ISRCTN52205353 https://doi.org/10.1186/ISRCTN52205353

Evaluation of Quality Improvement for People with Type 2 Diabetes

Submission date
11/03/2025

Recruitment status
Recruiting

Registration date
12/03/2025

Overall study status
Ongoing

Last Edited
12/03/2025

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
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 ≥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

Phase
Not Specified

Primary outcome(s)
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

Key secondary outcome(s))
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

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

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
United Kingdom
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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes