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# Evaluation of quality improvement for people with diabetes

**Submission date**
16/07/2022

**Recruitment status**
No longer recruiting

**Registration date**
18/10/2022

**Overall study status**
Completed

**Last Edited**
01/09/2023

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
People with diabetes who have raised blood sugar levels are at increased risk of complications such as sight loss, kidney disease and nerve damage. An insulin pump is a small electronic device that reduces blood sugar by giving insulin throughout the day via a small tube. Since 2008, national guidelines have recommended insulin pumps for people with type 1 diabetes people who have high blood sugar.
Around 90,000 people in England have high blood sugar but do not use an insulin pump. Importantly, insulin pump use varies according to where people live and their age, sex and ethnicity. People with diabetes, healthcare professionals and NHS England have all said that increasing insulin pump use is important.
The National Diabetes Audit (NDA) measures how many people with diabetes receive care recommended by guidelines. The NDA aims to drive changes that improve care by providing feedback to patients, policymakers and clinical teams. Despite giving feedback since 2016, large gaps in insulin pump use remain.
Researchers think that they can increase insulin pump use by supporting specialist diabetes teams (doctors, nurses and others) to act more effectively following NDA feedback. They have developed and tried a programme of workshops, coaching and sessions where teams learn from each other. The programme helps teams to choose actions according to their own circumstances and commit to these actions. The programme will be delivered virtually by the NDA and will be free to the teams.
This study will evaluate whether the support leads to greater change than feedback alone, understand how the support is delivered and how teams respond, and evaluate whether the support is value for money.

Who can participate?
Teams providing specialist diabetes care to adults in England and Wales

What does the study involve?
Participating teams will be randomly assigned to get the support or not during the study. The teams will be able to opt-out from the research but still receive the support. The researchers will measure how many people start and stay on the pumps for 3 months by gathering prescription data. This data is routinely extracted from medical records unless patients opt out. The

researchers will compare insulin pump use between those diabetes teams that got the support and those that did not. Immediately after the study, they will give the support to all teams that did not receive it during the study.
To see how those involved deliver and use the programme, the researchers will observe what happens in the virtual workshops, coaching and shared learning meetings. They will read documents that are produced and will interview people who delivered the support programme and diabetes team members who did or did not receive the support. They will describe the cost of delivering and receiving the support and evaluate whether the benefits outweigh the costs.

What are the possible benefits and risks of participating?
The findings will help the NDA 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 specialist diabetes teams participating in the study, there are no added risks and minimal burden as they would be eligible for and receive the quality improvement collaborative (QIC) if not participating in the study.
For people with diabetes who are eligible for insulin pumps there are no added risks from research participation because pumps are already recommended in routine clinical management and their relevant specialist diabetes teams would also receive the QIC 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?
July 2022 to April 2025

Who is funding the study?
The National Institute for Health and Social 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)
Principal Investigator

### Contact name
Dr Michael Sykes

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
316162

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
1.0, IRAS 316162, CPMS 52898

# Study information

### Scientific Title
An evaluation of quality improvement collaboratives aligned to a national audit to improve the uptake of insulin pumps for people with diabetes

### Acronym
EQUIPD

### Study objectives
The national diabetes audit plus quality improvement collaborative increases the use of insulin pumps more than the national diabetes audit alone.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 14/10/2022, London - Stanmore Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048387; Stanmore.Rec@HRA.nhs.uk), ref: 22/LO/0577

### Study design
Efficient cluster randomized controlled trial using routine NDA data with process and economic evaluations

### Primary study design
Interventional

### Secondary study design
Cluster randomised trial

## Study setting(s)
Community

## Study type(s)
Treatment

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

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

## Interventions
The intervention comprises a specified and theory-informed Quality Improvement Collaborative delivered alongside the National Diabetes Audit (NDA), involving virtual coaching sessions, workshops and multisite facilitation, and delivered as part of the new NDA contract. The control comprises standalone NDA feedback.
The total duration of the intervention is 15 months and the follow-up is 18 months.

Participating specialist teams will be randomised after agreement to participate and confirmation of eligibility. Allocation of specialist diabetes teams (clusters) to intervention or control will be undertaken independently by the Clinical Trials Research Unit (CTRU) using the CTRU automated 24-hour randomisation service. Specialist diabetes teams will be randomised on a 1:1 basis either to receive the intervention (starting in 2023) or waitlist only (receiving the intervention after the trial follow-up period ends in June 2024), using a computer-generated minimisation programme with a random element.
Minimisation factors will be:
1. Baseline proportion moving onto a pump in the 15 months prior to the intervention period (above or below median)
2. Size of target patient population in specialist team (above or below median)
3. Previous participation in the QIC pilot (yes or no)
Following randomisation, the clinical team lead will be informed of the cluster allocation and training will be scheduled. Each cluster will be given a unique identifier (ID) site code, which will be used on all relevant trial documentation.

## Intervention Type
Behavioural

## Primary outcome measure
The proportion of adults with poorly controlled type 1 diabetes (HbA1c above 69 mmol/mol) starting and continuing to use insulin pumps for at least 3 months within an 18-month follow-up period

## Secondary outcome measures
1. Change in blood glucose levels as measured by HbA1c in people with poorly controlled type 1 diabetes between the latest measurement in the 12 months preceding the start of the intervention and the latest measurements recorded during the study period
2. Any record of insulin pump prescribing, including for periods shorter than 3 months, measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-

up period
3. Insulin pump use sustained over at least 6 months, measured using data routinely collected as part of the National Diabetes Audit over the 18-month follow-up period

### Overall study start date
01/07/2022

### Completion date
30/04/2025

## Eligibility

### Key inclusion criteria
Teams providing specialist diabetes care to adults in England and Wales

### Participant type(s)
Health professional

### Age group
Adult

### Sex
Both

### Target number of participants
120 teams

### Key exclusion criteria
Does not meet the inclusion criteria

### Date of first enrolment
18/10/2022

### Date of final enrolment
01/02/2023

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**NHS England**
Waterfront 4
Goldcrest Way
Newcastle upon Tyne

United Kingdom
NE15 8NY

# Sponsor information

### Organisation
Northumbria University

### Sponsor details
Coach Lane Campus
Newcastle upon Tyne
England
United Kingdom
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laura.hutchinson2@northumbria.ac.uk

### Sponsor type
University/education

### Website
https://www.northumbria.ac.uk/

### ROR
https://ror.org/049e6bc10

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Planned publications in high-impact, open-access, peer-reviewed journals.

### Intention to publish date
30/04/2026

### Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol article | | 31/08/2023 | 01/09/2023 | Yes | No |