

# PLEASANT trial: to determine whether an NHS delivered public health intervention reduces exacerbation of asthma, and unscheduled NHS contacts, in school aged children associated with the return to school in September

<b>Submission date</b> 17/10/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/04/2018	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

In the UK there is a pronounced increase in the number of visits to the doctor by school age children with asthma in September. It is thought that this might be caused by the return to school, when children with asthma will be mixing with other children again and picking up bugs which can affect their asthma and make them poorly. During the summer holidays there is a drop in the number of prescriptions collected. August is a good month to be an asthmatic - children with asthma are not mixing with many other children and the pollen count is quite low therefore children with asthma might not take their medication as they should or allow their medication to run low. We hope that a simple postal intervention from the GP can help prevent children with asthma being poorly in September. To see if the intervention works we will ask some GPs to send out the intervention, to the parents of school aged children with asthma, and some GPs will not. We can then compare whether the intervention has had any effect. We will be looking at a number of factors including whether children who get the intervention see their GP less in September. In addition to the number of visits made to their doctor we will be looking at the number of prescriptions children with asthma have and the effect on costs to the NHS.

### Who can participate?

School aged children, 4-16 years, with asthma will be identified by the Clinical Practice Research Datalink (CPRD) and confirmed as eligible by their GP.

### What does the study involve?

140 General Practices (GPs) will be recruited and randomised to either of two arms, intervention or control (usual care). Practice recruitment and data collection will be done via the Clinical Practice Research Datalink (CPRD); an e-health secure research service that collects anonymised longitudinal data from medical records including primary care. CPRD will identify potential participants based on pre-identified codes and ask the GPs to check this list for eligibility. The

intervention practices will send out the postal intervention to those eligible during the last week in July 2013. Control practices need do nothing else. We anticipate approximately 100 participants per average GP site thus we will collect data on approximately 14000 children. The study team will not have access to any patient identifiable data and will receive fully anonymised data from the CPRD.

What are the possible benefits and risks of participating?

We hope that this study will improve adherence to prescribed medication and scheduled appointments for childhood asthma care and unscheduled appointments seen in September following the return to school. If the study shows positive results we would want this widely known with recommendation that the intervention be used for future management of childhood asthma. We would not expect any potential adverse effects following receipt of the intervention. The trial and subsequent intervention is hoping to optimise usual clinical care and promote adherence to current prescribed medication. GPs and practice staff will undertake on-going monitoring of their patients as per usual clinical care.

Where is the study run from?

Within general practices in England and Wales (UK)

When is study starting and how long is it expected to run for?

January 2013 to July 2015

Who is funding the project?

NIHR Health Technology Assessment Programme (UK)

Who are the main contacts?

1. Dr Steven Julious (s.a.julious@sheffield.ac.uk)
2. Dr Michelle Horspool (m.horspool@sheffield.ac.uk)

### **Study website**

<http://www.shef.ac.uk/scharr/sections/dts/ctru/pleasant>

## **Contact information**

### **Type(s)**

Scientific

### **Contact name**

Dr Steven Julious

### **Contact details**

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 11/01/10

## Study information

**Scientific Title**

Preventing and Lessening Exacerbations of Asthma in School-age children Associated with a New Term: a cluster randomised control trial

**Acronym**

PLEASANT

**Study hypothesis**

To determine whether a postal intervention will reduce seasonal exacerbation of asthma, and unscheduled NHS contacts, in school aged children associated with the return to school in September.

More details can be found at: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/110110/#/>  
Protocol can be found at: <https://njl-admin.nihr.ac.uk/document/download/2007097>

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Application due for review on 25/10/2012 by South Yorkshire REC

**Study design**

Cluster randomised trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

GP practice

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Condition**

Childhood asthma

### **Interventions**

70 GP practices undertaking the intervention and 70 control practices of usual care.

Postal intervention sent to all school aged children with asthma at the start of the school holidays in July vs usual care (no postal intervention)

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

The proportion of patients aged between 5-16 who have an unscheduled medical contact in September

### **Secondary outcome measures**

1. The proportion of patients who have an unscheduled medical contact in the period September-December
2. The total number of medical contacts (scheduled and unscheduled) per patient in September and in the period September-December
3. The time to first unscheduled medical contact in September and in the period September-December
4. The proportion of patients who have a medical contact (either scheduled or unscheduled) in September and in the period September-December
5. The total number of medical contacts (either scheduled and unscheduled) per patient in September and in the period September-December
6. The time to first medical contact in September and in the period September-December
7. The proportion of patients who have an unscheduled medical contact in September and in the period September-December associated with a respiratory diagnosis
8. The number of unscheduled medical contacts per patient in September and in the period September-December associated with a respiratory diagnosis
10. The number of prescriptions per patient in the month of August
11. The number of prescriptions in the 12 months following the intervention
12. The proportion of patients who have a scheduled medical contact (for example asthma review) in August
13. The proportion of patients who have a scheduled medical contact (for example asthma review) in the 12 months following the intervention.

The above analyses will be undertaken on patients aged 5-16, since asthma is difficult to diagnose in children below this age; patients aged <5 will be analysed separately to these.

### **Overall study start date**

01/01/2013

**Overall study end date**

31/07/2015

## Eligibility

**Participant inclusion criteria**

Children:

1. Between 4 and 16 years of age as of 01/09/2012
2. With a coded diagnosis of asthma
3. Who have been prescribed asthma medication in the previous 12 months

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

4 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

14000

**Participant exclusion criteria**

Children:

1. Aged 4 and under and 16 and over years of age as of 01/09/2012
2. Who are not considered appropriate for this intervention by their GP
3. With asthma who are not receiving asthma medication
4. With co-existing neoplastic disease

**Recruitment start date**

01/01/2013

**Recruitment end date**

31/07/2015

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
University of Sheffield  
Sheffield  
United Kingdom  
S1 4DA

## Sponsor information

**Organisation**  
NHS Sheffield (UK)

**Sponsor details**  
c/o Mr Ian Atkinson  
722 Prince of Wales Road  
Sheffield  
England  
United Kingdom  
S9 4EU

**Sponsor type**  
Hospital/treatment centre

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

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

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	16/09/2013		Yes	No
<a href="#">Results article</a>	results	01/12/2016		Yes	No
<a href="#">Results article</a>	results	01/05/2017		Yes	No
<a href="#">Results article</a>	results	20/04/2018		Yes	No