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Developing evidence based blood tests to monitor long term conditions in GP practices

Submission date
08/11/2024

Recruitment status
Recruiting

Registration date
13/11/2024

Overall study status
Ongoing

Last Edited
01/12/2025

Condition category
Other

[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
The number of blood tests performed in the NHS is increasing. Over half of these blood tests take place in general practice to monitor long-term conditions (LTC). Testing blood can be unnecessary, may cause distress and lead to further tests and treatments that are not be needed. However, not testing could miss important problems.
Patients aren't always told which blood tests they are having, and don't always understand what their test results mean. Current guidelines on which tests people with LTC should have are based on expert opinion rather than research evidence.
We have developed evidence-based testing strategies for people with high blood pressure, diabetes and kidney disease in general practice. This will let patients, doctors and nurses know which are the best tests for these conditions, how often to test patients, and how to use the results. It has the potential to free up resources from general practice, reduce unnecessary testing for patients and improve overall management of LTC.

Who can participate?
Patients aged 18 years or over who have a diagnosis of hypertension (high blood pressure), and /or chronic kidney disease and/or type 2 diabetes and are registered at a GP practice participating in the study.

What does the study involve?
We have developed evidence-based lists of tests for monitoring patients with diabetes, high blood pressure and kidney disease. We have also developed resources to help patients understand what their blood tests mean for their health. Together these make up the "Test Smart" intervention.

We will implement the Test Smart intervention in ten GP practices and will compare rates of testing with ten practices following usual testing practice. We will monitor hospitalisations to see whether there are any risks of having less tests. We will also look at patient outcomes including 'patient activation', to see if patients feel more in control of their health when they are given more information to help them understand their monitoring tests.

What are the possible benefits and risks of participating?
Patients in the intervention group will receive only evidence-based tests, which may mean less or more than usual. This reduces their risk of unnecessary tests and potential harms from over-testing, while increasing the chance of receiving beneficial tests. They will also get information about each test to help them understand its purpose and the meaning of their results.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
September 2024 to August 2026

Who is funding the study?
NIHR Programme Grant for Applied Research (UK)

Who is the main contact?
Penny Whiting, info-test-smart-study@bristol.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
346468

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR201616, CPMS 65214

Study information

Scientific Title
The clinical and cost-effectiveness of an evidence-based testing package to monitor long term conditions (LTC) in primary care: the “Test Smart” cluster randomised controlled trial

Acronym
Test Smart

Study objectives
Over 15 million people in England have a long-term condition (LTC); 13.8 million have hypertension, 4.1 million chronic kidney disease (CKD) and 6.5 million type-2 diabetes mellitus (T2DM), with considerable overlap between conditions. Most patients are managed in primary care, where regular blood test monitoring is used to assess disease progression, adherence and response to treatment, early detection of complications, and development of associated diseases e.g. cardiovascular disease, and renal failure. There is currently no robust evidence to inform recommendations on the selection of tests, or test frequency for people with LTC. Although guidance exists, this is based almost entirely on expert opinion.

Primary care pathology testing cost the NHS £1.8bn in 2015/16, with the average GP estimated to spend 1.5 to 2 hours per day reviewing test results. Monitoring of LTC accounts for around half of this pathology testing. Numbers of tests are increasing, with significant implications for NHS costs and clinician workload. There is substantial variation in testing rates between GP practices, suggesting clinical uncertainty in this area. A review of chronic disease monitoring recommendations of 20 general practices in North Devon showed that no two practices recommended the same set of blood tests.

The overall aim of this project is to optimise testing to monitor LTC (hypertension, T2DM and CKD) in primary care by developing an evidence-based testing package (the "Test Smart intervention") consisting of recommended testing panels and frequencies and accompanying patient and clinician materials to facilitate a better understanding of testing and test results for patients and clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/02/2025, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 2071048021; southyorks.rec@hra.nhs.uk), ref: 24/YH/0237

Study design
Multicentre pragmatic open-label two-arm cluster RCT (cRCT) with qualitative sub-study and economic evaluation

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Optimising blood tests for monitoring hypertension, chronic kidney disease and type 2 diabetes

Interventions
GP practices will be randomised to the Test Smart intervention or to the control on a 1:1 basis. Randomisation will be at the practice level and will be stratified by ICB.

The Test Smart intervention consists of an evidence-based testing panel and accompanying clinician and patient educational and communication resources. The final evidence-based testing panel consists of a list of tests that patients should receive as part of their regular monitoring for each of the three LTCs of interest. The panel also recommends how frequently each patient should be tested. The intervention components for GP practice staff consist of the information website, the introductory training videos, training videos for staff taking bloods, and laminated posters of the testing panels. The intervention components for patients consist of the information website, patient information leaflets, text message templates, and patient focused animations.

The duration of the intervention will be 12 months implementation and there is no follow-up.

Intervention Type
Mixed

Primary outcome(s)
1. Monthly practice-level blood testing rates are measured via automated searches of the primary care electronic health records in the 12 months prior to implementation and 12 months post implementation.
2. Patient activation is measured using the Patient Activation Measure (PAM) 1 week prior to the first long-term condition monitoring appointment, 2 weeks post-appointment, and 6 months post-appointment.

Key secondary outcome(s))
1. Serious Adverse Events (hospital admissions and significant harm events attributed to lack of testing) measured using GP records and laboratory records 6 months post-appointment.
2. Patient satisfaction measured using the NHS Friends and Family test at 1 week prior to the first long-term condition monitoring appointment, 2 weeks post-appointment, and 6 months post-appointment.
3. Patient understanding of test results measured using Questionnaire 3: Your blood test results (adapted from Ballets study) at 1 week prior to the first long-term condition monitoring appointment, 2 weeks post-appointment, and 6 months post-appointment.
4. Acceptability measured through qualitative interviews with health-care professionals (HCPs) and patients. Fidelity measured using GP records 12 months post implementation.
5. Cost-effectiveness measured using GP records at the end of the study.
6. Barriers and facilitators to the widespread adoption, integration and sustainability of the Test Smart intervention measured through qualitative interviews with health-care professionals (HCPs) at the end of the study.

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/07/2025:
GP practices in England will be eligible if they meet all the following criteria:
1. Located in the specified recruitment area.
2. Use Accurx text messaging software (98% of English practices use this system).
3. Practice staff willing to take part in qualitative interviews.
4. Phlebotomy is conducted at the practice level rather than via referral to a central location.
5. Practices that have existing LTC monitoring panels that include at least one additional test group beyond those in the Test Smart panels.

Patients will be eligible for recruitment to provide patient-reported outcomes if they are:
1. Aged 18 or over.
2. Registered at a participating practice and diagnosed with hypertension, and/or chronic kidney disease and/or type 2 diabetes at the start of the study period.
3. Attend for routine monitoring during the study period.

Previous inclusion criteria:
GP practices in England will be eligible if they meet all the following criteria:
1. Located in the specified recruitment area.

2. Use Accurx text messaging software (98% of English practices use this system).
3. Practice staff willing to take part in qualitative interviews.
4. Phlebotomy is conducted at the practice level rather than via referral to a central location.

Patients will be eligible for recruitment to provide patient-reported outcomes if they are:
1. Aged 18 or over.
2. Registered at a participating practice and diagnosed with hypertension, and/or chronic kidney disease and/or type 2 diabetes at the start of the study period.
3. Attend for routine monitoring during the study period.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 31/07/2025:
We will exclude practices meeting any of the following criteria:
1. Practices that currently use standardised testing protocols for LTC, and have equivalent testing panels as those in the Test Smart study.
2. Practices that currently use standardised communication protocols for LTC.
3. Practices that regularly use point of care (PoC) testing for LTC monitoring (eg PoC HbA1c testing). PoC tests would not be captured in our testing data and may replace laboratory testing and therefore data from these practices would not be comparable.
4. Practices that decline to provide a practice champion.

Patients will be excluded if they are:
1. Unable to understand written English or one of the two other study languages sufficiently to complete a questionnaire. The other study languages will be selected based on those most commonly spoken in the GP practices recruited to the study.
2. Decline consent or are unable to consent.
3. Have previously declined to be contacted for research purposes.

Previous exclusion criteria:
GP practices will be excluded if they meet any of the following criteria:

1. Practices that currently use standardised testing protocols for LTC.
2. Practices that currently use standardised communication protocols for LTC.
3. Practices that regularly use point of care (PoC) testing for LTC monitoring (eg PoC HbA1c testing). PoC tests would not be captured in our testing data and may replace laboratory testing and therefore data from these practices would not be comparable.
4. Practices that decline to provide a practice champion.

Patients will be excluded if they are:
1. Unable to understand written English or one of the two other study languages sufficiently to complete a questionnaire. The other study languages will be selected based on those most commonly spoken in the GP practices recruited to the study.
2. Decline consent or are unable to consent.
3. Have previously declined to be contacted for research purposes.

Date of first enrolment
01/09/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Population Health Sciences, Bristol Medical School
9th Floor
Whitefriars
Lewins Mead
Bristol
England
BS1 2NT

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All anonymised research data will be kept indefinitely in line with NIHR policy on data sharing. Non-essential study documentation will be deleted at the end of the study. All essential study documentation will be retained in a secure location during the conduct of the study and for 5 years after the end of the study in line with University archiving policy, after which these essential documents will be destroyed. Once the project is finished, the created dataset will be stored by The University of Bristol Research Data Storage Facility (RDSF), which provides secure, long-term storage for research data. This major investment provides nightly backup of all data, with further resilience provided by three geographically distinct storage locations. A tape library is used for backup purposes and also for long-term, offline data storage. Only authorised users can access data stored within the RDSF. The RDSF is managed by Bristol's Advanced Computing Research Centre (ACRC) which has a dedicated steering group and a rigorous data storage policy. The RDSF upholds and reinforces Bristol's wider Information Security policy.

o This study will be sponsored by the University of Bristol (sponsor representative - alia. ataya@bristol.ac.uk).
o The study CIs, Penny Whiting (penny.whiting@bristol.ac.uk) and Jessica Watson (jessica. watson@bristol.ac.uk) will be the data custodians.

• The type of data that will be shared
o Anonymised individual patient data.
• When the data will become available and for how long
o It will be available for sharing after publication of the main results of the study.

o Fully anonymised data collected in this study will be stored in the University of Bristol Research Data Storage Facility (RDSF) for 20 years after the study has ended, which provides secure, long-term storage for research data.

• By what access criteria data will be shared including with whom
o Only authorised users can access data stored within the RDSF.
o Any request approved will be covered by a written DSA, detailing limitations of use, transfer to 3rd parties, data storage and acknowledgements.
o The person applying for use of the data will be scrutinized for appropriate eligibility by members of the research team. All requests will require their own separate REC approval prior to data being released.
o This may involve the Bristol Data Service who will allow access according to our pre-specified criteria.

• For what types of analyses and by what mechanism
o A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research (e.g., a protocol for a systematic review)

• Whether consent from participants was obtained
o Individual consent will be obtained for participants completing patient questionnaires. The data will be fully anonymised.

IPD sharing plan summary
Stored in non-publicly available repository

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