

# A cluster randomised controlled trial to assess the effectiveness and costs of implementing asthma risk registers to identify and improve management of high risk asthma patients in primary care

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>04/05/2007   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>30/05/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/11/2012       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data                                              |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Jane Smith

**Contact details**  
School of Medicine  
Health Policy and Practice  
University of East Anglia  
Norwich  
United Kingdom  
NR4 7TJ

## Additional identifiers

**Protocol serial number**  
06/047

## Study information

## **Scientific Title**

### **Acronym**

ARRISA (At-Risk Registers In Severe Asthma study)

### **Study objectives**

Compared to routine care, the implementation and use of primary care-based registers of patients at high risk from severe and life-threatening exacerbations of asthma will:

1. Reduce exacerbations in these patients
2. Result in overall reduced healthcare costs associated with managing these patients

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval received from the Norfolk Research Ethics Committee on the 11th December 2006. Current protocol with minor amendments approved on 3rd March 2007 (ref: 06/Q0101/200).

### **Study design**

Cluster randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Asthma

### **Interventions**

Practices randomised to the intervention arm will add at-risk asthma patients to an at-risk register. Identified patients will be added to an asthma risk register involving:

1. Electronic tagging of each patients record on the practice computer system with a customisable alert (e.g. high risk asthma patient, prioritise appointment) that needs actively clearing from the screen whenever the record is called up, and
2. Placing a similar marker in patients written records

This designation will be made available to all practice staff and, where possible, out-of-hours services. In addition, all staff will be given a one hour training session, delivered by a General Practitioner (GP) (Dr Mike Noble) and asthma nurse (Ms Jenny Windley) experienced in implementing and using an asthma risk register at their practice, on the relevance of the alerts and action to be taken when a high risk patient contacts the practice.

### **Intervention Type**

Other

### **Phase**

Not Specified

**Primary outcome(s)**

Moderate-severe asthma exacerbations, measured at one year.

**Key secondary outcome(s)**

1. Exacerbations from:
  - 1.1. Death or hospitalisation
  - 1.2. Emergency attendance (at the hospital, the practice or via a home visit)
  - 1.3. Out-of-hours medical contact
  - 1.4. A course of oral prednisolone or a boost in oral steroids for those receiving them regularly
2. Asthma-related routine primary and secondary care attendances and medication use
3. Healthcare costs

All secondary outcomes measured at one year.

**Completion date**

28/02/2010

**Eligibility****Key inclusion criteria****PRACTICES:**

1. Participation is open to all practices with adequate computer systems which are used to support routine consultations
2. Practices covering urban and rural populations, deprived and affluent areas and various practice sizes and set-ups

**PATIENTS:**

High risk patients aged 5+ years at participating practices will, according to British asthma guideline recommendations, be identified on the basis of having:

1. Severe asthma, recognised by one or more of:
  - 1.1. Previous near-fatal asthma
  - 1.2. Hospital admission for asthma in the last five years
  - 1.3. Two or more attendances at Accident and Emergency (A&E) or out-of-hours services for asthma in the last year
  - 1.4. Requiring step four or five treatment
  - 1.5. Brittle asthma

**PLUS:**

2. A record in the notes (of patients or their primary carers for children) of adverse behavioural or psychosocial characteristics including one or more of:
  - 2.1. Poor adherence to recommended management
  - 2.2. Failure to attend primary care or hospital appointments
  - 2.3. Self-discharge from hospital
  - 2.4. Psychosis, depression, other psychiatric illness or deliberate self-harm
  - 2.5. Current or recent major tranquiliser use
  - 2.6. Alcohol or drug abuse
  - 2.7. Denial
  - 2.8. Obesity
  - 2.9. Learning difficulties
  - 2.10. Employment problems

- 2.11. Income problems
- 2.12. Social isolation
- 2.13. Childhood abuse
- 2.14. Severe domestic, marital or legal stress

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Other

**Sex**

All

**Key exclusion criteria****PRACTICES:**

Those with pre-existing at-risk asthma registers or similar strategies to study intervention.

**PATIENTS:**

Patients who meet the inclusion criteria but are felt not appropriate to be included on an at-risk register for some other factor will be individually negotiated.

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

28/02/2010

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****School of Medicine**

Norwich

United Kingdom

NR4 7TJ

**Sponsor information**

**Organisation**

Asthma UK (UK)

**ROR**

<https://ror.org/03z7xev21>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Asthma UK (UK) (ref: 06/047)

**Alternative Name(s)**

asthmalunguk, Asthma UK, Asthma + Lung UK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Research institutes and centers

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/12/2012   |            | Yes            | No              |