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The CHICO (Children with Cough) trial

Submission date 27/06/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2014	**Overall study status** Completed	
Last Edited 12/05/2017	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
This study is exploring whether it is possible to implement a web-based intervention for improving treatment for children with severe cough and respiratory tract infection. While most respiratory infections resolve themselves without treatment, a very small number of children require hospital care (e.g. for pneumonia and bronchiolitis). In consultations it is often difficult to establish which children will develop serious complications. The CHICO intervention will use the child's unique state of being (during the consultation) to provide individualised information for both doctors and carers to reduce this uncertainty.

Who can participate?
GPs and prescribing nurses recruit children who are aged between 3 months and 12 years coming in with cough and respiratory infection.

What does the study involve?
The clinician asks the parent/carer and child several questions about the child's cough during the consultation. The parent/carer is asked to respond to some questions about their child's illness and their interaction with health services once a week for up to 8 weeks or until their cough has gone. They have the option to complete the follow-up online or by phone and on paper.

What are the possible benefits and risks of participating?
The parent/carer will be helping us understand what information is given to them about their child's cough and how to care for their child at home. Disadvantages may be that the weekly phone call and home questionnaire, or the online questionnaire, will take a few minutes to answer.

Where is the study run from?
The study is run from the following Clinical Commissioning Groups in the UK: Bath and North East Somerset, Bristol, Gloucestershire, South Gloucestershire, North Somerset, Swindon and Wiltshire.

When is the study starting and how long is it expected to run for?
July 2014 to April 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2014-000903-28

Protocol serial number
16891

Study information

Scientific Title
A feasibility randomised controlled trial investigating the clinical and cost effectiveness of a complex intervention to improve the management of children presenting to primary care with acute respiratory tract infection

Acronym
CHICO

Study objectives
As this is a feasibility trial there is no hypothesis, however, the research aim is:

To assess the feasibility of implementing a web-based behavioural intervention to improve the approach to, and clinical management of, childhood RTI and the use of antibiotics.

Ethics approval required

Old ethics approval format

Ethics approval(s)
First MREC approval date 13/06/2014, ref: 14/NW/1034

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Children, Primary Care; Subtopic: All Diagnoses, Not Assigned; Disease: All Diseases, All Diseases

Interventions
30 practices are recruited with 10 in reserve. Randomisation at the practice level as it is a cluster RCT. 15 practices will be randomised to each arm initially and the 10 reserves may be randomised depending on how recruitment is going.

The control practices will be asked to conduct their consultation as usual with the children eligible to enter the CHICO study and to record brief details about the child's signs, symptoms and demographics on the CHICO web-based system.

CHICO intervention, Findings across the TARGET Programme were synthesised using Greene and Kreuter's Precede-Proceed model, which integrates across a number of behavioural theories into a unified model. Key findings from each Workstream were used to produce a summary of the evidence fitted to this model, identifying the behavioural and environmental factors shown to influence the decision to prescribe in our research.
This model was used to formulate a number of evidence-based recommendations for the intervention.

Follow Up Length: 7 month(s); Study Entry: Multiple Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Feasiblity; Timepoint(s): September 2014-September 2015

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/04/2015

Eligibility

Key inclusion criteria
Clinicians:
GPs and prescribing nurses are eligible to recruit children to the study

GP practices will be included if they have at least Internet Explorer version 8 on their IT systems

Children can be included into the study if they meet the following criteria:
1. Children aged =3 months and <12 years
2. Presenting with an acute RTI with cough for =28 days as a main symptom (including exacerbation of asthma)
3. Presenting with illnesses such as RTI and epilepsy or diabetes, including infective exacerbation of asthma (non-infective exacerbation of asthma is an exclusion criterion)

Target Gender: Male & Female; Upper Age Limit 11 years ; Lower Age Limit 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
11 years

Sex
All

Key exclusion criteria
Children will not be eligible for the study if:
1. They are aged < 3 months or = 12 years
2. The parent/carer/children are unable or unwilling to assist with study
3. The child has already been successfully recruited to the CHICO study
4. They present with acute non-infective exacerbations of asthma
5. They present with RTI without cough or symptoms >28 days
6. They are at greater risk of serious infection; they have chronic diseases/multi-morbidities that increase the risk of RTI complications

Date of first enrolment
01/07/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Social & Community Medicine
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (UK); Grant Codes: SSCMRK7516

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	results	09/05/2017		Yes	No
Protocol article	protocol	15/09/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes