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Digital multi-component intervention to improve the care of older people living with diabetes and chronic kidney disease

Submission date
22/10/2025

Recruitment status
Recruiting

Registration date
03/11/2025

Overall study status
Ongoing

Last Edited
03/11/2025

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
Diabetes related kidney disease (DKD) affects four in ten people with diabetes. More than two-thirds of them are aged over 70 years. Over time, people with DKD can progress to kidney failure and need dialysis or a kidney transplant. They also have a high risk of heart attack, stroke, and early death. DKD is not curable. It is possible to slow down its progress to kidney failure by a healthy lifestyle, good control of blood pressure (BP) and diabetes, and the use of certain drugs. These are recommended by UK guidelines. Research shows that treatment of DKD in general practice is poor, especially in older people, women, socially deprived and ethnic minorities. This is probably because treatment guidelines are not always followed. Pressure on general practitioner (GP) time is a key factor for this. Research shows that computer prompts can help GPs to follow guideline recommendations. This study aims to see if computer prompts can help support GPs to follow DKD guidelines, and if they can slow down the worsening of kidney function in older people with DKD. Nearly 3.5 million adults in the UK have chronic kidney disease, and around half of them have DKD. This leads to 100,000 hospital admissions and 45,000 premature deaths a year. The treatment costs £6.4 billion a year, mainly for dialysis treatment. If successful, this simple change in practice is likely to improve the care of these patients. It will also improve the outcome of people with DKD and reduce costs to the NHS.

Who can participate?
Healthcare professionals (HCPs) managing the clinical care of patients with type 2 diabetes (T2D) and patients with DKD.

What does the study involve?
In phase 1, the study will develop a computer prompt with the help of computer experts, patients, and GP staff. The prompt will support GP staff to follow the five main guideline recommendations. These are BP and blood sugar control, and the use of three kidney-protecting drugs. The prompt will appear on the computer when patients attend their appointment. The computer will record actions taken by the doctor. It will also send lifestyle advice to the patient. This will be a test run of the study in 10 GP practices to correct any problems the staff identify. A lifestyle advice document will be produced with the help of patients and carers. The document

will be in the form of a short video and a leaflet for those who do not have access to a smartphone or computer. This will be given to patients when they visit the GP and sent every 3 months during the study.

In phase 2 will test the prompt in 60 GP practices. The practices will be allocated at random to receive either the computer prompt (intervention) or no computer prompt (usual practice). There will be either no or very few extra visits for patients. Kidney function will be collected and other information taken during routine visits from GP computer systems for 2 years. The two groups will be compared to assess if it is possible to implement the computer prompt. The study will also assess if the use of the computer prompt slowed down the worsening of kidney function and if it is a good value for money for the NHS.

Setting and Clusters:
60 GP practices across England. Half the practices will be randomly allocated to the Intervention arm and the other half to the Usual care arm.
GP practices that use the Egton Medical Information Systems (EMIS) electronic patient record systems and share data with Clinical Practice Research Datalink (CPRD) will be eligible. The practices will be identified and invited to take part in the study by CPRD.

What are the possible benefits and risks of participating?
It is estimated that over 1.5 million people in the UK are living with significant DKD (stages 3-5). Widespread implementation of the digital management tool will potentially improve the care of people living with DKD across the country and reduce the risk of kidney failure, CV events and mortality. This in turn will significantly reduce resource utilisation and cost to the NHS. Furthermore, the multimedia lifestyle support document developed through this trial, may also be rolled out in primary care nationally. Both can potentially be adapted for other long-term conditions and benefit a large population of the UK in the future.
Participation does not involve any additional risks, as participants will continue to receive treatment as part of their usual care and may benefit from the intervention.

Where is the study run from?
University Hospital Birmingham NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
September 2024 to August 2028.

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

Who is the main contact?
Prof Indranil Dasgupta, indranil.dasgupta@uhb.nhs.uk
IMPROVE DKD study team, improvedkd@trials.bham.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332287

Protocol serial number
RG_25-042, CPMS 57752

Study information

Scientific Title
Digital multi-component intervention to IMPROVE the care of older people living with Diabetes and Chronic Kidney Disease (IMPROVE DKD): A type 2 hybrid effectiveness-implementation cluster randomised trial

Acronym
IMPROVE DKD

Study objectives
1. To evaluate the effectiveness of the digital management tool for general practice, developed for this trial to promote adherence to Joint Association of British Clinical Diabetologists and UK Kidney Association (ABCD-UKKA) guideline recommendations, at slowing Diabetic Kidney Disease (DKD) progression compared to usual care.

2. To evaluate the cost-effectiveness of the digital management tool compared to usual care Implementation.

3. To use routine data to evaluate GP adherence to five ABCD-UKKA guideline recommendations: (optimising 1. blood pressure, 2. glycaemic control, and the use of optimum doses of 3, RAASi, 4. SGLT-2i and 5. Statins).

4. To adopt mixed methods to explore and better understand the influences of fidelity, mechanisms of action and context on the implementation and effectiveness of the digital management tool.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/09/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048137; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0178

Study design
Type II hybrid effectiveness-implementation cluster randomized trial and SWAT

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic kidney disease (DKD)

Interventions
This is a type II hybrid effectiveness-implementation cluster randomised trial. The trial includes a study within a trial (SWAT) to assess the value of modelling trial outcomes using process of care data only, compared with intermediate outcome data and later clinical outcomes.

Setting and Clusters
The units of randomisation are Primary Care General Practices (60 GPs) across England.

Cluster eligibility criteria
GP practices that use Optum (previously branded as Egton Medical Information Systems electronic patient record systems [EMIS]) and software and share data with Clinical Practice Research Datalink (CPRD).

Research participants
Healthcare professionals (HCPs) managing the clinical care of patients with type 2 diabetes (T2D).

Patient's main eligibility criteria
Patients with T2D, aged ≥60 years, with estimated glomerular filtration rate (eGFR) between 30-59 ml/min/1.73m2 (CKD Stage 3).

Sample size
Both co-primary outcomes are powered at 90% (alpha=0.05) with 30 GP practices (clusters) per arm and each GP practice size (cluster size) being approximately 25. This equates to 750 patients in each group (1500 patients in total).

Interventions
Multicomponent intervention based on the Joint ABCD-UKKA Guidelines recommendations. The intervention has two parts:

1. Digital management tool: HCP-facing automatic point-of-care computer reminders, developed in an earlier work package of the trial, reinforcing five guideline recommendations:
1. Optimising blood pressure control (target systolic <130 mmHg)
2. Optimising glycaemic control (target Haemoglobin A1c (HbA1c) <58 mmol/mol)
3. Use of an optimum dose of a RAASi
4. Use of a sodium glucose co-transporter-2 inhibitor (SGLT2i)
5. Use of an optimum dose of a statin

2. Provision of patient-facing multimedia lifestyle advice. Developed in an earlier work package of the trial, promoting /reinforcing the following lifestyle recommendations for people with DKD: low salt intake (<5 g/day), moderate alcohol intake (<14 units/ week), regular moderate intensity physical exercise (150 min/ week), smoking cessation, maintaining healthy body mass index (BMI)(18.5 – 25 Kg/m2).

Outcome measures
• Effectiveness outcome: Change in eGFR over a period of 2 years obtained via routine data collection.
• Implementation outcome: GP adherence to the five key ABCD-UKKA guideline recommendations: optimising blood pressure (BP) and glycaemic control, and the use of optimum doses of RAASi, SGLT-2i and statin. This will be determined via routine data collection at 12 months post-randomisation.

Patient eligibility criteria: The digital management tool will select eligible patients automatically based on the following criteria.
Patients will be sent a link via email, text or letter from their GP practice. The link will take them to a website where they can view and engage with online lifestyle advice materials. Participants who do not have easy access to the internet will be given a one-page summary of the lifestyle advice. In addition to English, the lifestyle advice summary document will also be available in Urdu, Bengali, Bulgarian, Mandarin, Polish and Punjabi for those who would prefer a non-English version.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
A digital management tool comprising computerised reminders for health care professionals.

Primary outcome(s)

1. Change in eGFR (ml/min/1.73m2) calculated from the serum creatinine (SCr) value using the CKD-Epi Creatinine Equation using data obtained via routine data collection for a period of 2 years post-randomisation
2. GP adherence to all five Joint ABCD-UKKA guideline recommendations will be measured using anonymised routine data, initially recorded in the EHR, which will include documentation and/or recorded action taken (e.g. measurement and/or prescription) at 12 months post-randomisation

Key secondary outcome(s))
The following secondary outcome measures are measured using anonymised routine data at 12 months post-randomisation:
1. A composite of eGFR decline >50%, end-stage kidney disease (ESKD) and all-cause mortality
2. Non-fatal myocardial infarction (MI), non-fatal stroke, hospitalisation for heart failure
3. Components of the implementation endpoints – BP control, glycaemic control and the use of RAASi, SGLT2I and statin

Completion date
31/08/2028

Eligibility

Key inclusion criteria
Cluster
General practices (GPs) will be eligible to take part in the research if they are:
1. Using Optum software for patient care records
2. Signed up and reporting data to CPRD

Cluster patients
1. Type 2 diabetes mellitus
2. Aged 18-80 years (although a subset of these patients ≥60 will inform the main analysis data-set)
3. eGFR 30-59 ml/min/1.73m2 (CKD stage 3)

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Type 1 diabetes mellitus, known primary renal disease (e.g., glomerulonephritis, vasculitis, adult polycystic kidney disease)
2. On immunosuppression therapy
3. On dialysis or received a kidney transplantation
4. Active malignancy
5. On end-of-life care/pathway
6. Dementia
7. Opted out of contributing data to CPRD

Date of first enrolment
15/11/2025

Date of final enrolment
15/11/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
Primary care practices
United Kingdom
B152TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

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?
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