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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

Submission date
17/10/2012

Recruitment status
No longer recruiting

Registration date
19/10/2012

Overall study status
Completed

Last Edited
23/04/2018

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

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

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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
31/07/2015

Eligibility

Key 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

Key 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

Date of first enrolment
01/01/2013

Date of final enrolment
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
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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?
Protocol article	protocol	16/09/2013		Yes	No
Results article	results	01/12/2016		Yes	No
Results article	results	01/05/2017		Yes	No
Results article	results	20/04/2018		Yes	No