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Electronic Risk Assessment for Cancer for Patients in General Practice

Submission date 08/03/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/03/2019	**Overall study status** Completed	
Last Edited 05/02/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-assessing-at-the-usefulness-of-electronic-tools-to-assess-the-risk-of-cancer-erica

Contact information

Type(s)
Scientific

Contact name
Prof Willie Hamilton

ORCID ID
https://orcid.org/0000-0003-1611-1373

Contact details
College House
University of Exeter Medical School
Heavitree Road
Exeter
United Kingdom
EX1 2LU
01392 726097
W.Hamilton@exeter.ac.uk

Type(s)
Public

Contact name
Dr Raff Calitri

ORCID ID

https://orcid.org/0000-0003-0889-4670

Contact details
Exeter Clinical Trials Unit
College House
University of Exeter Medical School
Heavitree Road
Exeter
United Kingdom
EX1 2LU
01392 726047
r.calitri@exeter.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1819/19

Study information

Scientific Title
A pragmatic cluster randomised controlled trial of electronic risk-assessment for cancer to help identify early stage cancer in patients in general practice (The ERICA trial)

Acronym
ERICA

Study objectives
The overarching aim of the trial is to assess the clinical effectiveness and cost effectiveness of electronic Risk Assessment Tools (eRATs) for cancer compared to usual care for patients in general practice. The specific objectives of this study are to compare the effects of eRATs (vs usual care) on: cancer staging at time of diagnosis, cost to the NHS, patient experience of care, and service delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/05/2019, London – City and East REC (Henry VIII Committee Room, St Bartholomew's Hospital, North Wing, EC1A 7BE; 0207 1048033; nrescommittee.london-cityandeast@nhs.net), ref: 19/LO/0615

Study design
Pragmatic cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cancer

Interventions
The eRATs are electronic clinical decision support tools embedded into the general practices' principal clinical system. They work by collating relevant Read-coded symptoms, supplemented by existing routine blood tests already in the GP's clinical system, which are then assessed for the possibility of cancer using published algorithms developed by Hamilton and colleagues. There are six eRATs of interest to the study (lung, colorectal, oesophago-gastric, bladder, kidney, and ovary) and they are housed within a Macmillan-sponsored Clinical Decision Support Tool. The eRATs have two main ways of working. Firstly, a prompt appears on screen when a patient has a risk of any one of the studied cancers of 2% or higher. Secondly, the clinician may specifically open a 'symptom checker' which lists the relevant symptoms of each studied cancer, allowing the patient's symptoms to be added and the risk of cancer to be (re)calculated.

530 general practices will be randomised 1:1 to receive either the intervention (access to the suite of electronic Risk Assessment Tools; eRATs) or usual practice. The clusters will be practices. There will also be embedded process and health economics evaluations along with a parallel study modelling the impact of eRATs on NHS service delivery.

Randomisation
This is a pragmatic, cluster RCT. The 530 practices will be randomised using a 1:1 ratio into one of two trial arms: usual diagnostic practice (control) and usual diagnostic practice plus access to the suite of Macmillan electronic risk assessment tools (eRATs) (as the intervention), for a total of 265 practices per arm. Randomisation will be remote and web-based, conducted by an independent member of the data team at the Exeter Clinical Trials Unit, overseen by the CTU statistician (not the trial statistician). The sequence of randomisation will be computer generated. To ensure there is balance between the trial arms regarding practices' propensity to refer patients for cancer investigation, we will minimise the randomisation by two week wait referral rate (the best available proxy) in national tertiles. We will use simple randomisation to allocate the first 50 practices (~10% of the total target), and then apply minimisation by two week wait referral rate, taking into account the previous allocations to inform the minimisation algorithm. To promote allocation concealment, all allocations using the minimisation algorithm will retain a stochastic element.
Once the member of the CTU data team has performed the randomisation, they will alert the trial manager (via email or phone call) who will in turn inform the practice of their allocation outcome. Although this randomisation with minimisation approach should make it almost impossible for the study team to predict the trial arm allocation for practices being processed (i. e., interested and undergoing screening), to ensure allocation concealment the last ten practices to be recruited will be randomised simultaneously – i.e., we will delay randomisation until we have ten final practices signed up to the study.

Data collection procedures
All primary and secondary outcome measures will be available from the cancer registry: applications for data release will be made to NCRAS. Public Health England (NCRAS) have, in

principle, assigned us an in-house statistician to support the data collection process. We will be guided by NCRAS but anticipate requesting two data exports. Currently, there is approximately a 12 month time lag in availability of some of the outcome data we require. As a result, our first export will occur at the end of the trial data collection period. Our second export will occur 12 months after that. Data will not contain any personally identifiable information; we will be requesting and collecting depersonalised (pseudo-anonymised) data. The Public Health England Office for Data Release (ODR) guidelines indicate that no legal gateway (e.g., section 251 approval) will be necessary to obtain these data. For each export, data will be securely transferred in accordance with the registry's policies and placed into a database developed by Exeter CTU situated on secure computer servers. The CTU will ensure the appropriate security measures are in place to comply with ODR and other required regulatory policies.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Proportion of the combined six cancers diagnosed during 2-year follow-up that were at Stage 1 /2 (early – cure likely) at diagnosis versus Stage 3/4 (late – cure not likely).

Key secondary outcome(s))
Current secondary outcome measures as of 13/01/2023:
A range of secondary outcomes will be examined:
1. The binary stage at diagnosis of a further six cancers without eRATs will be identified from NCRAS and compared between intervention and control practices. This is to investigate the possibility of a 'spill-over' effect whereby eRATs are associated with increased diagnostic activity beyond the eRAT cancers.
2. The practice's number of patients diagnosed with the six eRAT cancers combined, and the total number of cancer cases, from NCRAS.
3. The number of patients investigated or referred under the 2-week wait system for the six eRAT cancers combined, and in total, from Cancer Waiting Times data.
4. Route to diagnosis from the Routes to Diagnosis Dataset, which uses Hospital Episode Statistics data. This will be categorised into four possible routes: emergency attendance, 2-week wait referral, GP referral, and "other". We will collect this information for each of the six eRAT cancers, and for the six comparator non-eRAT cancers.
5. 2-week wait performance measures, from Cancer Waiting Times data, for the six eRAT cancers combined, and for all cancer referrals:
5.1. Whether a patient on a 2-week wait pathway received a diagnosis of cancer. When aggregated, for example at the practice level, and expressed as the proportion of patients who received a cancer diagnosis, this is known as the conversion rate.
5.2. The duration between the 2-week wait referral and diagnosis of cancer in days
5.3. Whether patients referred on a 2-week wait referral and who received a cancer diagnosis were diagnosed within 28 days, the Faster Diagnosis Standard (introduced in 2022).
5.4. Detection rate – the proportion of a practice's cancers which are identified via the 2-week wait pathway.
6. Survival measures (from date of diagnosis): 30-day; 1-year (identified from NCRAS). 5-year

survival will also be reported, but the main trial will report on 30 days and 1 year, with 5-year data being a subsidiary report. These outcomes will use all-cause mortality data from the Office for National Statistics.
7. Adverse events (using data from the Diagnostic Imaging Dataset): these are expected to be few, and largely related to complications from hospital investigations such as colonoscopy. There is no mechanism for adverse events to be collected using routine data. We will, however, estimate any change in the expected number of adverse events from imaging investigations (colonoscopies, sigmoidoscopies, upper gastro-intestinal endoscopies, chest x-rays, abdominal ultrasounds, and abdominal CT scans) through investigating any change in the rate of these investigations in intervention practices relative to control practices (see data analysis section). Potential adverse psychological consequences of being labelled with 'possible cancer' will be further explored in the process evaluation.

Previous secondary outcome measures:
1. The stage at diagnosis of a further six cancers without eRATs will be explored and compared in intervention vs. control practices. This is to investigate the possibility of a 'spill-over' effect whereby eRATs are associated with increased diagnostic activity beyond the eRAT cancers.
2. Operational measures:
2.1 The practice's number of patients diagnosed with the six eRAT cancers combined, and the total number of cases (excluding non-melanoma skin cancer).
2.2 Number of patients investigated or referred under the two-week wait system or equivalent for the six eRAT cancers combined, and in total (using waiting times data).
3. Proportion of patients diagnosed with cancer who were diagnosed via each route to diagnosis (this can be identified by Routes to Diagnosis Dataset, which uses HES data. Specifically, we will investigate the proportion diagnosed via the following routes: emergency attendance, two-week wait referral, GP referral, and "other". We will collect this information for each of the six eRAT cancers, and for the six comparator non-eRAT cancers.
4. Two-week wait performance measures (using waiting times data), for the six eRAT cancer combined (restricting the sample to patients from relevant pathways) and for all cancer referrals:
4.1 "Conversion rate" – the proportion of patients from each practice referred under a two-week wait pathway who received a cancer diagnosis.
4.2 Target success – the proportion of patients from each practice referred under a relevant two week wait pathway for whom the target of being seen within two weeks was met. Additionally, we will explore the actual waiting time for these patients.
5. Survival measures: 30-day; 1-year (these two can be identified from patient records of the cancer registry dataset). 5-year survival will also be measured, but the main trial will report on 30 day and 1-year, with 5-year data being a subsidiary report.
6. Imaging investigations: the number of patients from each practice receiving colonoscopies, sigmoidoscopies, upper gastro-intestinal endoscopies, chest x-rays, abdominal ultrasounds, and abdominal CT scans. These measures will enable us to estimate any change in the expected number of adverse events from investigations that may arise from eRAT usage.
7. Adverse events: These are expected to be few, and largely related to complications from hospital investigation such as colonoscopy. There is no mechanism for these to be collected using routine data.

Completion date
31/10/2024

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 23/01/2023:
We will not recruit participants to the main RCT. It is a cluster RCT with the clusters being GP practices across England.
Practices must host either EMIS, or SystmOne, principal clinical systems. Only practices completing an agreement to engage with the research processes and the intervention/control arms will be eligible; in a practice agreement the practice will confirm that a practice meeting has taken place and at least fifty per cent of their GPs have agreed to participate in the trial. Practices that are proposing a split or a merger are not eligible.
We will also run a series of nested studies which will involve the recruitment of patients:
1. Patient interviews to explore their experience of care following an eRAT trigger and
2. Patient use of health services and their quality of life following an eRAT trigger.
For 1. only intervention practices will participate, and we'll seek to recruit 12-18 patients for whom an eRAT triggered and the GP made a referral/order investigations.
For 2. intervention (N=28) and control (N=28) practices will be recruited, and we'll aim to recruit 140 patients from each arm. In the intervention arm this will be patients who received an eRAT trigger and for whom the GP made a referral/order investigations. In control practices, patients will be those for whom an eRAT would have trigger in the practice and for whom the GP made referral/order investigations. Patients will be invited to participate via the practice.

Previous participant inclusion criteria as of 13/01/2023 to 23/01/2023:
We will not recruit participants to the main RCT. It is a cluster RCT with the clusters being GP practices across England.
Practices must host either Microtest, or SystmOne, principal clinical systems. Only practices completing an agreement to engage with the research processes and the intervention/control arms will be eligible; in a practice agreement the practice will confirm that a practice meeting has taken place and at least fifty per cent of their GPs have agreed to participate in the trial. Practices that are proposing a split or a merger are not eligible.
We will also run a series of nested studies which will involve the recruitment of patients:
1. Patient interviews to explore their experience of care following an eRAT trigger and
2. Patient use of health services and their quality of life following an eRAT trigger.
For 1. only intervention practices will participate, and we'll seek to recruit 12-18 patients for whom an eRAT triggered and the GP made a referral/order investigations.
For 2. intervention (N=28) and control (N=28) practices will be recruited, and we'll aim to recruit 140 patients from each arm. In the intervention arm this will be patients who received an eRAT trigger and for whom the GP made a referral/order investigations. In control practices, patients will be those for whom an eRAT would have trigger in the practice and for whom the GP made referral/order investigations. Patients will be invited to participate via the practice.

Previous participant inclusion criteria:
We will not recruit participants to this RCT. It is a cluster RCT with the clusters being GP practices across England.
1. Practices must host either Microtest, SystmOne, or Vision principal clinical systems. Only practices completing an agreement to engage with the research processes and the intervention /control arms will be eligible; in a practice agreement the practice will confirm that a practice meeting has taken place and at least fifty per cent of their GPs have agreed to participate in the trial.

Participant type(s)
Other

Healthy volunteers allowed

No

Age group
Other

Sex
All

Key exclusion criteria
1. If a practice is planning to merge or restructure over the course of the trial (to the extent that the practice size will change by at least 10%) they will not be permitted to participate

Date of first enrolment
01/06/2019

Date of final enrolment
21/01/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
University of Exeter Medical School
Heavitree Road
Exeter
United Kingdom
EX1 2LU

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Charity

Funder Name
The Dennis and Mireille Gillings Foundation

Funder Name
University of Exeter

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as it will contravene cancer registry policies.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		20/03/2023	21/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
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