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Intervention to improve antibiotic use in the community

Submission date	Recruitment status	[ ] Prospectively registered
07/06/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/06/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2024	Other	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Antibiotic resistance is an important public health problem, and Spain is the developed country with the highest consumption of antibiotics. 90% of this consumption is at the community level, especially for the treatment of upper respiratory infections which account for two-thirds of the community consumption. The aim of this study is to evaluate the effectiveness of a community intervention to improve the use of antibiotics in the treatment of upper respiratory infections.

Who can participate?
Primary care physicians and pharmacists in the study area

What does the study involve?
Primary care physicians will take two online courses about doctor-patient communication and diagnosis and treatment of upper respiratory infections. Community pharmacists take two online courses about pharmacist-patient communication and the management of upper respiratory infections.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Center for Biomedical Research in Epidemiology and Public Health Network (CIBERESP) (Spain)

When is the study starting and how long is it expected to run for?
November 2019 to December 2023

Who is funding the study?
Instituto de Salud Carlos III (Spain)

Who is the main contact?
Adolfo Figueiras, Adolfo.figueiras@usc.es

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
PI19/01006

Study information

Scientific Title
Community intervention to improve antibiotic use

Acronym
eRes+

Study objectives
The deficient training of the general population in the self-diagnosis and treatment of self-limited respiratory infections (flu, common cold, pharyngitis, acute bronchitis, rhinosinusitis) is associated with an increase in patient pressure on doctors and pharmacists for prescription and non-prescription antibiotics. The empowerment of patients in these diseases, together with interventions in doctors and pharmacists to improve their knowledge and attitudes in these pathologies and their communication skills with the patient, can decrease prescription and over-the-counter dispensing and, therefore, inappropriate and excessive use of antibiotics at the level community.

H1. Health training for the general population on trivial respiratory diseases and self-care reduces the demand for antibiotics without prescription (pharmacies) and with prescription (primary care consultations)
H2. Strengthening the knowledge and attitudes of health professionals reduces prescribing and dispensing antibiotics
H3. Strengthening the communication skills of health professionals reduces prescribing and dispensing antibiotics

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 28/11/2019, Comité de ética de la investigación con medicamentos de Galicia (CEIm-G) (Galicia Drug Research Ethics Committee, Edificio Administrativo San Lázaro, 15703 Santiago De Compostela, Spain; +34 (0)881546425; ceic@sergas.es), ref: 2019/598

Primary study design
Interventional

Study design
Cluster quasi-experimental controlled study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Antibiotic prescription and antibiotic dispensation by health professionals

Interventions
A multifaceted community intervention (multifactorial and multidisciplinary) is proposed that encompasses the three main people involved in the use of antibiotics: doctors, pharmacists, and the general population. The control group will not perform interventions but, like those of the group of intervention, they will be exposed to other campaigns that can be carried out simultaneously.

Intervention in doctors and pharmacists in three sanitary health areas:
A1. Online course on professional-patient communication: This will be offered free of charge in order to improve communication skills. The STAR model of training in training skills will be used. Communication, which has already been cost-effective in other settings. In this course (designed and carried out by psychologists from the research group) the expectations of patients and how to manage them, resources will be made available to improve patient communication and assertiveness techniques.
A2. Online course on diagnosis and treatment of acute respiratory infections. A free online course to update knowledge about infection management respiratory will be designed by team members (clinical pharmacologists, specialists in family and community medicine, preventive, primary pharmacists) based on clinical guidelines. The course will be accredited by the continuing medical education system. In addition, this course will provide support material in the consultation for the doctor and to deliver to the patient.

The courses will be offered in a face-to-face session in November 2021. In this session, the researchers will explain the aim of the study. The courses will be accredited by the continuing medical and pharmaceutical education system. In addition, this course will provide support material in the consultation for the health professional and to deliver to the patient.
After the intervention, the researchers will compare the prescription and antibiotics sales in each group in the following year.

B. Intervention in the community: Educational interventions will be carried out in the community indirectly through the health professionals on whom the intervention is carried out, and directly through the neighbourhood associations and city councils.

The areas chosen to carry out the intervention will be those in which the main researchers are working at the time of the study.

Intervention Type
Behavioural

Primary outcome(s)
The number of monthly DHDs (the defined daily dose (DDD) per 1,000 inhabitants per day (DHD)) of each sanitary health area measured using pharmaceutical billing data and consumption data obtained from sales in pharmacies each month in the 12 months following the intervention

Key secondary outcome(s)
European Surveillance of Antimicrobial Consumption (ESAC) indicators: ratio of the consumption of broad-spectrum (J01 (CR+DC+DD+(F-FA01))) to the consumption of narrow-spectrum penicillins, cephalosporins and macrolides (J01(CE+DB+FA01)), measured using pharmaceutical billing data and consumption data obtained from sales in pharmacies each month in the 12 months following the intervention.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Primary care physicians and community pharmacists

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clinico Universitario de Santiago de Compostela
Choupana sn
Santiago de Compostela
Spain
15706

Sponsor information

Organisation
Instituto de Salud Carlos III

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Charity

Funder Name
Fundación Instituto de Investigación Sanitaria de Santiago de Compostela

Alternative Name(s)
Health Research Institute of Santiago de Compostela Foundation, The Health Research Institute of Santiago de Compostela Foundation, Fundación IDIS, IDIS Foundation, FIDIS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Adolfo Figueiras (Adolfo.figueiras@usc.es).

IPD sharing plan summary
Available on request