ISRCTN95472706 https://doi.org/10.1186/ISRCTN95472706

At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK

Submission date
02/12/2014

Recruitment status
No longer recruiting

Registration date
05/12/2014

Overall study status
Completed

Last Edited
23/04/2025

Condition category
Respiratory

[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
Asthma is a common long-term condition that can cause coughing, wheezing, chest tightness and breathlessness. Many UK asthma patients are admitted to hospital or die every year. Current treatments should allow asthma to be controlled in most patients. However, certain asthma patients are at greater risk of being admitted or dying than others and intensive support of these patients may improve their health. This study will confirm we can improve the care of these patients, cost to the NHS, and the effect on care of other asthma patients.

Who can participate?
We will recruit 270 GP practices and expect they will identify 10,530 patients who are at risk of having severe asthma attacks.

What does the study involve?
Half of the GP practices will be randomly allocated to have a computerised alert message whenever any of the 'at risk' patients make contact with anyone in the practice. Practice staff will be trained on what to do when they see the alert; for example, remind receptionists to book urgent appointments; remind GPs and nurses to advise patients to take their medication and follow their written asthma action plans (personalised documents which advise patients what to do when their asthma gets worse or better); and remind pharmacists to ensure patients take their medicines. Routinely available anonymised data from patients will be collected from participating practices. Practices will be followed up for 12 months, after which we will count visits to Accident and Emergency, hospital admissions, and deaths due to asthma. We will also measure asthma control, medications prescribed, attendance for routine appointments and smoking cessation. We will calculate how much this costs and whether it improves (or interferes with) the care of other patients with asthma in the practices. With informed consent, we will arrange focus groups and interviews for patients and staff, to discuss thoughts about the at-risk registers, the training, and how it worked in practice. Patients at the other GP practices will receive care as usual.

What are the possible benefits and risks of participating?
There may be no direct benefit to participants in taking part in this research study but their involvement will give them the opportunity to have their say about their experiences of the

ARRISA-UK programme and may help improve treatment for patients with asthma. We do not anticipate there being any significant risks to participant health by taking part in the study.

Where is the study run from?
Norwich Clinical Trial Unit, UEA, Norwich (UK)

When is the study starting and how long is it expected to run for?
December 2014 to October 2023

Who is funding the study?
The National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
HTA 13/34/70

Study information

Scientific Title
At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): a pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support

Acronym
ARRISA-UK

Study objectives
The study aims to test the hypothesis that systematically identifying patients at risk of severe exacerbations of asthma, flagging their primary care EHR to provide enduring prompts at the time of all contacts with the practice, training all practice staff about the systematic management of these patients and providing ongoing practice support will reduce crisis asthma events (asthma-related deaths, hospitalisations and A&E attendances) and be clinically acceptable and cost-effective without detriment to the care of non-at-risk asthma patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales REC (Central & East) of the National Institute for Social Care and Health Research, UK, 26/11/2014, ref: 14/WA/1211

Study design
Two-arm cluster randomized controlled multi-centre trial integrating a mixed-methods process evaluation and economic evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Asthma care in general practice, specifically the prevention of severe exacerbations of asthma that lead to crisis asthma events (asthma-related deaths, hospitalisations and A&E attendances)

Interventions
This is a complex intervention comprising the following four components:
1. Establishment of register of at-risk patients
2. Practice-wide internet-based training
3. Computerised Decision Support System: a computerised alert
4. Practice support: phone call and video reminders
The intervention will target all healthcare professionals and reception staff within the whole practice to improve the care of patients with asthma who are at high risk of crisis events related to exacerbations of their disease.

The control arm will receive care as usual in the UK.

Intervention Type
Mixed

Primary outcome(s)

The primary outcome is the difference in the proportion of at-risk patients (as identified by the initial search) who have an asthma-related crisis event (A&E attendance, hospitalisation or death) in the 12 months from the date the flags go live on the computer system in the intervention practices compared to the control group practices.

Key secondary outcome(s))

1. The time to first asthma-related crisis event for at-risk patients
2. The percentage of all patients with an asthma-related crisis event and the time to first of these events
3. The percentage of all asthma patients with good control – answering no to all of the 'RCP 3 questions for asthma' (difficulty sleeping, daytime symptoms, interference with usual activities)
4. The percentage of all patients with asthma with a hospital admission or death for any reason
5. The number of the following (per patient per year) for both at-risk asthma patients and all asthma patients:
5.1. Short-acting bronchodilator prescriptions issued
5.2. Prescriptions of systemic corticosteroids for asthma exacerbations and antibiotic-treated lower respiratory tract infections
5.3. Modifications of the prescription of asthma-related medications to align more closely with current guidelines (e.g. increased use of inhaled corticosteroids)
5.4. Written personalised asthma action plans and patient self-monitoring with peak flow diaries
5.5. Inhaler technique assessments recorded
5.6. Smoking cessation advice or smoking cessation medications
5.7. Flu vaccinations
The rate of the following (per patient per year)
5.8. 'Did not attend' at primary and secondary care routine appointments
5.9. Adherence to medication determined from validated computer-based calculations from prescription data

Health economic outcome
The main outcome measure in the economic analysis will be based on the primary outcome for the study. The number of asthma-related crisis events will be estimated for both study arms. The incremental effect will be the estimated mean difference (between arms) in number of asthma crisis events, after taking account of clustering.

Process evaluation outcomes
The outcomes include quantitative and qualitative assessments of the views of healthcare professionals and patients, practice procedures and processes of care, staff behaviours and awareness, and indicators of intervention uptake, implementation and compliance. The process evaluation will also explore how key intermediary and primary and secondary outcomes (e.g. asthma control) are affected by contextual characteristics (e.g. practice characteristics), including identification of factors that will improve effectiveness and sustainability in practice.

Completion date

31/10/2023

Eligibility

Key inclusion criteria

1. The unit of randomisation is the cluster (or GP practice). The only inclusion criterion for the clusters is that they are General Practices within the UK

2.
The individual participants (for the purpose of the primary endpoint) within the clusters are patien

3. In addition, for the purposes of process evaluation and health economic analysis practice staff will also be included as participants (as we require data from these individuals)

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
168661

Key exclusion criteria
The unit of randomisation is the cluster (or GP practice). The exclusion criteria for the clusters are:

1. Practices already implementing a formal prospective process of identification of patients with at

2. Practices hosting or affected by research which might significantly influence the practice-wide process of care of patients with 'at-risk' asthma

The individual participants within the clusters also have exclusion criteria:
1. Patients with recorded refusal for use of anonymous data in research
2. Terminally ill patients receiving palliative care only

In addition for the purposes of the focus groups and interviews we have the following exclusion cri

1. Patients less than 16 years of age
2. Patients unable to communicate in English.

Date of first enrolment
01/03/2015

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Norwich Clinical Trial Unit
University of East Anglia
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Sponsor information

Organisation
University of East Anglia

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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