

Audit-based education to implement NICE clinical recommendations of things 'not to do' in people with cardiometabolic diseases: a two-round cluster randomised trial

Submission date 06/10/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/11/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/04/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The National Institute for Health and Care Excellence (NICE) has identified over 800 'Do-Not-Do' clinical interventions for potential disinvestment. Implementation of these recommendations could help reduce inappropriate prescribing as well as hospital admissions due to adverse events, and may lead to cost savings. However, these recommendations are often overlooked by clinicians due to competing commitments and finite time resources. Audit-based education (ABE) is an evidence-based quality improvement method that could be used to implement 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity. This study investigates an ABE tool to implement ten NICE 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity can improve adherence to these recommendations compared with standard care alone.

Who can participate?

Primary care practices in England that are members of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network.

What does the study involve?

The study will be an unblinded, cluster randomised controlled trial that will be run over two rounds, each lasting 12 months. Eligible practices will be those signed up to in the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. In Round 1, forty-two practices will be randomised 1:1 to either the intervention or control arm through simple randomisation, based on a single sequence of random assignments. Intervention practices will receive an ABE package that will comprise a dashboard to monitor prescribing (as per five 'Do-Not-Do' recommendations) in people with cardiometabolic multimorbidity, and pre-recorded webinars. The control practices will continue with their usual care. An intention-to-treat approach will be applied. Round 2 of the trial will use the same methodology but with an additional twenty practices (62 in total), and the ABE package will include five additional preselected recommendations.

What are the possible benefits and risks of participating?

There are potential long-term benefits to patients with cardiometabolic multimorbidity. Increased adherence to NICE 'Do-Not-Do' recommendations could help reduce inappropriate prescribing as well as hospital admissions due to adverse events with improved clinical practice. This may lead to cost savings.

The trial will assess an intervention delivered to GP practice staff aimed at promoting adherence to national clinical guidance. The study is not testing or promoting any novel aspects of care, and as such, we do not foresee any risks to patients.

If at the end of the trial, practices receiving the audit-based education package are significantly more likely to adhere to NICE 'Do-Not-Do' recommendations compared to practices in the control group, we will have demonstrated that tailored audit-based education packages are an effective tool to implement NICE 'Do-Not-Do' recommendations.

Where is the study run from?

Nuffield Department of Primary Health Care Sciences at the University of Oxford (UK).

When is the study starting and how long is it expected to run for?

June 2022 to March 2026

Who is funding the study?

The study is funded by NIHR via the Applied Research Collaboration (ARC) as part of Multiple Long term Conditions Programme (via East Midlands ARC) (UK)

Who is the main contact?

Prof Simon de Lusignan, simon.delusignan@phc.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Simon de Lusignan

ORCID ID

<https://orcid.org/0000-0002-8553-2641>

Contact details

Nuffield Department of Primary Care Health Sciences

University of Oxford

Eagle House

7 Walton Well Road

Oxford

United Kingdom

OX2 6ED

+44 1865 617 283

simon.delusignan@phc.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

304871

Protocol serial number

IRAS 304871, CPMS 53490

Study information

Scientific Title

Audit-based education to implement NICE 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity: a two-round cluster randomised trial

Acronym

MONITORY

Study objectives

An audit-based education (ABE) package designed to implement National Institute for Health and Care Excellence (NICE) 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity can improve adherence to these recommendations compared to standard care alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 09/06/2022, Medical Sciences Interdivisional Research Ethics Committee (Research Services, Boundary Brook House, Churchill Drive, Headington, Oxford, OX3 7GB, UK; +44 (0)1865 616575; ethics@medsci.ox.ac.uk), ref: R79496/RE001
2. Approved 29/09/2022, Health Research Authority (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 22/HRA/2607

Study design

Two-round unblinded cluster randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Exploring the effect of an ABE intervention tool to assist general practices on the implementation of NICE 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity.

Interventions

Current interventions as of 25/04/2025:

The study will be an unblinded, cluster randomised controlled trial to explore whether an ABE package to assist general practices can lead to an improvement in the implementation of NICE 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity. The trial will be run over two rounds, each lasting 12 months. Practices will be randomised 1:1 to either the intervention or control arm. Intervention practices will receive an audit-based package for select medications in people with cardiometabolic multimorbidity, whilst the control practices will continue with their usual care.

The ABE package will comprise two components:

1. Healthcare professionals working in primary care, with prescribing responsibilities (GPs, nurses and/or practice pharmacists), will complete continuing professional development (CPD) accredited training; this will comprise webinars, or videos and podcasts, covering the importance of the 'Do-Not-Do' guidelines and how to use and interpret the ABE feedback. Materials relevant to learning, appraisal and re-accreditation will be provided.
2. The practice dashboard will provide practice-level feedback for each of the NICE 'Do-Not-Do' recommendations. This will be updated monthly and will comprise aggregated data.

Previous interventions:

The study will be a 12-month unblinded, cluster randomised controlled trial to explore whether an ABE package to assist general practices can lead to an improvement in the implementation of NICE 'Do-Not-Do' recommendations in people with cardiometabolic multimorbidity. Intervention practices will receive an audit-based package for select medications in people with cardiometabolic multimorbidity, whilst the control practices will continue with their usual care.

The ABE package will comprise two components:

1. Healthcare professionals working in primary care, with prescribing responsibilities (GPs, nurses and/or practice pharmacists), will complete continuing professional development (CPD) accredited training; this will comprise webinars, or videos and podcasts, covering the importance of the 'Do-Not-Do' guidelines and how to use and interpret the ABE feedback. Materials relevant to learning, appraisal and re-accreditation will be provided.
2. The practice dashboard will provide practice-level feedback for each of the NICE 'Do-Not-Do' recommendations. This will be updated monthly, and will comprise aggregated data.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 25/04/2025:

Proportion of patients inappropriately treated as per the NICE 'Do-Not-Do' recommendations at baseline, and after implementation of the ABE intervention, measured using the Oxford-Royal College of General Practitioners Clinical Informatics Data Hub (ORCHID) database.

Previous primary outcome measure:

Proportion of patients inappropriately treated as per the NICE 'Do-Not-Do' recommendations at baseline, and 12 months after implementation of the ABE intervention, measured using the Oxford-Royal College of General Practitioners Clinical Informatics Data Hub (ORCHID) database.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/03/2026

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 25/04/2025:

Practice inclusion criteria:

Primary care practices in England that are members of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. The Oxford-RCGP RSC has a secure analytics hub based at the University of Oxford (ORCHID-secure) and has >20 million registered patients across >2000 practices. Each GP practice will be selected to participate in the study based on whether their data can reliably be extracted. This is vital for the purpose of being able to refresh the practice dashboard with updated data monthly, as well as for analysis at the end of the study.

Patient inclusion criteria:

Data from computerised medical records (CMRs) of patients with cardiometabolic multimorbidity will be used to update the practice dashboard, which is part of the ABE package. Data from CMRs will also be used for analysis at the end of the trial to explore the effectiveness of the intervention compared to standard care alone. The data will be collected via the Oxford-Royal College of General Practitioners Clinical Informatics Data Hub (ORCHID) database. The database includes pseudonymised data of computerised medical records for patients registered with GP practices that are members of Oxford-RCGP RSC network.

Patients with cardiometabolic multimorbidity will be flagged and have data extracted in participating practices providing they meet the following inclusion criteria:

1. Aged 18-64 years
2. Confirmed diagnosis of two or more cardiometabolic diseases.

Previous participant inclusion criteria:

Practice inclusion criteria:

Primary care practices in England that are members of the Oxford-Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) network. The Oxford-RCGP RSC has a secure analytics hub based at the University of Oxford (ORCHID-secure) and has >15 million registered patients across >1800 practices. Each GP practice will be selected to participate in the study based on whether their data can reliably be extracted. This is vital for the purpose of being able to refresh the practice dashboard with updated data monthly, as well as for analysis at the end of the study.

Patient inclusion criteria:

Data from computerised medical records (CMRs) of patients with cardiometabolic multimorbidity will be used to update the practice dashboard, which is part of the ABE package. Data from CMRs will also be used for analysis at the end of the trial to explore the effectiveness of the intervention compared to standard care alone. The data will be collected via the Oxford-Royal College of General Practitioners Clinical Informatics Data Hub (ORCHID) database. The database includes pseudonymised data of computerised medical records for patients registered with GP practices that are members of Oxford-RCGP RSC network. All data for patients that have explicitly opted-out of data sharing will be excluded from the analysis.

Patients with cardiometabolic multimorbidity will be flagged and have data extracted in participating practices providing they meet the following inclusion criteria:

1. Aged 18-64 years
2. Confirmed diagnosis of two or more cardiometabolic diseases.

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

64 years

Sex

All

Key exclusion criteria

1. Primary care practices that are not members of the Oxford RCGP RSC network.
2. Patients <18 years old and/or without cardiometabolic conditions.

Date of first enrolment

10/10/2022

Date of final enrolment

31/10/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University Oxford

University Offices

The Chancellor, Masters and Scholars of the University of Oxford

Wellington Square

Oxford

United Kingdom

OX1 2JD

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research via the Applied Research Collaboration East Midlands

Results and Publications

Individual participant data (IPD) sharing plan

Data sharing agreements are in place between all collaborative sites and the sponsor, University of Oxford. All data will be processed as per the GDPR regulations, Good Clinical Practice (GCP), Data code of practice (UK) and the University of Oxford confidentiality policies.

IPD sharing plan summary

Not expected to be made available

Study outputs

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