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Enhancing the quality of information-sharing in primary care for children with respiratory tract infections

Submission date 17/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/04/2006	**Overall study status** Completed	
Last Edited 10/07/2014	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G106/1225

Study information

Scientific Title

Acronym
EQUIP - Enhancing the QUality of Information-sharing in Primary care

Study objectives
To evaluate the use of a complex intervention, consisting of a novel 'interactive leaflet' and training in its use, in primary care consultations involving children with Respiratory Tract Infections (RTIs). The evaluation will examine the impact that use of the leaflet has on use of consultation behaviour (including re-consultation for the same illness episode and future consulting for respiratory tract infections over the following year), use of antibiotics, parental empowerment (as measured by an adaptation of the Patient Empowerment Instrument), length of time to recovery, and adverse events such as complications and hospitalisations. We will also conduct a cost-effectiveness evaluation and a process evaluation with clinicians involved in the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Wales Research Ethics Committee - Panel D, 11/01/2005, ref: 04/WSE04/109

Study design
Cluster randomised controlled trial of the use of a new leaflet for parents on RTIs in children or usual practice.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory Tract Diseases

Interventions

Intervention: use of a new 'interactive' leaflet on respiratory tract infections by general practitioners within the consultation, and then provided to parents as a take-home resource. Comparison: usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Re-consultation for same episode of illness
2. Antibiotic prescription for the presenting illness at any point in the 2 week follow-up period

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2005

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Subjects aged 6 months to 14 years who have been ill for 7 days or less, and have been diagnosed by their GP as having acute respiratory tract infection. This will include children suspected of having both upper and lower respiratory tract infections, and viral or bacterial infections, and will include sore throat, otitis media and sinusitis.

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
14 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. With suspected pneumonia
2. Who have been formally diagnosed with asthma or who are currently taking or in need of oral or inhaled steroids or inhaled bronchodilators
3. Judged to need immediate admittance to hospital or with serious/concerning features
4. With serious concomitant illness (i.e. malignancy, cystic fibrosis)
5. Whose carer is unable to comply with the study protocol
6. Who have been seen previously for this illness episode
7. Who have been previously recruited into the trial (each child can only be recruited into the trial once)
8. Have a sibling who has been recruited into the trial (each family can only be recruited into the trial once)

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Department of General Practice
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor
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United Kingdom
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davieskp2@cardiff.ac.uk

Sponsor type
University/education

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) G106/1225 (UK)

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	24/04/2008		Yes	No
Results article	results	29/07/2009		Yes	No
Results article	results	01/12/2013		Yes	No