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Assessing the impact of an eHealthResp intervention on antibiotics use

Submission date
21/07/2022

Recruitment status
No longer recruiting

Registration date
22/07/2022

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The emergence of antibiotic resistance (ABR) is one of the most serious public health threats globally. One of the main drivers for the increase and development of ABR is the inappropriate use of antibiotics, which contributes to a greater risk of therapeutic ineffectiveness.

It is estimated that ABR, due to misuse or overuse, could contribute to an additional worldwide mortality of about 10 million people by 2050. Several studies have shown that about 20-30% of antibiotics prescribed in primary care are inappropriate. There are several factors that can significantly contribute to the global inappropriate or excessive consumption of antibiotics, such as, gaps in knowledge, lack of patient adherence to medical prescriptions and deviation from the guidelines in force in each country by prescribing health professionals. Moreover, considering that inappropriate antibiotic use is associated with the emergence and dissemination of resistant strains, unjustified prescribing, self-medication and dispensing without prescription are three potentially modifiable factors that would enable resistances to be reduced. Therefore, it is of utmost importance to develop specific guidelines and implement efficient strategies and initiatives to prevent resistance development. These may consist in multifaceted educational interventions targeted to healthcare professionals, namely primary care physicians and community pharmacists, with the goal of raising awareness to the risks of resistance and promoting a rational use of antibiotics, both in terms of prescription and dispensing, as well as improving quality indicators, thus leading to a decrease in the spread of ABR. One of the proposed methods, which has shown to be quite promising in improving clinical decision-making, particularly regarding antibiotics prescribing according to the guidelines, is the implementation of clinical decision support systems. In agreement, this study aims to evaluate the effectiveness of e-Health tools to support clinical decision in upper respiratory infections management. We designed and developed the eHealthResp, a digital platform that includes:
1. Two online courses aimed at primary care physicians and community pharmacists that contains respectively 6 and 4 modules (based on national and international clinical practice guidelines) and four clinical cases
2. A clinical decision support system in the form of a mobile application aimed at physicians and pharmacists. The major goal is to provide support to health professionals, particularly in the therapeutic approach of respiratory tract infections, thus contributing to an improvement in patient care and assistance.

Who can participate?
All primary care physicians and community pharmacists working under the catchment area of Portugal's Centre Regional Health Administration (ARS-C)

What does the study involve?
This study involves the implementation of an educational intervention, composed of a 45-minute session on antibiotic resistances, an online course and a mobile application to support health professionals' decisions in the management of respiratory tract infections, together with the distribution of relevant educational material (flyers and posters), alerting for an adequate antibiotic use and addressing antibiotic bacterial resistances, to be disseminated among the primary care physicians and community pharmacists attending the educational intervention. A randomised study with an 8-cluster distribution (4 intervention and 4 control) determined by the respective catchment areas of ARS-C will be conducted. To prevent cross-contamination between groups, spatial clusters, rather than professional clusters, will be used as units of allocation.
- Intervention group clusters: primary care physicians and community pharmacists within the area of the intervention group will undertake the educational intervention.
- Control group clusters: primary care physicians and community pharmacists in the area of control clusters will not receive this intervention.

What are the possible benefits and risks of participating?
This study's main benefits are the reduction of antibiotic use/consumption among the general population, as well as the improved knowledge and good clinical practices acquirement among health professionals, particularly regarding the prescription and dispensing of antibiotics for respiratory tract infections. There is no risk or harm for those participating in the study.

Where is the study run from?
iBiMED – Institute of Biomedicine, University of Aveiro (Portugal)

When is the study starting and how long is it expected to run for?
February 2022 to May 2023

Who is funding the study?
Foundation for Science and Technology, Portuguese Science and Technology Foundation (Portugal)

Who is the main contact?
Prof Dr Maria Teresa Herdeiro (Portugal)
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Assessing the impact of an eHealthResp intervention on antibiotics use: A cluster randomised controlled trial with primary health care professionals

Acronym
eHealthResp

Study objectives
The purpose of this study is to evaluate the effectiveness of a multifaceted educational intervention, based on the use of the eHealthResp tools, which includes an online course and a mobile application, both directed to primary care physicians and community pharmacists, to support clinical decision and patient empowerment in respiratory infections management, through a cluster randomised controlled trial. We hypothesised that this intervention might effectively improve the quality of prescribing and dispensing practices of primary care physicians and community pharmacists, thus increasing the impact of adequate antibiotic use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2022, Health Ethics Committee of the Portugal's Centre Regional Health Administration (Administração Regional de Saúde do Centro I.P., ARS-C, Alameda Júlio Henriques S/n, Apartado 1087, 3001-553 Coimbra, Portugal; +351239796 800; secretariado.ca@arscentro.min-saude.pt); ref: 18/2022

Study design
Interventional pragmatic cluster randomized controlled study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Antibiotic prescribing in respiratory tract infections

Interventions
An educational intervention has been designed considering data from previous focus groups and cross-sectional studies on physician and pharmacist attitudes and knowledge that respectively influence antibiotic prescribing and dispensing. A cluster-randomized controlled trial will be conducted on the study population, which comprises all primary care physicians and community pharmacists working in Portugal's Centre Regional Health Administration (ARS-C). This randomised study will be carried out with an 8-cluster distribution defined by the regions covered by the Nomenclature of Territorial Units for Statistics level II (NUTS II). After randomisation of the 8 clusters, 4 were allocated to the intervention group (IG) and 4 to control group (CG). To prevent cross-contamination between both groups, spatial rather than professional clusters, were used as allocation units.
IG clusters: Primary care physicians and community pharmacists were contacted and invited to participate in the intervention sessions through contacts with the clinical and technical directors of each primary care centre and community pharmacy, respectively, within the area of the IG clusters.

Participation in the study was voluntary and all participants gave informed consent before participation. The educational intervention consisted of:
1. A 45-minute session directed to both health professionals about antibiotic resistance, the eHealth tool developed and how to use it, followed by delivery of educational material (flyers and posters) alerting for rational antibiotic use
2. An online course, composed of 6 or 4 modules, respectively targeted to physicians and pharmacists, and 4 clinical cases addressing respiratory tract infections
3. A clinical decision support system in the form of a mobile application

CG clusters: Physicians and pharmacists in control clusters have not received this intervention.

Intervention Type
Other

Primary outcome(s)
Monthly antibiotic prescription data in defined daily doses (DDD) retrieved from the official System of Information and Monitoring of the Portuguese NHS public-access platform between January 2019 and May 2023. An approximately 12-month follow-up period will take place post-intervention.

Key secondary outcome(s))
1. Monthly count of health professionals completing the online course measured using the eHealthResp platform from the beginning of the educational interventions (May 2022)

2. Monthly count of health professionals (users) who accessed the mobile application measured using the eHealthResp platform from the beginning of the educational interventions (May 2022)
3. Number of diagnostics consulted by the health professionals when using the mobile application measured using the eHealthResp platform from the beginning of the educational interventions (May 2022)

Completion date
31/05/2023

Eligibility

Key inclusion criteria
Primary care physicians and community pharmacists working exclusively at primary healthcare centres or community pharmacies under the catchment area of Portugal's Centre Regional Health Administration

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
116

Key exclusion criteria
1. Retirement
2. Extended sick leave
3. Not involved in any clinical activity (e.g., are engaged in administrative tasks, analysis, etc)

Date of first enrolment
18/04/2022

Date of final enrolment
29/06/2022

Locations

Countries of recruitment
Portugal

Study participating centre

Portugal's Centre Regional Health Administration (Administração Regional de Saúde do Centro, ARS-C)
Alameda Júlio Henriques S/n
Apartado 1087
Coimbra
Portugal
3001-553

Sponsor information

Organisation
University of Aveiro

ROR
https://ror.org/00nt41z93

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Portuguese Science and Technology Foundation, Foundation for Science and Technology, Fundacao para a Ciencia e a Tecnologia, The Foundation for Science and Technology (FCT), FCT

Funding Body Type
Government organisation

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

Location
Portugal

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Dr Maria Teresa Herdeiro, teresaherdeiro@ua.pt. The existing data can

be made available in anonymised form, in accordance with the general data protection regulation (GDPR) (the informed consent in Portuguese is attached), for 5 years. It should be noted that the data (primary outcome) are prescription data collected from a public platform of general access and the secondary outcome are data on the number of professionals who access the online course, mobile application and the number of diagnoses consulted on the mobile application.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	22/07/2022	22/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes