# ARRISA-UK England and Wales

**CONFIRMATION RISP**

Research Information Sheet for Practices

<table>
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<tr>
<th>Study Title</th>
<th>At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK)</th>
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| NIHR Portfolio Ref | UKCRN ID 18118  
IRAS ID 161432                                                                                 |
| Type of study (please state if CTIMP) | Interventional |
| Study design | A pragmatic cluster randomised trial with nested economic and process evaluations. |
| Study Aim and Objectives | Some patients with asthma are at increased risk of emergency hospital admission or a fatal attack. This is despite the availability of effective medications and long-standing national guidelines. The characteristics of these “at-risk” patients include poor adherence and a tendency to crisis manage their disease. Evidence suggests that improving access to primary care services and enhancing opportunistic management could improve outcomes.  
The study aims to test the hypothesis that systematically identifying “at-risk” patients and flagging their primary care Electronic Health Record (EHR) to facilitate access and opportunistic management will reduce crisis asthma events (hospitalisations and A&E attendances, asthma related deaths) and be clinically acceptable and cost effective. This will be achieved by practices agreeing an in-house strategy involving the whole practice team but does not require any changes to the standard treatment of asthma. |
| Practice target | Because this study’s design is a cluster randomised trial, and there is no patient recruitment involved, there is no practice recruitment target per say.  
Electronic risk stratification will identify the top 7% of asthma patients most at-risk equating to 30-50 patients in an average sized practice.  
Planning to roll out initially in Norfolk and Waveney as a pilot area, then to Eastern, then nationally.  
Note: Only practices willing to have data collected (at no cost to the practice) by [Optimum Patient Care (OPC)](http://www.optimumpatientcare.com) will be able to participate as data for the study will be extracted through this route. OPC is an organisation(s) with significant anonymous data extraction experience in primary care for publicly funded studies. |
| Duration of study recruitment in practice | Individual patients are not recruited in this study – there are no clinical visits or recruitment forms to fill.  
After sign-up and construction of the register practices will be randomised into intervention and control arms. Recruitment of practices will run until 30/04/2018. |
| Service Support Costs to be paid to the practice | This is to support the process evaluation aspect of the study (interviews and focus groups)  
South West Peninsula and North West Coast: £132.80 per practice  
NIL in other regions/country |
| Research costs to be paid to the practice | Research costs correspond to either £600.00 or £1,266.00 per control and intervention practices respectively.  
A contract will be set in between the individual participating practices and the University of East Anglia (sponsor) for the direct payment of the aforementioned Research costs. The Research Team will advise you when payment are due |
### Excess Treatment Costs

Each GP Practice, in the intervention arm, will have to undertake tasks for which the overall ETC of **£662.50 per practice** (with Practice Pharmacist) or **£569.33 per practice** (without Practice Pharmacist) will be paid.

**Note:** Depending on the funding source for these ETCs, they are either to be paid to practice directly by their CCG or are set out as part of the practice contract – to be paid by the study team to the practice.

### Excess treatment costs agreed by CCG

This is region specific. However, the financial checks undertaken during local NHS permission review ensure that this is in place before providing the green light to the study.

### Regional Research Contracts (e.g. RSI in Eastern)

This is a recruiting study.

No prior research experience is needed to undertake the ARRISA-UK study and therefore practices with no, modest or extensive research experience can participate.

As mentioned above, this study’s design is a cluster randomised trial, and the register is under practice control, therefore consent is not required for these patients. It is uncertain if these patients will be recognised as recruits (accruals) but this will be clarified as soon as possible.

However, at least 3 staff members from sites (representatives – see description in the section Practice Activities) or 4, if you are a dispensing practice, at each practice will be recruits. Please note that for intervention practices, any additional staff undertaking the first part of the training (45 min) will also count as recruits (accruals) but that the corresponding training times won’t be reimbursed.

### Eligibility Criteria

**Inclusion:**
- Clusters: GP practices
- Participants: Patients having at-risk asthma, identified from an algorithm via routinely collected data

**Exclusion:**
- Cluster: 1) practices already implementing a formal prospective process of flagging or otherwise targeting patients with at-risk asthma to direct care to these individuals on a practice-wide basis 2) practices hosting or affected by research which might influence the care of people with ‘at-risk’ asthma
- Participants: patient with recorded refusal for use of anonymous data in research

**NB:** Participation of some patients in other asthma trials, such as drug trials, is not an exclusion. For further information, please refer to the document detailing practice eligibility available on the following ARRISA-UK web page ([https://www.uea.ac.uk/arrisa-uk/gp-practices](https://www.uea.ac.uk/arrisa-uk/gp-practices)) or contact the study team ([ARRISA-UK.MED@uea.ac.uk](mailto:ARRISA-UK.MED@uea.ac.uk))

### Principal Investigator(s) & Institution

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## ARRISA-UK England and Wales
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#### Research Information Sheet for Practices

<table>
<thead>
<tr>
<th>Study Funding Source</th>
<th>The ARRISA-UK study is funded by the National Institute for Health Research’s Health Technology Assessment (HTA) Programme</th>
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<tr>
<td>Sponsor</td>
<td>University of East Anglia</td>
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### Study Activities:

#### Research Team Activities

The Research Team, from the Norwich Clinical Trial Unit (NCTU), will ensure for

**All Practices:**

- Provision of study website
- Administration of the practice survey
- Provision of practice self-assessment of eligibility for the study and a contact for the study team where clarification is needed
- Provision of study set up paperwork and Assurance Letter
- Provision of timelines for the practice as well as confirmation of eligibility followed by pre-randomisation tasks instructions
- Provision of the randomisation result with relevant set of instructions to the Control and Intervention practices
- Provision of site file
- Payment of research costs and excess treatment costs
- Communication to sites regarding approvals and amendments
- Collection of the anonymised routine data through the anonymous research database
- Dissemination of results to participating practices at the end of the study

**Intervention Practices:**

- Provision of online training package
- Provision of a point of contact and support for Practice staff: If needed, this will include support to Practices Database Managers or IT leads to generate the “at-risk” patient register. A IT helpline will also be provided for Practice staff in case of any problem with the e-Learning training

#### Network Activities

Networks will provide support for practices identification:

- Development of RISP for the study and promotion
- Support and connections for securing Excess Treatment Costs (ETCs) and Study Support Costs (SSCs)
- Contact all appropriate practices in their region and provide information about the study as well as the Practice survey. (available on the study webpage [https://www.uea.ac.uk/arrisa-uk/gp-practices](https://www.uea.ac.uk/arrisa-uk/gp-practices))
- Return Practice Agreement, and if relevant the Site Agreement, to the research team (NCTU)
- Forward any data on sites to the research team (NCTU)
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Practice Activities

**All Recruited Practices:**

- As part of the UEA Site agreement, agree to sign up to the approved research database for anonymous data extraction, if not already done (sign up documents will be supplied by the study team in the trial pack available on the study webpage [https://www.uea.ac.uk/arrisa-uk/gp-practices](https://www.uea.ac.uk/arrisa-uk/gp-practices))

- Completion (by Practice asthma lead if possible) of a short baseline questionnaire aimed at gathering practice characteristics and information on asthma management.

- Practice to sign and return study and site agreements to the study team

Once Eligibility is confirmed:

- Practice managers will be asked, by the study team, to nominate a Practice Champion (preferably, but not necessarily, the asthma Nurse or research Nurse) and a representative from each of the four main staff disciplines

**Note:**

- One of these representatives can be the Practice Champion
- The four staff categories are the following: GP (including trainee GP), Nurse (including HCA), Receptionist (including Admin staff) and Dispenser/Pharmacist (include dispensing staff) in dispensing practices.

- Practice's Database Managers will search their practice database, as directed (supported by the study team), and produce a list of “at-risk” asthma patients (1 hr)

Once an anonymised summary of the list is sent to the study team, practices will be randomised to either the control or the intervention arm and will be informed about the randomisation outcome and explained what to do next.

**Control Practices (in addition to the above)**

- Usual care to be continued

- At the end of the study (12 months): completion of the end of process (exit) questionnaire

**Intervention Practices (in addition to the above)**

*From the list below, you will notice that most of the staff time needed for the intervention is to undertake the 2 modules of the web based training.*

- Finalisation of the Register and summary of changes to the study team: GPs and asthma Nurses will have the opportunity to review the list of “at-risk” asthma patients generated and make amendments if needed (2 clinicians - 30 min each)

- Practice-wide internet-based training: Module one (45 minutes) undertaken by Practice Champion and Staff Representatives; Module two (45 minutes) completed, as a group by the staff representatives and chaired by the Practice Champion, after having discussed the first module with their individual teams. At the end of the training the practice will have an agreement on the implementation of the register and associated flag,
including the practice “at-risk” flag wording/position/design, and of the actions to be taken when viewing the flag.

Please note that all the practice staff are welcome and encouraged to undertake the training but that this will not impact the Research and Excess Treatment Costs to be paid but would count toward the RSI accruals.

- Webinar (up to 30 min): Practice Champions and Staff Representatives to attend a short webinar (or recording supplied) aimed at facilitating the exchange of experiences, ideas and potential barriers with other practices to help further tailoring of their implementation.
- Completion of the post-training questionnaire (up to 30 min).
- Activation of the flag and start of the intervention: Database Managers will then activate the agreed “at-risk” flag to the database (start of the Intervention- day “0” on the timeline) and inform the Research Team (1 hr).
- 12 months intervention: From the implementation of the flag (day “0”) Practice staff will be expected to act accordingly to the internally defined protocols each time they face the “at-risk” flag.
- Practice Champions to receive a support phone call (15 min) at week four.
- Practice Champions and Staff Representatives to receive two support e-mails, containing links to short videos (up to 5 min each), at week six and 24 respectively.
- At the end of the study (12 months): completion of the end of process (exit, up to 30 min) questionnaire and summary of register change sent to the study team.

### Requirements that could affect practice ability to take part in the study

<table>
<thead>
<tr>
<th>i.e. Google Chrome use, stable internet connection, stable mobile phone coverage</th>
<th>A stable internet connection is required for staff to undertake the web based training. Please note that the training is designed to work with the following browsers: Internet Explorer 9 and onwards, Edge, Chrome, Mozilla Firefox or Safari. Although optimised to work on a desktop/laptop, mobile devices such as tablets can also be used.</th>
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### GCP trained staff in practice needed

- **No**

### Study specific training

- **Offered in practice: web based**

### Potential for practice hub and spoke working

- **Not applicable**

### Resources provided by the study team:

- A series of documents will be given to practices in the Trial Pack, providing guidance on each step of the study as well as the Research Team contacts details. Helpline assistance will be available for questions that arise from the patient identification searches. An IT helpline will also be available for the e-Learning training.

### Associated SOPs and WIs

- **NIL**

### Patient Involvement

- The intervention being directed at practice staff and because only anonymous routine data is being used, there is no direct patient involvement.

### What are the likely benefits to the patient/practice?

- The potential benefits depend on whether a practice is in the intervention arm or the control arm. (Control practices will be offered the intervention after the completion of the study.)
### For the staff
as a provider of respiratory care, the study may assist in improving the efficiency of contact with at-risk asthma patients (e.g. reducing DNAs and enhancing opportunistic management) and improve their clinical.

**For the practice and patients**, patient satisfaction with care provision may improve and there may be reduced severe exacerbations and hospitalisations.

### Archiving Requirements
(please state time period if applicable)

During the study a single ring binder will contain all of the needed site file documentation. At the end of the study the research team will provide all of the relevant information that needs to be archived in an electronic file (a .ZIP compressed archive file) that will contain no patient identifiers. Only this file will need to be held as archive for 5 years.

### Arrangements for dissemination of study findings to sites and participants

The result of the trial will be disseminated regardless of the direction of effect. Research results will be reported and disseminated in peer reviewed scientific journals, at conferences and published on the study website. The results will also be made available to the wider community via the websites of Asthma UK, HTA and academic, patient care, and research organisations such as the Asthma UK Centre for Applied Research and the Primary care Respiratory Society. The participating GP practices will be given and encouraged to display links to the research. Press releases and website links to summaries of the research will be publicised on the web-sites of prominent campaigning and charitable organisations such as Asthma-UK.

### Assurances/Approvals
*delete as appropriate*

Local NHS Assurance documents are available by region on [https://www.uea.ac.uk/arrisa-uk/gp-practices](https://www.uea.ac.uk/arrisa-uk/gp-practices)

### Patient confidentiality

Only anonymised routine GP patient data will be used in the outcome analysis and thus all patient information will be kept strictly confidential. All information will be stored and used according to guidelines on data protection and confidentiality as outlined in the Data Protection Act 1998.

### Research Team contact

ARRISA-UK.MED@uea.ac.uk  
Dr. Stanley Musgrave 01603 – 593309  
Dr. Estelle Payerne 01603 – 591263

### CRN contact

This is region specific please contact your CRN directly

If you are willing to take part in this study, please complete the online **Practice Survey** available as an online form at [https://norwichcrtu.uea.ac.uk/ARRISA-UK/GPPracticeSurvey.aspx](https://norwichcrtu.uea.ac.uk/ARRISA-UK/GPPracticeSurvey.aspx) (Please note that you will need you practice NHS ID to login)

Please do not hesitate to contact the study team if you have any questions about the study