ISRCTN29801086 https://doi.org/10.1186/ISRCTN29801086

Evaluation of an easy and pragmatic intervention to reduce antibiotic use for symptomatic respiratory infections in China

Submission date 18/09/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/09/2022	**Overall study status** Ongoing	
Last Edited 05/10/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Antibiotics are over-used for patients with respiratory-tract infections (RTIs, coughs & colds) in primary care, especially in the rural areas of China. This study proposes a tailored message package for educating patients with symptomatic RTIs to reduce antibiotic use. The study aims to assess the message package's efficacy through a randomized controlled trial (RCT).

Who can participate?
30 township health centres from 2 cities across Anhui Province, China will be selected as study sites. All the patients with RTIs who present to the 30 clinics during the study period will be invited to participate in the study.

What does the study involve?
The control arm maintains usual care; while eligible patients in the intervention arm, will be sent 12 tailored massages in 12 consecutive days (once a day).
For any recruited patient, the baseline interview happens within 1-2 days of his/her visit to the health center; while the follow-up interviews are scheduled at 7, 14, 21,180 and 365 days after the baseline.

What are the possible benefits and risks of participating?
There are no major risks from taking part in the study. However, the baseline and follow up interviews will take 8 to 15 minutes each time. Possible benefit could be that participants will learn the harm of antibiotics and what to do after re-infection.

Where is the study run from?
Anhui Medical University (China)

When is the study starting and how long is it expected to run for?
February 2022 to July 2027

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
Miss Rong Liu
liurongang123@163.com

Contact information

Type(s)
Scientific

Contact name
Miss Rong Liu

ORCID ID
https://orcid.org/0000-0002-7968-5932

Contact details
Anhui Medical University
81 Meishan Road
Hefei
China
230032
+86 551-65116395
liurong@ahmu.edu.cn

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of a tailored message package for educating patients to reduce antibiotics use for symptomatic respiratory-tract infections

Study objectives
The tailored message package for educating patients intervention will reduce unnecessary antibiotic uses for patients with symptomatic respiratory-tract infections (RTI) in township health centres in rural China.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2022, Anhui Medical University Biomedical Ethics Committee (Anhui Medical University, 81 Meishan Road, Hefei, Anhui, China; +86 0551-65161053; renzhenhua@ahmu.edu.cn), ref: 81220189

Study design
Multi-centre cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Symptomatic respiratory tract infectious

Interventions
A total of 30 township/community health centers within 2 cities, Anhui Province, China will be recruited. All the township/community health centers will be randomised at a 1:1 ratio to the control arm or the intervention arm. Each arm will have 15 township/community health centers. The control arm maintains usual care; while eligible patients in the intervention arm, will be sent 12 tailored massages in 12 consecutive days (once a day). Project evaluation applies to all arms using the same data collection methods and by the same field data collectors.

A novel computerized program has been developed for tailoring the messages to the need and context of individual patients. Each of the messages is designed as a template inserted with substitution variables which are replaced with relevant values and/or text according to the actual conditions and contexts of the patient under concern. The whole process of the message design, modification, translation (of substitution variables) and sending is facilitated by the user-friendly mini computer program.

Intervention Type
Behavioural

Primary outcome(s)
Number of days in which antibiotics are used by patients with symptomatic RTIs measured using telephone questionnaire at initial consultation, 7 and 14 days

Key secondary outcome(s))
1. Patients’ knowledge about and attitude toward antibiotics measured using telephone questionnaire at 180 and 365 days
2. Patients’ quality of life measured using EQ-5D at initial consultation 7, 180 and 365 days
3. Patients' symptom severity and duration measured using telephone questionnaire at initial consultation, 7, 14 and 21 days
4. Times of re-visits to clinics and antibiotics re-prescription for the same RTI episode measured using telephone questionnaire at 14 and 21 days
5. Times of re-occurrence of RTIs within six or twelve months after the intervention and related

health service seeking and antibiotics consumption measured using telephone questionnaire at 180 and 365 days

Completion date
30/12/2027

Eligibility

Key inclusion criteria
1. 18 years or older and able to give consent to participate in the patient survey and/or follow-up interviews
2. Diagnosed with an 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)
3. Able to read messages
4. Have a mobile phone that can receive messages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Have previously sought treatment for this illness from a normal clinic
2. Unable to provide fully informed consent (e.g. due to dementia, psychosis, or severe depression)
3. Can't receive messages
4. Unable to read messages

Date of first enrolment
01/12/2023

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
China

Study participating centre
Anhui Medical University
81 Meishan Road
Hefei
China
230032

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

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

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/10/2023	05/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			21/09/2022	No	No