

Evaluation of Quality Improvement for People with Type 2 Diabetes

Submission date 11/03/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/03/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There are about 65,000 young adults in England with type 2 diabetes who have high blood glucose levels, which can lead to serious health problems and early death. Different groups of general practices, called Primary Care Networks (PCNs), vary in how well they help patients manage their blood glucose levels. This study aims to find out if providing extra support to PCNs can help them improve patient care and if these methods are cost-effective.

Who can participate?

All PCNs in England will be randomly assigned to one of three groups to participate in the study.

What does the study involve?

PCNs will receive one of the following:

Medium-intensity support through virtual meetings and NDA feedback.

Low-intensity support through email and NDA feedback.

NDA feedback alone, with support provided later.

Researchers will analyze data on patient care and outcomes, including blood glucose levels, and recordings of virtual meetings.

What are the possible benefits and risks of participating?

The findings will help the National Diabetes Audit to decide whether to provide support in the same way in future. The findings will also help other national clinical audits (e.g. for cancer, heart disease) decide whether to provide similar support to improve patient care. For healthcare professionals in Primary Care Networks participating in the study, there are no added risks and minimal burden as they would be eligible for and receive the support for improvement if not participating in the study.

For young adults with diabetes there are no added risks from research participation because the intervention seeks to implement recommended practice and their relevant primary care teams would also receive the support for improvement if they were not participating in the study.

Where is the study run from?

Northumbria University (UK)

When is the study starting and how long is it expected to run for?
January 2025 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Michael Sykes, michael.sykes@northumbria.ac.uk

Study website
<https://hosting.northumbria.ac.uk/studyimprove>

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
340839

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61114, NIHR168871

Study information

Scientific Title

An evaluation of two large-scale quality improvement interventions embedded with a national clinical audit to improve the care for young adults with type 2 diabetes (EQUIPD2)

Study objectives

Aim: To evaluate two facilitation co-interventions added to NDA feedback to improve the achievement of blood glucose goals in young adults with type 2 diabetes.

Objectives

Assess the effectiveness of NDA feedback with (i) medium-intensity facilitation and (ii) low-intensity facilitation compared to NDA feedback alone in reducing the HbA1c of young adults with type 2 diabetes and HbA1c ≥ 58 mmol/mol.

Understand facilitation implementation, engagement, fidelity and tailoring of actions.

Estimate the cost-effectiveness of medium- and low-intensity facilitation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/02/2025, Northumbria University (Coach Lane Campus, Northumbria University, Newcastle upon Tyne, NE7 7XA, United Kingdom; +44 191 232 6002; ETHICSSUPPORT@NORTHUMBRIA.AC.UK), ref: Sykes 2025-8864-10621

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

We will undertake a three-arm cluster randomized controlled trial to evaluate the effectiveness of NDA feedback with low- or medium intensity facilitation compared to NDA feedback alone in reducing the number of young adults with a raised blood glucose.

Medium-intensity feedback facilitation: Email invite to PCN-level clinical pharmacists and diabetes leads to join two webinars and subsequent multi-site facilitated calls with peers about

type 2 diabetes. The email will contain information about health consequences and feedback on outcome of behaviour from a credible source. Participants will be invited to a choice of webinar dates. The 2 one-hour webinars include behaviour change techniques specified in the logic model (e.g. information about health and social consequences, instruction on how to identify patients and analyse influences upon performance). The webinar seeks to implement improvement actions tailored to their local context by each PCN. After the webinar, the medium-intensity feedback facilitation arm PCNs will be invited to five bi-monthly multisite calls (one-hour each). It will be possible to attend the calls without having attended the webinar. The facilitated virtual calls will prompt monitoring, ask participants to describe work undertaken and encourage collaboration through shared lessons and resources (e.g. patient leaflet, staff training materials).

Low-intensity feedback facilitation: The low-intensity intervention will include similar content (e.g. information about health and social consequences, instruction on how to identify patients and analyse influences upon performance) to the medium-intensity feedback facilitation delivered through email and virtual worksheets.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

HbA1c level at 18 months post-randomisation in young adults (18-39 years) with type 2 diabetes and baseline HbA1c ≥ 58 mmol/mol measured using measured using National Diabetes Audit data

Secondary outcome measures

Measured in young adults (18-39 years) with type 2 diabetes and baseline HbA1c ≥ 58 mmol/mol:

1. HbA1c measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-up period
2. Prescription of both metformin and SGLT2 inhibitor measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-up period
3. Statin prescription measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-up period
4. Proportion receiving NICE-recommended care processes in the preceding 12 months: blood pressure check; serum creatinine testing; urinary albumin: creatinine ratio testing; foot examination and risk classification; smoking status; retinal screening; body mass index; and referral to a structured education programme measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-up period

Overall study start date

03/01/2025

Completion date

30/06/2027

Eligibility

Key inclusion criteria

Primary care networks in England

Participant type(s)

Other

Age group

Other

Sex

Both

Target number of participants

Planned Sample Size: 1263; UK Sample Size: 1263

Key exclusion criteria

None

Date of first enrolment

17/03/2025

Date of final enrolment

31/03/2027

Locations**Countries of recruitment**

United Kingdom

Study participating centre**NHS England**

Diabetes Programme

Wellington House

133-155 Waterloo House

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Sponsor information**Organisation**

Northumbria University

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Sponsor type

University/education

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ROR

<https://ror.org/049e6bc10>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date