controlled study with each participating GP practice forming a cluster

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
iDiabetes (intelligent Diabetes) will provide a precision approach to diabetes care. This will be achieved by making better use of the health data that is already routinely collected for patients with diabetes across Scotland, supplemented by additional blood tests that are taken to enable better risk prediction for diabetes complications. iDiabetes will be fully implemented within the NHS environment, with near-real-time access to anonymised data to evaluate efficacy and cost-effectiveness, and to support new discovery and model development.

iDiabetes will be implemented for patients with diabetes in Tayside using a cluster-randomised design. GP practices will be randomised to usual care, iDiabetes care or iDiabetesPlus care (7500 patients in each arm) with evaluation to see if the iDiabetes care approaches result in better outcomes and whether they are cost-effective. Patients will be informed if their GP practice has been randomised to iDiabetes care or iDiabetesPlus care and will be given the option to opt-out if they would rather receive usual care.

The iDiabetes platform will form the central intervention in this study. The iDiabetes platform will incorporate patient data and facilitate the generation of recommendations based on the most recent evidence for each patient. The recommendations will be accessible by both healthcare professionals via the iDiabetes dashboard and by patients themselves via My Diabetes My Way (MDMW). MDMW is an interactive online patient portal used by patients with diabetes in Scotland. It provides them with information about their condition and secure access to their own diabetes-related healthcare records, including test results.

iDiabetes (guideline support):
Patients will attend their annual diabetes review and be assessed as per usual care including routine diabetes blood testing. The iDiabetes platform will generate automated, individualised treatment recommendations, using routine clinical information and blood test results from annual appointments. Recommendations will be determined by the latest treatment guidelines such as the American Diabetes Association's Standard of Care for Diabetes and the National Institute for Health and Care Excellence (NICE) Clinical Knowledge Summaries. Medicine optimisation recommendations will be provided where a patient has renal or cardiovascular disease. For example, advice will be given to optimise ACE inhibitors or angiotensin receptor blockers for patients with proteinuria or optimise statins for patients with cardiovascular.

iDiabetesPlus:
Patients will undergo routine assessments at their annual diabetes review in the same way as iDiabetes (guideline support). However, in addition to the routine diabetes blood testing, iDiabetesPlus will incorporate additional reflexive laboratory testing including C-peptide concentration, cardiac risk biomarkers +/- echocardiography, non-invasive liver fibrosis scoring +/- Fibroscan and individual genotyping (to allow for cardiovascular and type 1 diabetes genetic risk scoring) Tab. Enhanced phenotyping and genotyping will allow for improvement in diagnostic accuracy of diabetes type and determination of current and future risk of end-organ complications. Medicine optimisation recommendations will be provided in the same way as iDiabetes (guideline support) with additional recommendations for patients with liver disease. Further to this, risks of myocardial infarction and all-cause mortality will be predicted for patients with T2D using models developed by My Way Digital Health (MWDH). Treatment recommendations for each patient will be evidence-based and determined according to their competing cardiorenal or liver risk, risk of hypoglycaemia and predicted diabetes drug treatment response using a treatment selection algorithm. All recommendations will be accessible to the patient and their diabetes care team

The researchers will evaluate the efficacy of the programme using a hierarchical outcome as our endpoint to evaluate the reduction in mortality, hospitalisation, renal function decline and HbA1c. A comprehensive health economic model will be developed to assess the cost-effectiveness of this approach.

A nested qualitative study will explore the views and experiences of those delivering and receiving iDiabetes and iDiabetesPlus care, using semi-structured interviews with patients and health professionals involved in the implementation and use of the iDiabetes platform and the delivery of iDiabetes-informed care.

Semi-structured interviews will be conducted with patients and clinical and non-clinical primary care staff from clusters allocated to the iDiabetes platform and will be carried out in three rounds.

Alongside clinical effectiveness, the iDiabetes platform must also represent value for money to the healthcare system. To assess this, a health economic evaluation will be conducted. A model-

based cost-effectiveness analysis of the iDiabetes (guideline support) and iDiabetesPlus arms versus the usual care arm will be conducted. The cost per complication avoided and Quality-Adjusted Life Years gained (QALYs – the standard health economic utility measure) for each strategy will be predicted by incorporating the study data into an existing diabetes simulation model.

The iDiabetes IQ engine (providing the decision support) developed by the University of Dundee iDiabetes developers, will be registered as a Class 1 medical device (under the UK Medical Device Directive) according to ISO standards prior to the study start by the iDiabetes team.

A patient and public involvement (PPI) focus group was formed specifically for this study, consisting of patients and family members recruited from the NHS Scotland Diabetes Research Register and via social media outreach. The focus group was consulted on all aspects of the project including shaping the study concept prior to funding application.

Intervention Type
Mixed

Primary outcome(s)
A composite hierarchical outcome evaluated utilising the Win-Ratio statistical methodology. Composite composed of (in decreasing order of clinical importance):
1. All-cause mortality
2. All-cause hospitalisation rate
3. Proportion with >40% eGFR reduction from baseline, or new development of end-stage kidney disease (ESKD)
4. Proportion with absolute HbA1C reduction >0.5% (>5.5 mmol/mol)
All data is routine clinically collected data accessible in the Sci-Diabetes system and SMR01 at baseline and 2 years.

Key secondary outcome(s))
1. All-cause mortality rate
2. All-cause hospitalisation rate
3. Proportion with >40% eGFR reduction from baseline, or new ESKD
4. Proportion with absolute HbA1C reduction >0.5% (>5.5 mmol/mol)
5. Hospitalisation rate secondary to heart failure
6. Drug adherence rate – frequency of prescription encashment of diabetes and cardiovascular drugs
7. Rate of severe hypoglycaemia – severe hypoglycaemic episodes requiring paramedic callout
8. Proportion of patients treated according to guidelines – prescription of diabetes drugs (compared to updated ADA/EASD guidelines)
All data is routine clinically collected data accessible in the Sci-Diabetes system and SMR01 at baseline and 2 years

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Registered patients with a diagnosis of diabetes
2. Age >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/05/2024

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Tayside
Kings Croos
Clepington Road
Dundee
United Kingdom
DD3 8EA

Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Tayside Health Fund

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 06/08/2024:
The datasets generated and/or analysed during the current study will be available on request from Prof Ewan Pearson (e.z.pearson@dundee.ac.uk). Individual-level patient data will not be made publicly available due to data privacy/GDPR. Additional access to the final study dataset on the Health Informatics Centre Trusted Research Environment (University of Dundee) will be approved by the chief investigator with an appropriate data-sharing agreement in place.

Previous IPD sharing plan:
The datasets generated and/or analysed during the current study will be available on request from Prof Ewan Pearson (e.z.pearson@dundee.ac.uk).

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/11/2024	02/12/2024	Yes	No
Other files			07/08/2024	No	No
Protocol file	version 4	21/03/2024	22/04/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes