ISRCTN16678243 https://doi.org/10.1186/ISRCTN16678243

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

Registration date
16/11/2022

Overall study status
Ongoing

Last Edited
25/04/2025

Condition category
Other

[_] 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 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 signficantly 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 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

Study website
https://orchid.phc.ox.ac.uk/index.php/monitory/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304871

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

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

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/06/2022

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
62 practices in total. Round 1 will include 42 practices. Round 2 will include 20 additional practices.

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
England

United Kingdom

Study participating centre
University Oxford
University Offices
The Chancellor, Masters and Scholars of the University of Oxford
Wellington Square
Oxford
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Sponsor information

Organisation
University of Oxford

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Joint Research Office
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Publication and dissemination plan
The results will be published in a scientific journal for dissemination and results reported in the ISRCTN registry. There may be further publicising of results in line with any restrictions imposed by the journal publishing the study.

Intention to publish date
31/03/2026

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