

# Multi-faceted intervention to improve antibiotic use in ambulatory care

<b>Submission date</b> 05/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/01/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
FMM-2008-FF

## Study information

**Scientific Title**

Multi-faceted intervention to improve antibiotic use in ambulatory care: a cluster-randomised controlled trial

**Acronym**

INT-ATB-MED

**Study objectives**

Antibiotic resistance is one of the principal public health problems world-wide. Inappropriate use of antibiotics is currently regarded as the main determinant of such resistance.

**Hypotheses:**

1. The attitudes and knowledge towards antibiotics generate habits of prescription
2. The identification of the attitudes, knowledge and factors that generate habits of inadequate prescription will allow the design of specific educative interventions to improve the use of antibiotics
3. The intervention designed from gaps detected in knowledge and attitudes with respect to antibiotics and resistance will improve the prescription of antibiotics
4. The intervention will collaborate in the control of the bacterial resistance

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Spanish accredited Ethics Committee (Comité Ético de Investigación Clínica de Galicia), May 2007, ref: 2007/052

**Study design**

Cluster randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

GP practice

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a participant information sheet

**Health condition(s) or problem(s) studied**

Antibiotics prescriptions

**Interventions**

This is a cluster randomised controlled trial covering all general practitioners in a northwest region of Spain (Galicia). A specific educative intervention, designed from gaps detected in knowledge and attitudes with respect to antibiotics and resistance, will be carried out on the intervention group. The control group will not receive any specific intervention.

The intervention will consist of group outreach visits (40 minutes), and will be targeted at changing the knowledge-attitudes previously found to be associated with poor prescribing of antibiotics. An observational cohort study of a sample of 1500 primary care physicians will be carried out to identify knowledge-attitudes associated with inappropriate prescribing of antibiotics. The independent variables (knowledge-attitudes) will be assessed by a self-administered postal questionnaire and dependent variables are some quantity and quality indicators of the prescribing antibiotics.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Current primary outcome measure as of 06/09/2018:

Quality indicators for antibiotic prescribing drawn up by the European Surveillance of Antimicrobial Consumption Network (ESAC-Net), measured monthly from the last intervention to the end of study

Previous primary outcome measure:

Various quality indicators of the prescribing of antibiotics, assessed based on Infectious Diseases Clinical guidelines in Primary Care, measured monthly from the last intervention to the end of study

### **Secondary outcome measures**

Various quantity indicators of the prescribing of antibiotics, measured monthly from the last intervention to the end of study.

### **Overall study start date**

01/12/2011

### **Completion date**

30/09/2013

## **Eligibility**

### **Key inclusion criteria**

1. General practitioners working during the period of the study
2. Aged approximately 30 - 60 years old, female or male

### **Participant type(s)**

Health professional

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

Estimated to include 3000 GPs (1500 at intervention group and 1500 at control group)

**Total final enrolment**

2610

**Key exclusion criteria**

General practitioners who work for private insurances during the period of the study

Added 06/09/2018:

Temporary staff and medical residents in training physicians exclusively assigned to emergencies

**Date of first enrolment**

02/12/2011

**Date of final enrolment**

30/09/2012

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

**Departamento de Salud Pública**

Santiago de Compostela

Spain

15782

## Sponsor information

**Organisation**

The Foundation for Medical Research Mutua Madrileña (Fundación de Investigación Médica Mutua Madrileña) (Spain)

**Sponsor details**

C/Fortuny, 18

Madrid

Spain

28010

**Sponsor type**

Research organisation

**Website**

<http://www.mutua-mad.es/FundMM/jsp/Fhome.jsp>

**Organisation**

Instituto de Salud Carlos III

**Sponsor details**

C/ Sinesio Delgado, 4 (entrada por Avda. Monforte de Lemos, 5)

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**Sponsor type**

Research organisation

**Website**

<http://www.isciii.es/ISCIII/es/general/index.shtml>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

The Foundation for Medical Research Mutua Madrileña (Fundación de Investigación Médica Mutua Madrileña) (Spain) - grant received

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

30/09/2018

**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. The datasets include global antimicrobial prescriptions in the Health Care System of Galicia

(NHS). The data was provided by the NHS of Galicia, so their authorization is needed before sharing it.

## IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	07/12/2020	26/01/2021	Yes	No