NHS
National Institute for Health Research

CPMS ID: 37163	**IRAS number:** 229389
Study Title: The Children with Cough Cluster Randomised Controlled Trial (CHICO)	
Chief investigator: Professor Pete Blair	**Host Institution:** NHS Bristol, North Somerset & South Gloucestershire CCG
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Expected START date	Expected CLOSURE date
01 / Oct / 2018	**30/ Nov/ 2021**

Study Overview

The CHICO trial is evaluating the clinical effectiveness of a clinical decision support tool used alongside information leaflets for parents in consultations of children aged 0-9years presenting to primary care with coughs and respiratory tract infections (RTI).

Participating practices will be randomly assigned to intervention or usual care, and will be followed up for 12 months. There will be no recruitment of patients during the trial and instead the nominated practice champion will encourage clinical staff to use the intervention in all consultations during the 12-month follow up period (in the intervention arm).

Intervention
The clinical decision support is designed to identify patients at very low risk of requiring hospital care for an RTI related infection in the next 30 days, and reassure clinicians and nurses by providing this information during consultations. Information leaflets will be provided to parents to give them more information to help them care for the child at home.

Primary Outcome
Data will be collected from central databases and the local CCG regarding hospitalisation rates and prescribing rates in order to measure the clinical effectiveness and safety of the intervention.

Study Target Population

Practices using EMISweb are the target population. Exclusion criteria: Practices participating in interventional research programmes that may impact on antibiotic prescribing.

The intervention will be used for Children aged 0-9years presenting with coughs and RTI. Patients will not be

required to undergo any recruitment process as the clinical staff will determine if the intervention would be useful during the consultation and no personal data will be collected.

Practice Involvement

Prior to randomisation

Baseline Questionnaire: All practices will complete a short baseline questionnaire prior to randomisation.

Practices will then be randomly allocated to Intervention or Usual Care arm.

Intervention arm

Intervention importing: The intervention will be imported into EMISweb by the practice manager or IT manager according to provided guidance. This will take approximately 30-60mins at the beginning of the trial.

Intervention champion: A nominated staff member will ensure information and training materials about the intervention are made available to the clinical staff and encourage the use of the intervention during the 12month follow up period.

Intervention usage: The intervention will be available to use in all consultations of children under 10 presenting with coughs and RTI. Each month the practice will run a search query (provided by the research team) which will identify the number of consultations that the intervention has been used in and provide this to the CHICO study team.

Optional Qualitative interviews: A sample of practices will be contacted to conduct a short interview about the intervention

Usual Care Practices

Usual care practices will continue with their usual practice for patients with coughs and RTIs.

End of Trial

Follow up Questionnaire: All practices will complete a short follow up questionnaire in month 12.

Intervention deactivation: Intervention practices will deactivate the CHICO intervention at the end of month 12.

Practice Payment

Baseline and Follow up Questionnaire: £21.98 – For completing both questionnaires; this will be provided to practices by the University of Bristol at the end of the trial.

Intervention usage data: £291.76 – For providing 12 months intervention usage search data; this will be provided to practices by the University of Bristol at the end of the trial.

Intervention Importing: Upto £314.58 – Provided via the CRN to cover the excess treatment cost of importing and training staff to use the intervention.

Optional Qualitative Interviews: £46.40 per interview conducted.

Further Information:

Please contact: chico-study@bristol.ac.uk