

Intervention to improve antibiotic use in the community

Submission date 07/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/06/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Miss Olalla Vazquez Cancela

ORCID ID

<http://orcid.org/0000-0001-5306-9587>

Contact details

Os Concheiros 52

Santiago De Compostela

Spain

15703

+34 (0)630151474

olallavazquez3@gmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Study design

Cluster quasi-experimental controlled study

Primary study design

Interventional

Secondary study design

Cluster quasi-experimental controlled study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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.

Overall study start date

28/11/2019

Completion date

31/12/2023

Eligibility

Key inclusion criteria

Primary care physicians and community pharmacists

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

The medical doctors of 143 primary care centres and the pharmacist of 484 pharmacy offices

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

Sponsor details

Avenida Monforte de Lemos n°4

Madrid

Spain

28029

+34 (0)981951192

adolfo.figueiras@usc.es

Sponsor type

Government

Website

<http://www.isciii.es/>

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, ISCIII

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Publication and dissemination plan

Publication of articles in high impact journal and attendance at conferences.

Intention to publish date

02/05/2024

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