Information sheet: GP Surgery

We are inviting your GP surgery to take part in a research project called:
Electronic Risk Assessment for Cancer (ERICA) led by Professor Willie Hamilton at the University of Exeter Medical School.

Please read this information to help you decide whether your GP surgery would like to take part in the study.

You can watch two short videos containing the core trial information:
erica-hub.co.uk

What is this research about?
The UK is not as good as other countries in diagnosing cancer early. It has been estimated that between 5,000-10,000 lives are lost each year as a result of late diagnosis. As the gatekeepers for most tests, GPs are in a difficult position. They perceive pressure from patients who are keen for tests to be undertaken to either identify or rule out cancer. At the same time, GPs don't want to flood secondary care with referrals, especially in the current challenging economic climate. There is a need for well evidenced tools to support selection; aids that can help both GPs and patients.

A team led by researchers at the University of Exeter has developed new electronic risk assessment tools (otherwise known as eRATs) to help GPs identify possible cancer. The eRATs are housed within Macmillan's electronic Clinical Decision Support software module, a medical device that can be embedded into the major principle clinical software systems (e.g., EMIS, SystmOne).

The eRATs have two main functions: the prompt and the symptom checker. The prompt appears as a pop-up on screen when a patient has at least a 2% risk of one or more of the seven cancers in the eCDS software (lung, oesophago-gastric, kidney, bladder, ovary, colorectal, pancreas). GPs can explore the possibility of cancer further in consultation with the patient using the symptom checker function of the tool. The symptom checker allows the GP to add new symptoms and will automatically recalculate the risk of cancer.

The aim of the ERICA study is to assess the clinical and cost effectiveness of 6 eRATs –lung, oesophago-gastric, kidney, bladder, ovarian, and colorectal (we are not studying pancreas). We want to recruit 530 practices across England. If your practice joins the trial, you will be randomly allocated to either the intervention arm, where you will receive access to the suite of eRATs, or to the control arm, where you will provide your usual care.

Our primary outcome is the cancer stage at time of diagnosis. We hope to see a 4.8% improvement in stage, making some previously incurable patients curable. If we do find this, then it adds up to approximately 6,000 cancer deaths avoided per year! Our secondary outcomes include routes to diagnosis, 30-day and 1-year survival rates.

All of our outcome data will be depersonalised (not personally identifiable) patient data collected over a two year period from national cancer registries – not from your clinical systems.

Nested Studies

A small proportion of practices from both trial arms will be offered additional nested studies which will look at:

1) GP eRAT usage and GP and patient experience of care.
2) Patients' health resource use.

You will only be asked to participate in one nested study. Nested study 1 involves multiple activities. Practices can select which activity (if any) they would like to participate in. There will be no obligation to sign up to any of the nested studies.

Who can take part in the ERICA trial?

- Only practices running with EMIS, or SystmOne are eligible to participate.
- Only practices with two week wait referral wait data publicly available are eligible to participate (research team will confirm at point of expression of interest)
- Practices about to restructure (merger/separation/closure) are not eligible.
- Practices already using eRATs or alternative cancer risk tools are not eligible to take part.

- Only practices who have completed a practice agreement showing their commitment to the trial will be eligible to take part.

What does taking part involve?

You will be asked to nominate a 'research champion' within your practice. This person will be the main contact with the ERICA team. We will ask you to organise a practice team meeting to discuss the trial and to seek agreement from your colleagues to participate. Our suite of trial videos can be used to provide summary trial information. If you would like to participate, the research champion and practice manager/GP lead will need to complete a practice agreement indicating a meeting has taken place and at least half of GPs are supportive of the study and using the eRATs within their clinical practice.

Your practice will then be randomly allocated to either the intervention arm or the control arm. Practices allocated to the intervention arm will be given access to the eRATs. The study team will help with the process. There will be some training videos on the use of the eRATs along with a short quiz for the research champion to complete prior to the start of the study.

Once the eRATs have been embedded in the practice they should work across all practice computers and be available to all participating GPs. GPs will use eRATs as support tools – the eRATs do not give orders. The GP will not be expected to refer every time the RAT prompt goes off. Instead we hope the eRATs will provide a useful tool to alert GPs to the small possibility of cancer. The GP will use their clinical judgement on how best to manage the patient, be it referral, in-house testing, or safety netting.

Practices allocated to the control arm will provide care as usual.

We will ask the research champion to complete a brief 'interim questionnaire' after a few months into the study and an 'exit questionnaire' at the end of the study that will ask about how the study has impacted on the GP surgery.

If you agree to a nested study

1) GP eRAT usage and GP and patient experience of care.

A selection of GPs (from intervention and control practices) will be invited to take part in a brief interview to discuss their experience of providing care during the trial. GPs in intervention practices will also be asked about their experiences of using eRATs. Potentially interested GPs will be sent the GP interview information sheet to review [which can also be viewed on the trial website: www.theericatrial.co.uk]

A selection of patients will be invited to take part in an interview to discuss their experience of care. We are interested in the patient's diagnostic pathway and will invite them to participate in up to three interviews across a 12 month period to explore their experiences of any ongoing care. We will need support from somebody in the practice to help us identify and send initial invite letters to potential participants. The study team will provide the letter and all materials.

The information booklet that we will send to patients can be viewed on the trial website: [www.theericatrial.co.uk]

2) Patients' health resource use.

A selection of identified patients will be sent a letter from the practice (written by the research team, all materials provided by the research team). The letter will ask participants to a) either give permission for the research team to review their medical records or b) give permission to review their medical records and provide consent to complete a short questionnaire about quality of life and resource use at two time points over the next couple of months. The questionnaire will ask patients to report on the use of specialised NHS resources that are typically difficult to identify via medical notes review. If patients agree to medical notes review, a member of the research team will need to be provided with computer log-in details and allocated some space at the practice to conduct the review. Medical record review will capture the patients' NHS resource use over a two month period, from the date in which the eRAT fired (or would have done in control practices, if eRATs were available).

If you agree to help us invite patients to participate in one of the nested studies:

We will ask intervention Practice's to run the eRATs reporting function. You will be asked to turn this on for a two week period. This will tell us who the eRATs were used on during that period. In control practices we would like to run some pre-written searches to identify people for whom an eRAT would have fired for. We may ask intervention practices to run these searchers if the eRAT reporting function does not work. We may ask you to repeat this activity on two more occasions if no or too few patients are identified from the searches. If you agree to help with this activity, we will ask someone in the practice to review the report and securely send the patient information to the research team, either via NHS to NHS email or via secure upload to university servers.

The eRAT report contains patient information (e.g., gender, sex) and lists the eRAT(s) that were fired during the consultation along with the risk score and the symptoms that

were recorded on the symptom checker. We have the relevant permission from the confidentiality advisory group to collect this data.

Does my GP Surgery have to take part?

No. Participation is entirely voluntary. If your surgery does take part in the study the research champion and practice manager will be asked to sign a practice agreement. You are always free to withdraw at any time. You do not have to give a reason for withdrawing. If you do withdraw any information collected will remain part of the study.

What are the benefits or advantages of taking part?

Practices allocated to the intervention arm will be given £470.55 to cover research costs. Practices allocated to the control arm will be given £204.40 to cover research costs. Research costs include staff time required for study set-up and staff time for supporting the nested studies (you will get the full amount irrespective of whether you support the nested studies or not). Service support costs will also be provided for help with participant identification in the nested studies (i.e., database searches and screening). Participating in research like this helps to improve future patient care. This research is exploring whether the eRATs are effective in catching cancers earlier, and therefore may potentially save lives. By taking part in this research you will help us definitively answer whether eRATs are clinically effective and cost effective.

What are the risks or disadvantages of taking part?

We do not see any additional risks for practice staff. The research will explore the risks to patients. These are expected to be few, and largely related to complications from hospital investigation such as gastroscopy. Psychological adverse events of being labelled with 'possible cancer' are explored within the nested studies. We will also report at the end of the study the number of 'false positives' – the number of individuals who were referred for investigations/tests and who did not receive a diagnosis of cancer.

One question we have addressed in preliminary work is whether the GP is at medico-legal risk if the prompt goes off, and the GP chooses not to investigate or refer. The prompt is a 'help' not an 'order', and actually should reduce the risk of a complaint, as we expect the eRATs will help GPs to make 'better' referral decisions. There will be a small number of times where the prompt gives a 'score' >3% where there is a clear alternative explanation (say a patient with chronic renal failure and recurrent abdominal pain from renal stones). In this instance, the GP would not want to refer, and would probably want to disable the prompt. This would be correct medicine, and pose no medico-legal problems.

What if there is a problem?
If you are unhappy about any aspect of the study then please contact the trial manager (details given below) who will address your issues. You can also contact Ms Pam Baxter at the University of Exeter who as Sponsor Representative specialises in making sure that research studies are run appropriately. Pam's contact details are:

Ms Pam Baxter
Senior Research Governance Officer
University of Exeter
Research Ethics and Governance Office
Lafrowda House
St Germans Road
Exeter
EX4 6TL
Tel: 01392 723588
Email: p.r.baxter2@exeter.ac.uk

Will patient participation be kept confidential?
Yes. Practices will be asked to put up a poster to alert patients to the trial. We will be collecting depersonalised data from the National Cancer Registration and Analysis Service (NCRAS). The registry will send us depersonalised data sets. We will not share this information with anybody outside of the research team.

How will the trial data be used?
Aggregate level data will be used to inform the main study questions. The group level data will be used for educational purposes, in research reports, research presentations or for publication.

Who will you share the trial data with?
Access to all trial data will be restricted to the ERICA research team.

What will happen to the data after the study?
We will retain cancer registry data under secure conditions on University of Exeter Clinical Trials Unit servers. Data will be collected and retained in accordance with the UK Data Protection Act 2018, and managed in accordance with the trial-registry policy for data management.

How will the results of the research study be used?
Once the study is complete, the results will be written up and published in scientific journals and presented at national and international academic conferences. If you would like a copy of any publication or a summary of the results, please let the researcher know.

Note on data processing

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a 'UK-only' version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the 'public interest'. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter's Data Protection Officer via the link;
https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/

If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Pam Baxter, Senior Research Governance Officer.

Ethical approval and review

This project has been granted ethical approval by London – City & East Research Ethics Committee (ref: 19/LO/0615)

Thank you for reading this information

If you would like to take part or have any further questions, please contact:

Dr Hannah Baber
ERICA Trial Manager
University of Exeter Medical School
Room 2.27 College House
St. Luke's Campus
Magdalen Road
Exeter EX1 2LU
T: 01392 726555
E: h.l.baber@exeter.ac.uk

ERICA research team
T: 01392 726 555
E: erica@exeter.ac.uk

You can also watch two short videos containing the core trial information:

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