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The CHIldren with COugh Randomised Controlled Trial

Submission date
09/04/2018

Recruitment status
No longer recruiting

Registration date
20/04/2018

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Coughs and colds (also known as respiratory tract infections or RTIs) are the most common reason that children are taken to family doctors and nurses (from here on 'clinicians'). Clinicians are not always sure how to treat them and often use antibiotics 'just in case'. There are now concerns that clinicians are using antibiotics too often, and that this is increasing the number of resistant bugs (bacteria that can't be killed by antibiotics). An intervention has been developed that helps clinicians to know which children are very unlikely to benefit from an antibiotic. Seven symptoms can be used to predict which children will and won't be hospitalised for their RTI. The researchers wish to see if using a scoring system, listening to parents' concerns and giving them a personalised leaflet with care and safety advice, reduces the number of antibiotics collected by parents at pharmacies. A study of 500 children showed that the intervention is quick, technically reliable, widely used and acceptable. The aim of this study is to get all clinicians in a group of practices to use the intervention for all children with cough or RTI, and compare with another group of practices where the clinicians are providing usual care. The data collected by the NHS will be used to work out if antibiotic prescribing levels are different between these groups, while hospitalisation rates stay the same. The main aim of the study is to see if the intervention is effective, safe and easy to use.

Who can participate?
Children aged 0-9 at participating GP practices in England

What does the study involve?
Participating GP practises are randomly allocated to either use the intervention or to provide usual care. 'Practice champions' (individual pharmacists or clinicians at each practice) in the intervention group encourage its use and feedback how well they are doing during the study. The intervention is also embedded within the computer systems already used at each practice for ease of access. The rate of prescribing of oral liquid antibiotics for children aged 0-9 years is measured using routinely reported NHS prescribing data, along with the number of children admitted to hospital for RTIs. This information does not report any patient details. The study also looks at if there are any differences in dispensing rates between GPs and nurses and for children of different ages.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
December 2017 to December 2021

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

Who is the main contact?
Penny Seume
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Contact information

Type(s)
Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
37163

Study information

Scientific Title
A clinical effectiveness investigation of a multi-faceted intervention (incorporating a prognostic algorithm) to improve management of antibiotics for CHIldren presenting to primary care with acute COugh and respiratory tract infection (CHICO): an efficient cluster RCT informed by a feasibility RCT

Acronym
The CHICO RCT

Study objectives
Coughs and colds (RTIs) are the most common reason that children visit GP surgeries. Clinicians (doctors and nurses) are not always sure how best to treat them and often use antibiotics 'just in case'. There are concerns that clinicians use antibiotics too often and that this is increasing the number of resistant bugs (bacteria that are not killed by antibiotics). From a 5 year programme of NIHR funded work, the research team have developed an intervention that helps clinicians to know which children are very unlikely to benefit from an antibiotic. The intervention includes a decision aid which lets the clinician know if a child is likely to get well without antibiotics (the tool provides information, but the clinician still makes the final decision on the treatment received, based on what they believe is in the child's best interests). Clinicians will listen to parents' concerns and giving them a personalised leaflet with care and safety advice. The main aim of the study is to see if the intervention is effective, safe and easy to use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2018, London – Camden and Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8086; nrescommittee.london-camdenandkingscross@nhs.net), ref: 18/LO/0345

Primary study design
Interventional

Study design
Randomized; Both; Design type: Process of Care, Management of Care, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory tract infections

Interventions
310 GP practices will take part in the study for 12 months. GP practices will be randomised 1:1 into intervention or usual care. The randomisation will be minimised within each CCG taking part by total population of 0-9yo patients and previous annual prescribing rate.

The intervention is a clinical rule to predict hospitalisation of children with RTI. This rule was produced using signs, symptoms and demographic characteristics of over 8,300 children collected across England. Seven predictors of risk (STARWAVe) were identified from the baseline data collected and analysis of the prediction rule suggested good sensitivity and specificity. The prediction rule identifies children at low, medium and high risk of hospitalisation with advice given on how the clinician can use this information in conjunction with their own clinical judgement to decide the best course of action for each child. The rule will be embedded in EMIS software and activated in GP practices within the intervention arm of the trial.

Data collected will be used to work out if antibiotic dispensing levels are different between the practices using the intervention compared to those that do not, and whether the hospitalisation rates remain the same in both groups of practices. Data will be collected on children aged 0-9 years old.

Intervention Type
Other

Primary outcome(s)
1. The annual rate of dispensed amoxicillin and macrolide prescribed for children (aged 0-9 years registered at the start of the designated period) at each practice over a 12-month period
2. The rate of hospital admission for RTI amongst children aged 0-9 years over a 12-month period

Key secondary outcome(s)
1. ED attendance rates for RTI over a 12-month period
2. The costs to the NHS of using the CHICO intervention in a cost-consequence analysis
3. Proportion of locums used in the practice
4. Practice antibiotic dispensing rates in 12 months prior to recruitment
5. Effects of the CHICO intervention on practices with GP prescribers only and those with nurse prescribers as well
6. Effects of the CHICO intervention on different child age groups (5-year epochs)
7. Use of the CHICO intervention by practice and over time in terms of both usage over a 12-month period and seasonality
8. The acceptability and the use of the intervention, how it was embedded into practice and whether it was used, assessed using qualitative interviews with clinicians. The CCG staff interviews will be exploring how well practices embedded the intervention into their systems and daily life from their perspective

Completion date
31/12/2021

Eligibility

Key inclusion criteria
The CHICO RCT will recruit GP practices from 15 Clinical Commissioning Groups (CCGs) from demographically diverse regions across England. The population studied will be all children aged 0-9 years registered at practices using the EMISWeb system. The recruitment of practices will be via CCGs using established channels of communication. An internal pilot phase lasting 3 months and using 3 CCGs will help establish best practice for recruiting and communicating with practices before widening to the remaining CCGs over a staggered 4-month recruitment period.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 Years

Upper age limit
9 Years

Sex
All

Total final enrolment
294

Key exclusion criteria
Practices will be asked directly whether they are participating in any antimicrobial stewardship activities during the study period and these will be recorded. If these activities involve concurrent intervention studies where there is potential to confound or modify the effects of our intervention, these practices will be excluded.

Children aged 10-14 were considered for inclusion but at this age an increasing number are given antibiotics in tablet form and given the much lower consultation rate in older children the research team decided to exclude this group from the study population.

Date of first enrolment
01/06/2018

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Population Health Sciences,
Bristol Medical School
Canynge Hall (Room 1.01)
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/31/98

Results and Publications

Individual participant data (IPD) sharing plan
Anonymous research data will be stored securely and kept for future analysis. Members of the TMG will develop a data sharing policy consistent with UoB policy. Data will be kept anonymous on secure access computers, and access will be via written confidentiality and data sharing agreements (DSA) with the CI (or his appointed nominee), supervised by the CI with the involvement of other members of the research team. Post-trial this may involve the Bristol Data Service who will allow access according to our pre-specified criteria. Any request approved will be covered by a written DSA, detailing limitations of use, transfer to 3rd parties, data storage and acknowledgements. The person applying for use of the data will be scrutinized for appropriate eligibility by members of the research team. All requests will require their own separate REC approval prior to data being released. Data will not be released prior to analyses for purposes that might detrimentally affect the trial integrity.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	04/07/2022	Yes	No
Results article		26/04/2023	27/04/2023	Yes	No
Results article		01/12/2023	11/01/2024	Yes	No
Protocol article		29/03/2021	31/03/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Nested qualitative study	01/06/2024	06/05/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes