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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 30-36 Newport Road Cardiff Wales United Kingdom CF24 0DE 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?
<u>Protocol article</u>	protocol	24/04/2008		Yes	No
Results article	results	29/07/2009		Yes	No
Results article	results	01/12/2013		Yes	No