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Evaluation of the effectiveness of an educational intervention in community pharmacists to improve pharmaceutical care in upper respiratory infections, including flu, colds, sore throat and sinusitis

Submission date
28/02/2018

Recruitment status
No longer recruiting

Registration date
04/06/2018

Overall study status
Completed

Last Edited
27/07/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Antimicrobial resistance (when antibiotics don't work any more because they no longer kill bacteria) is an important problem in public health. It generates a lot of deaths and increases healthcare costs. The inappropriate use of antibiotics in the community makes this problem worse. Spain has one of the highest rates of antibiotic use per person, in most cases taken for the treatment of upper respiratory infections (colds, flu, sore throats etc). Some people get antibiotics without a prescription when they have an infection and this contributes to the problem. Antibiotics can be bought without a prescription in some pharmacies, although this is unlawful. It is known that several beliefs and attitudes of pharmacists increase this practice. The study aims to investigate whether training pharmacists about antimicrobial resistance and other treatment options offered in pharmacies for flu, colds and other upper respiratory tract infections will reduce the sale of antibiotics without prescription.

Who can participate?
Community pharmacists in the study area

What does the study involve?
All the pharmacies of two regions of the northwest of Spain are grouped into 6 groups, depending on the different health regions. All the pharmacies of three of these groups (randomly selected) will receive the intervention. It consists of:
1. A health professional will visit each pharmacy and give training to the pharmacist relating to antibiotic resistance, identifying people who should see a doctor and selecting over-the-counter (non-prescribed) medicines that can help with symptoms of colds, flu, sore throats etc. The health professional will also demonstrate the eRes app for mobile devices. The pharmacist can use the app by inputting the patient's symptoms. The app will then give a likely diagnosis and suggest over-the-counter medicines and self-care tips that the patient can use. It will also

suggest a duration of illness and recommend when the patient should see a doctor. The health professional will recommend that the pharmacist takes an online training course and will leave information for the pharmacist and for patients on respiratory tract infections and their treatment.
2. An online course about pharmacy care process in upper respiratory tract infections. The duration of the course is 10 hours and consists of five theory parts, one practical part and a final test. The course counts as 1.8 credits of continuous professional training to those who pass the test.
3. Access to the eRes app.
Pharmacies in the control group will not receive any part of the intervention. Like those of the intervention group, they are exposed to other campaigns that can be carried out simultaneously.

What are the possible benefits and risks of participating?
The benefit for intervention pharmacies is to provide better care to their patients with respiratory infections. They improve their knowledge through the online course, the app and the training visit. Therefore, they will have more confidence to refuse to sell an antibiotic without a prescription, and to offer the most appropriate over-the-counter treatment. There is no risk or harm for those who participate in the study, neither for pharmacies nor for general population. Since we do not contact the pharmacies of the control group, they are not exposed to any risk. Once the study ends, they will benefit from the app or future online training courses.

Where is the study run from?
University of Santiago de Compostela (Spain). The study takes place in two regions in the northwest of Spain.

Who is funding the study?
The Carlos III Health Institute (Spain)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PID15/00844

Study information

Scientific Title
Evaluation of the effectiveness of an educational intervention in community pharmacists to improve pharmaceutical care in influenza, colds and upper respiratory infections: a cluster randomized controlled trial (IMATID)

Acronym
IMATID

Study objectives
Inappropriate antibiotic use exacerbates the phenomenon of antimicrobial resistance. Community pharmacists should guarantee the proper use of antibiotics in general population, avoiding the dispensing of antimicrobials if they are not prescribed by a physician.
Hypothesis: An educational intervention and a computerised decision support system improves pharmaceutical care for flu, colds and upper respiratory tract infections (in terms of decreasing the number of antibiotic dispensed without a prescription)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Galician Clinical Research Ethics Committee (Comité de Ética de investigación de Galicia), 20/10/2015
2015/597

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Outpatient antibiotic consumption in patients with upper respiratory tract inffections

Interventions
All the pharmacies in the study area were grouped into 6 spatial clusters, depending on the different health areas. We assigned a number to each cluster. Using the Epidat program, a random 1:1 distribution was made.
The three randomly selected clusters received the intervention. It consisted of:
1. A formative session about antimicrobial resistance and the responsibility of community pharmacists. A health professional visited each pharmacy. These visitors explained some current data of antibiotic resistance, the need to discover new antimicrobials, the association between antibiotic consumption and resistances development andthe role of pharmacist in health education, patient adherence to the antibiotic treatment, selection of appropriate over-the-counter medicines and identifying cases that should be referred to the doctor, thus avoiding dispensing antibiotics if they are not prescribed by a physician.
They also explained the opportunity to use new technologies, showing an application for mobile devices (eRes), designed for this study, as a decision support system based on the patient's symptoms. Finally, they offered the possibility of updating their knowledge through an online course, also designed exclusively for this study. They gave a triptych as a reminder of the app and the online course. In addition, they gave informative materials for patients about the ineffectiveness of antibiotics against viral infections.
2. An online course about pharmaceutical care in upper respiratory tract infections. The course duration was 10 hours and consisted of 5 theoretical parts, one practical part and a final evaluation. The course granted 1.8 credits of continuous professional training to those who did it satisfactorily.
3. Access to an application for mobile devices (eRes), as a decision support system based on patient's symptoms. The objective was that the application could be used at the time of dispensing. It starts with the main symptom of the patient (cough, nasal symptoms, sore throat or fever) and then it asks a battery of questions about other symptoms. Finally, the most probable diagnosis is shown, with other sections such as over the counter treatment, self-care, the disease duration and situations when it is necessary to consult a doctor.

The visits were made from February 2017 to March 2017.

Pharmacists still have access to the mobile application. Due to the high number of pharmacists who wanted to do the online course, several consecutive editions were made. The last edition ended in July 2017.

Pharmacies of the control clusters did not received the intervention but, like those of the intervention group, they were exposed to other campaigns that may have been carried out simultaneously.

To quantify the effect of the intervention the sale of antibiotics without prescription (Yes/No) was measured, both in control and intervention pharmacies, using the technique of simulated patients.

Intervention Type
Behavioural

Primary outcome measure
Number of antibiotics dispensed without a medical prescription, 1 month before and 1 month after the intervention, by the simulated client method. The simulated patient presents with a respiratory infection, for which he requested an antibiotic without prescription. Four gradual levels of pressure are used to obtain the antibiotic.

Secondary outcome measures
1. Quality of pharmaceutical care was measured 1 month before and 1 month after the intervention using the simulated client method . It was evaluated by recording which other medications were offered, the reasons for not dispensing antibiotic and all the questions related to possible adverse reactions or contraindications.
2. Pressure level to obtain antibiotic was measured 1 month before and 1 month after the intervention using the simulated client method. Four gradual levels of demand were used to obtain the antibiotic. At the beginning the patient requests something for the symptoms and ends up requesting a specific antibiotic (amoxicillin)

Overall study start date
01/01/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All community pharmacists in two provinces in the northwest of Spain (A Coruña and Pontevedra).

Participant type(s)
Health professional

Age group
All

Sex
Both

Target number of participants
6 clusters with 150 pharmacies per cluster approximately

Total final enrolment
977

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2016

Date of final enrolment

28/04/2017

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Santiago de Compostela
Spain
15782

Sponsor information

Organisation
Facultad de Farmacia. Universidad de Santiago de Compostela

Sponsor details
Praza Seminario de Estudos Galegos, s/n. Campus sur
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Sponsor type
University/education

ROR
https://ror.org/030eybx10

Funder(s)

Funder type
Not defined

Funder Name
Health Research Fund (Fondo de Investigación Sanitaria) from the Carlos III Health Institute (Instituto de Salud Carlos III)

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high-impact peer-reviewed journal in 2018.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available, because this point was not included in the protocol and the approval conditions of the ethics committee.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	27/07/2020	Yes	No