

# Evaluation of Quality Improvement for People with Type 2 Diabetes

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
11/03/2025	Recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
12/03/2025	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
12/01/2026	Nutritional, Metabolic, Endocrine	<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

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Michael Sykes

### ORCID ID

<https://orcid.org/0000-0002-2039-7397>

### Contact details

Coach Lane Campus

Northumbria University

Newcastle upon Tyne

United Kingdom

NE7 7XA

+44 (0)191 232 6002

michael.sykes@northumbria.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

340839

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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  $\geq 58$  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

### **Study type(s)**

Treatment

### **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

## **Primary outcome(s)**

HbA1c level at 18 months post-randomisation in young adults (18-39 years) with type 2 diabetes and baseline HbA1c  $\geq 58$  mmol/mol measured using data routinely collected as part of the National Diabetes Audit

## **Key secondary outcome(s)**

Measured in young adults (18-39 years) with type 2 diabetes and baseline HbA1c  $\geq 58$  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

## **Completion date**

30/06/2027

# **Eligibility**

## **Key inclusion criteria**

Primary care networks in England

## **Participant type(s)**

Other

## **Healthy volunteers allowed**

No

## **Age group**

Other

## **Sex**

All

## **Total final enrolment**

0

**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

London

England

SE1 8UG

## Sponsor information

**Organisation**

Northumbria University

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

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

## Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		06/01/2026	12/01/2026	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes