ISRCTN30652037 https://doi.org/10.1186/ISRCTN30652037

Evaluation of an intervention to improve antibiotic prescribing for respiratory infections at rural health facilities in China

Submission date 24/11/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/12/2020	**Overall study status** Completed	
Last Edited 19/01/2026	**Condition category** Respiratory	

Plain English summary of protocol

Current plain English summary as of 04/08/2021:
Background and study aims
Antibiotics are over-prescribed for patients with respiratory-tract infections (RTIs, coughs & colds) in primary care, especially in the rural areas of China. This study is aimed to evaluate an intervention to improve antibiotic prescribing by doctors and reduce unnecessary antibiotic consumption for coughs and colds (respiratory infections).

Who can participate?
40 Township health centres from 10 counties within 4 regions across the Anhui Province will be selected. All the practitioners who see patients with RTI in the selected township health centres will be invited to participate in this study, and all the patients with RTIs who are present to seek consultation in their clinics will be also invited to participate in this study.

What does the study involve?
Practitioners: a researcher from Anhui Medical University will contact you, and may arrange a bespoke training about appropriate antibiotics prescribing in clinical practice, a computer-based decision support system, and access to a WeChat peer support group.
Patient: a researcher from Anhui Medical University will contact and also observe your consultation with the doctor. A researcher mayalso contact you by phone to ask you a few questions about your recovery at 7 days, 14 days, and 21 days after your initial consultation. Each phone call will take about 10 minutes.

What are the possible benefits and risks of participating?
Practitioners: the main burden for you is the time it will take to participate in the training, the WeChat group, completing the short interviews during your consultation with patients in your clinic. However, you will receive training in the current National Guidelines and research for treating respiratory infections; and you will also receive a computer programme to help you follow the guidelines.

Patient: there are no risks from taking part in the study. You will receive treatment for your illness that follows the National Chinese guidelines for treating this type of illness. You will not benefit from taking part in this study, but you will help us improve treatment for future patients

Where is the study run from?
1. Anhui Medical University (China)
2. University of Bristol (UK)

When is the study starting and how long is it expected to run for?
February 2019 to December 2022.

Who is funding the study?
This project is jointly funded by National Natural Science Foundation of China and Medical Research Council of the UK. The RCT ethics has been reviewed by the Biomedical Research Ethics Committee of Anhui Medical University and registered within Research Governance Team at the University of Bristol (UK).

Who is the main contact?
Prof Linhai Zhao, zhao700110@126.com
Prof Debin Wang, dbwang@vip.sina.cn

Previous plain English summary:
Background and study aims
Antibiotics are over-prescribed for patients with respiratory-tract infections (RTIs, coughs & colds) in primary care, especially in the rural areas of China. This study is aimed to evaluate an intervention to improve antibiotic prescribing by doctors and reduce unnecessary antibiotic consumption for coughs and colds (respiratory infections).

Who can participate?
One village clinic each from 64 areas overseen by a township hospital will be selected. All the village healthcare professionals who see patients with RTI in the selected village clinics will be invited to participate in this study; and all the patients with URTIs who are present to seek consultation in their clinics will be also invited to participant in this study.

What does the study involve?
Village clinician: a researcher from Anhui Medical University will contact you, and may arrange a bespoke training about appropriate antibiotics prescribing in clinical practice, a computer-based decision support system and access to a wechat peer support group.
Patient: a researcher from Anhui Medical University will contact and also observe your consultation with the doctor. A researcher will also contact you by phone to ask you a few questions about your recovery at 3 days, 7 days, 14 days and 21 days after your initial consultation. Each phone call will take about 10 minutes.

What are the possible benefits and risks of participating?
Village clinician: the main burden for you is the time it will take to participate in the training, the WeChat group, completing the short interviews during your consultation with patients in your clinic. However, you will receive a training in the current National Guidelines and research for treat respiratory infections; and you will also receive a computer programme to help you follow the guidelines.
Patient: there is no risks from taking part in the study. You will receive treatment for your illness that follows the National Chinese guidelines for treating this type of illness. You will not benefit from taking part in this study, but you will help us improve treatment for future patients

Where is the study run from?
1. Anhui Medical University (China)
2. University of Bristol (UK)

When is the study starting and how long is it expected to run for?
February 2019 to December 2022.

Who is funding the study?
This project is jointly funded by National Natural Science Foundation of China and Medical Research Council of the UK. The RCT ethics has been reviewed by the Biomedical Research Ethics Committee of Anhui Medical University and registered within Research Governance Team at the University of Bristol (UK).

Who is the main contact?
Prof Linhai Zhao, zhao700110@126.com
Prof Debin Wang, dbwang@vip.sina.cn

Contact information

Type(s)
Scientific

Contact name
Prof Debin Wang

ORCID ID
https://orcid.org/0000-0002-5106-6427

Contact details
81 Meishan Rd
School of Health Services Management
Anhui Medical University
Hefei
China
230032
+86 55165116395
dbwang@vip.sina.com

Type(s)
Public

Contact name
Prof Linhai Zhao

Contact details
81 Meishan Rd
School of Health Services Management
Anhui Medical University
Hefei
China

230032
+86 15955134608
zhao700110@126.com

Type(s)
Public

Contact name
Dr Wenjuan Cong

ORCID ID
https://orcid.org/0000-0002-5034-8182

Contact details
Population Health Sciences
Bristol Medical School
Canynge Hall, 39 Whatley Road
Bristol
United Kingdom
BS8 2PS
+44 (0)1173314528
wenjuan.cong@bristol.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
STAR-CHINA RCT Trial protocol 27May20

Study information

Scientific Title
Evaluation of effectiveness and cost-effectiveness of a Training, decision Aid and Peer Support (TAPS) intervention aimed at township healthcare professionals and patients to improve antibiotic prescribing for respiratory-tract infections (RTIs)

Acronym
TAPS

Study objectives
Current study hypothesis as of 04/08/2021:
The training, decision aid and peer support (TAPS) intervention will reduce unnecessary antibiotic prescriptions for patients with respiratory-tract infections (RTI) in township health centres in rural China.

Previous study hypothesis:
The training, decision aid and peer support (TAPS) intervention will reduce unnecessary antibiotic prescriptions for patients with respiratory-tract infections (RTI) in village clinics in rural China.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/09/2020, Biomedical Research Ethics Committee of Anhui Medical University (81 Meishan Rd, Hefei, 230032, China; +86 (0)55165161057; chengfan@ahmu.edu.cn), ref: 20180259

Study design
Interventional mixed-methods study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Reduction of unnecessary antibiotic prescribing for adult patients with suspected respiratory tract infections

Interventions
Current interventions, as of 16/05/2022:
A cluster-randomised controlled trial will be carried out to estimate the effectiveness and cost-effectiveness of a complex intervention in reducing antibiotic prescribing at rural health facilities in Anhui Province, China. 40 township health centres from 10 counties within 4 regions across Anhui Province, will be recruited.

A baseline audit of 400 RTI patients across 40 township health centres (10 RTI patients per clinic) will be conducted. This baseline audit will only collect primary outcome data i.e. antibiotic prescribing rates at each clinic. Then all the township health centres will be randomised at a 1:1 ratio to usual care group vs intervention group, using the baseline antibiotic prescribing rates to balance high and low prescribing clinics between the arms. Each group will have 20 township health centres. In the intervention group, practitioners will receive an intervention comprising: training to support appropriate antibiotic prescribing for RTI; a computer-based decision support system; virtual peer support; a leaflet for patients; and a letter of commitment to optimise antibiotic use to display in their clinic. The control arm will continue to provide usual care. After 9-12 months, a follow-up audit of 1200 RTI patients for 40 township health centres (30 RTI patients per clinic) will be conducted; both primary outcome data and secondary outcome data will be collected.

Previous interventions as of 04/08/2021:
A cluster-randomised controlled trial will be carried out to estimate the effectiveness and cost-effectiveness of a complex intervention in reducing antibiotic prescribing at rural health facilities in Anhui Province, China. 40 township health centres from 10 counties within 4 regions geographically dispersed across Anhui Province, will be recruited.

A baseline audit of 400 RTI patients across 40 township health centres (10 RTI patients per clinic) will be conducted. This baseline audit will only collect primary outcome data i.e. antibiotic prescribing rates at each clinic. Then all the township health centres will be randomised at a 1:1 ratio to usual care group vs intervention group, using the baseline antibiotic prescribing rates to balance high and low prescribing clinics between the arms. Each group will have 20 township health centres. In the intervention group, practitioners will receive an intervention comprising: training to support appropriate antibiotic prescribing for RTI; a computer-based decision support system; virtual peer support; a leaflet for patients; and a letter of commitment to optimise antibiotic use to display in their clinic. The control arm will continue to provide usual care. After 9-12 months, a follow-up audit of 1200 RTI patients for 40 township health centres (30 RTI patients per clinic) will be conducted; both primary outcome data and secondary outcome data will be collected.

Previous interventions as of 28/04/2021:
A cluster-randomised controlled trial will be carried out to estimate the effectiveness and cost-effectiveness of a complex intervention in reducing antibiotic prescribing at village clinics in Anhui Province, China. 64 village clinics, each from a different non-contiguous township area and geographically dispersed across Anhui Province, will be recruited.

A baseline audit of 2000 RTI patients across the 64 village clinics will be conducted. This baseline audit will collect all primary and secondary outcome data, including the antibiotic prescribing rates at each clinic. Then all the village clinics will be randomised at a 1:1 ratio to usual care group vs intervention group, using the baseline antibiotic prescribing rates to balance high and low prescribing clinics between the arms. Each group will have 32 village clinics. In the intervention group, village practitioners will receive an intervention comprising: training to support appropriate antibiotic prescribing for RTI; a computer-based decision support system; virtual peer support; a leaflet for patients; and a letter of commitment to optimise antibiotic use to display in their clinic. The control arm will continue to provide usual care.

Previous interventions:
This is a 12-month, cluster randomised controlled trial and a total of 64 village clinics from different townships (one village clinic per township) within 6-8 cities, Anhui Province, China will be recruited. A baseline audit of 2000 URTI patients across the village clinics will be conducted. Then all the village clinics will be simply randomised at a 1:1 ratio to usual care group vs intervention group. Each group will have 32 village clinics. After 9-12 months, a follow-up visit will be made for both study arms.

Health professionals working in village clinics will receive training on AMR and URTI symptoms treatment, latest national prescribing guideline, address key concerns and misapprehensions, communication skills with patients during the consultation. Training will be delivered by a senior clinician from a tertiary hospital in the region. Village doctors will be required to sign a public declaration letter stating that they are committed to reducing unnecessary antibiotic prescribing and display this in their clinics.

A computer-based decision aid tool will be installed in the village clinics of the intervention group to facilitate appropriate antibiotic prescribing in the clinical practice. A WeChat peer support group will be established to enable village healthcare professionals to support each other's learning and practice. Health professionals will be provided with a leaflet to give to patients to support no-antibiotic treatment decisions.

Intervention Type
Behavioural

Primary outcome(s)

The prescribing rate of antibiotic (oral and intravenous) for RTI patients during the consultations at baseline and follow-up audit (9-12 months after intervention) using patient records

Key secondary outcome(s))

Current secondary outcome measures as of 16/05/2022:
1. Patient symptom severity will be assessed through follow-up telephone interview at 7, 14, and 21 days after consultation
2. Patient recovery situation will be assessed through follow-up telephone interview at 7 and 14 days after consultation
3. Patient consumption of prescribed antibiotics will be recorded through follow-up telephone interview at 7, 14 days after consultation
4. Patient attitude, knowledge of the patient leaflet and beliefs will be assessed through followup telephone interview at 7 days after consultation
5. Patient costs will be assessed through follow-up telephone interview at 14, 21 days after consultation
6. Patient EQ5D-5L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) will be assessed during the initial consultation and also telephone interviews at 7, 14, and 21 days after consultation

Previous secondary outcome measures as of 04/08/2021:
1. Patient symptom severity and duration will be assessed through follow-up telephone interview at 7, 14, and 21 days after consultation
2. Patient satisfaction will be assessed during the initial consultation
3. Patient recovery situation will be assessed through follow-up telephone interview at 7 and 14 days after consultation
4. Patient consumption of prescribed antibiotics will be recorded through follow-up telephone interview at 7, 14, and 21 days after consultation
5. Patient attitude, knowledge of the patient leaflet and beliefs will be assessed through follow-up telephone interview at 7 days after consultation
6. Patient cost-effectiveness evaluation will be assessed through follow-up telephone interview at 21 days after consultation
7. Patient EQ5D-5L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) will be assessed during the initial consultation and also telephone interviews at 7, 14, and 21 days after consultation

Previous secondary outcome measures as of 28/04/2021:
1. Patient symptom severity and duration will be assessed through follow-up telephone interview at 7, 14, and 21 days after consultation
2. Patient satisfaction will be assessed during the initial consultation
3. Patient recovery situation will be assessed through follow-up telephone interview at 7 and 14 days after consultation
4. Patient consumption of prescribed antibiotics will be recorded through follow-up telephone interview at 21 days after consultation
5. Patient attitude, knowledge of the patient leaflet and beliefs will be assessed through follow-up telephone interview at 7 days after consultation
6. Patient cost-effectiveness evaluation will be assessed through follow-up telephone interview at 21 days after consultation
7. Patient EQ5D-5L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) will be assessed through follow-up telephone interview at 7, 14, and 21 days after consultation

Previous secondary outcome measures:
1. Patient symptom severity and duration will be assessed through follow-up telephone interview at 3, 7, 14, 21 days after consultation
2. Patient satisfaction will be assessed during the initial consultation
3. Patient recovery situation will be assessed through follow-up telephone interview at 7, 14 days after consultation
4. Patient consumption of prescribed antibiotics will be recorded through follow-up telephone interview at 21 days after consultation
5. Patient attitude, knowledge of the patient leaflet and beliefs will be assessed through follow-up telephone interview at 3 days after consultation
6. Patient cost-effectiveness evaluation will be assessed through follow-up telephone interview at 21 days after consultation
7. Patient EQ5D-5L (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) will be assessed through follow-up telephone interview at 3, 7, 14, 21 days after consultation

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 04/08/2021:
Practitioners:
All the practitioners working in the recruited township health centres will be invited to participate in the study

Patients:
1. Patients with RTIs who are present to seek consultation in the recruited township health centres
2. Aged ≥18 years old
3. Diagnosed with an RTI in the recruitment consultation: blocked/runny nose, coughing with or without sputum, dry/sore throat, breathing problems, fever, ear inflammation (blocked ear, tinnitus, ear discharges, earache).

Previous participant inclusion criteria as of 28/04/2021:
Village Practitioners:
1. All the practitioners working in the recruited village clinics will be invited to participate in the study

Patients:
1. Adult (aged ≥18 years old)
2. Diagnosed with RTIs in the recruitment consultation: blocked/runny nose, coughing with or without sputum, dry/sore throat, breathing problems, fever, ear inflammation (blocked ear, Tinnitus, ear discharges, earache)

Previous participant inclusion criteria:
Village Healthcare Professionals:
1. All the village healthcare professionals working in the village clinics with URTI patients

Patients:
2. All the patients with URTIs who are present to seek consultation in the recruited practices

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
1021

Key exclusion criteria
Current participant exclusion criteria as of 04/08/2021:
Practitioners:
1. Do not have basic computer skills
2. Not involved in clinical diagnosis and medicine prescribing

Patients:
1. Have previously sought treatment for this illness from a normal clinic (not a specialist Covid clinic)
2. Unable to provide fully informed consent (e.g. due to dementia, psychosis, or severe depression)
3. Pregnancy

Previous participant exclusion criteria as of 28/04/2021:
Village Practitioners:
1. Have basic computer skills
2. Not involved in clinical diagnosis and medicine prescribing

Patients:
1. Previously sought treatment for this illness from a normal clinic (not a specialist Covid clinic)
2. Unable to provide fully informed consent (eg dementia, psychosis, or severe depression)
3. Pregnant
4. Immunological deficiencies
5. Non-infective conditions (e.g. pulmonary embolus, heart failure, oesophageal reflux, or serious allergy).

Previous participant exclusion criteria:
Village healthcare professionals:

1. Healthcare professionals who are not computer literate
2. Healthcare professionals who are not involved in the clinical diagnosis and medicine prescribing

Patients:
1. Patient has sought repeat consultation for this illness will be excluded.
2. Patients who is unable to provide consent form (eg, dementia, psychosis, or severe depression)
3. Patient who is pregnant
4. Patient with immunological deficiencies
5. Patient with non-infective disorder (eg, pulmonary embolus, heart failure, oesophageal reflux, or allergy)
6. Patient use of antibiotics in the previous month

Date of first enrolment
01/12/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
China

Study participating centre
School of Health Services Management Anhui Medical University
81 Meishan Rd
Hefei
China
230032

Sponsor information

Organisation
Anhui Medical University

ROR
https://ror.org/03xb04968

Organisation
University of Bristol

ROR

https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China, Grant Ref: 81861138049

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Medical Research Council, Grant Ref: MR/S013717/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2024	20/11/2024	Yes	No
Protocol article		03/01/2022	05/01/2022	Yes	No
Other publications	Qualitative process evaluation	16/01/2026	19/01/2026	Yes	No
Participant information sheet			02/12/2020	No	Yes
Participant information sheet			02/12/2020	No	Yes
Participant information sheet			28/04/2021	No	Yes