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Evaluation of a pharmaceutical service for managing minor ailments

Submission date	Recruitment status	[_] Prospectively registered
15/04/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
24/06/2024	Other	

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) defines the pharmacy practice mission as “contributing to health improvement and helping patients with health problems to make the best use of their medicines”. Minor ailments are “self-limiting conditions which may be diagnosed and managed without a medical intervention”. Traditionally, patients present in community pharmacy for these conditions or alternatively self-select a non-prescription medication. The aim of this study is to evaluate the outcomes of a Minor Ailment Service (MAS) in community pharmacy compared with usual care.

Who can participate?
Patients aged 16 and over (or between 2 and 16 years of age if accompanied by a responsible adult), seeking care (i.e. presenting symptoms or requesting a product) for the following minor ailments: skin problems (cold sore, foot fungi), digestive disturbance (diarrhoea, flatulence, heartburn or vomiting), pain (dysmenorrhea, headache, sore throat) and upper respiratory tract (cough, cold or nasal congestion).

What does the study involve?
MAS is provided through a face-to-face encounter between the pharmacist and the patient, so individual interviews are carried out in the community pharmacy. When patients attend the pharmacy either requesting a direct product request (non-prescription medicine) or presenting symptoms covered in the study they are informed about the study. 10 days after this consultation a researcher phones them at the number provided during the consultation in the pharmacy for an interview about the minor ailment outcomes.

What are the possible benefits and risks of participating?
The benefits are managing the minor ailment consulted with the best recommendation possible for the patient's specific situation. The risks are limited because in case the health problem presented in the pharmacy was out of scope for the pharmacists, patients are referred to the appropriate health professional.

Where is the study run from?
Universidad de Granada (Spain)

When is the study starting and how long is it expected to run for?
January 2017 to June 2018

Who is funding the study?
1. Spanish Society of Community Pharmacy (Spain)
2. Pharmaceutical Association of Valencia (Spain)

Who is the main contact?
Noelia Amador Fernández
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IndicaPRO-2016-v1

Study information

Scientific Title
INDICA+PRO study: evaluation of a minor ailment service in community pharmacy

Acronym
INDICA+PRO

Study objectives
A co-designed minor ailment service can lead to better clinical, humanistic and economic outcomes for patients than usual practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/07/2017, University of Granada Ethics Committee (Gran Vía de Colon 48 2 planta, 18071, Granada, Spain; +34 (0)958 243008; investigacion@ugr.es), ref: 331/CEIH/2017
2. Approved 29/07/2017, Xátiva-Ontinyent Ethics Committee "Lluís Alcanyís" (Hospital Lluís Alcanyís, ctra Xátiva-Alzira km 2, 46800 Xátiva, Spain; +34 (0)962 28 93 00; comitebioetica_dsxo@gva.es), ref: not applicable

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Minor ailments: dermatological problems (cold sore, foot fungi), gastrointestinal disturbance (diarrhoea, flatulence, heartburn or vomiting), pain (dysmenorrhea, headache, sore throat), upper respiratory tract (cough, cold or nasal congestion)

Interventions
Patients requesting a non-prescription medication (direct product request) or presenting minor ailments receive the Minor Ailment Service (MAS) or usual care (UC) and are followed up by telephone 10 days after the consultation.

The pharmacist-patient intervention consists of a standardised consultation on a web-based program using co-developed protocols pharmacists' training, practice change facilitators and patients' educational material.

Intervention Type

Mixed

Primary outcome(s)
Measured at the pharmacist–patient consultation, completed by the pharmacist:
1. Appropriate medical referral: patient referral by the pharmacist made in accordance with the designed protocols, calculated as the proportion of patients appropriately referred divided by the total number of patients.
2. Modification of direct product request: treatment requested by the patient modified by the pharmacist due to not approved indication of use for the minor ailment, wrong dose, dosage or formulation. The summary of product characteristics determined by the Spanish Agency was used as the standard.

Key secondary outcome(s)
1. Symptom resolution: relief of symptoms measured using a Likert scale from 1 “not at all” to 5 “completely” at 10-day telephone follow-up with interview conducted by the research group
2. Reconsultation rate for the same minor ailment, whenever the patient had to consult again for the same ailment
3. Health-related quality of life (HRQoL) measured using EuroQol 5D-5L (EQ-VAS) and Utility at pharmacist–patient consultation and at 10-day telephone follow-up
4. Cost-effectiveness: incremental cost-effectiveness ratio (ICER) of the service measured at pharmacist–patient consultation and at 10-day telephone follow-up

Completion date
10/06/2018

Eligibility

Key inclusion criteria
1. Patients aged ≥16 years or over 2 years of age if they are accompanied by a responsible adult
2. Seeking care i.e. presenting symptoms or requesting a product (direct product request) for minor ailments. The minor ailments considered in the study are: dermatological problems (cold sore, foot fungi), gastrointestinal disturbance (diarrhoea, flatulence, heartburn or vomiting), pain (dysmenorrhea, headache, sore throat) and upper respiratory tract (cough, cold or nasal congestion)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
808

Key exclusion criteria
1. Patients younger than 16 years old not accompanied by a responsible adult
2. Third person different than the patient consulting in community pharmacy

Date of first enrolment
01/12/2017

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Spain

Study participating centre
Community pharmacies in Benaguasil (Valencia, Spain)
Benaguasil
Spain
46180

Study participating centre
Community pharmacies in Bétera (Valencia, Spain)
Bétera
Spain
46117

Study participating centre
Community pharmacies in L'Eliana (Valencia, Spain)
L'Eliana
Spain
46183

Study participating centre
Community pharmacies in Vilamarxant (Valencia, Spain)
Vilamarxant
Spain
46191

Study participating centre

Community pharmacies in Aldaia (Valencia, Spain)
Aldaia
Spain
46960

Study participating centre
Community pharmacies in Buñol (Valencia, Spain)
Buñol
Spain
46360

Study participating centre
Community pharmacies in Chiva (Valencia, Spain)
Chiva
Spain
46370

Study participating centre
Community pharmacies in Godelleta (Valencia, Spain)
Godelleta
Spain
46388

Study participating centre
Community pharmacies in Manises (Valencia, Spain)
Manises
Spain
46940

Study participating centre
Community pharmacies in Quart de Poblet (Valencia, Spain)
Quart de Poblet
Spain
46930

Study participating centre

Community pharmacies in Riba-roja de Túria (Valencia, Spain)
Riba-roja de Túria
Spain
46190

Study participating centre
Community pharmacies in Puçol (Valencia, Spain)
Puçol
Spain
46530

Study participating centre
Community pharmacies in Sagunt (Valencia, Spain)
Sagunt
Spain
46500

Study participating centre
Community pharmacies in Agullent (Valencia, Spain)
Agullent
Spain
46890

Study participating centre
Community pharmacies in Albaida (Valencia, Spain)
Albaida
Spain
46860

Study participating centre
Community pharmacies in Aielo de Malferit (Valencia, Spain)
Aielo de Malferit
Spain
46812

Study participating centre

Community pharmacies in L´Alcudia de Crespins (Valencia, Spain)
L´Alcudia de Crespins
Spain
46690

Study participating centre
Community pharmacies in Benigánim (Valencia, Spain)
Benigánim
Spain
46830

Study participating centre
Community pharmacies in Bocairent (Valencia, Spain)
Bocairent
Spain
46880

Study participating centre
Community pharmacies in Canals (Valencia, Spain)
Canals
Spain
46650

Study participating centre
Community pharmacies in L'Ollería (Valencia, Spain)
L'Ollería
Spain
46850

Study participating centre
Community pharmacies in El Palomar (Valencia, Spain)
El Palomar
Spain
46891

Study participating centre

Community pharmacies in Ontinyent (Valencia, Spain)
Ontinyent
Spain
46870

Study participating centre
Community pharmacies in Terrateig (Valencia, Spain)
Terrateig
Spain
46842

Study participating centre
Community pharmacies in Villanueva de Castellón (Valencia, Spain)
Villanueva de Castellón
Spain
46270

Study participating centre
Community pharmacies in Xátiva (Valencia, Spain)
Xátiva
Spain
46800

Sponsor information

Organisation
Spanish Society of Community Pharmacy

Organisation
Pharmaceutical Association of Valencia

Funder(s)

Funder type
Research organisation

Funder Name
Spanish Society of Community Pharmacy

Funder Name
Pharmaceutical Association of Valencia

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 the main investigator Fernando Martínez Martínez (femartin@ugr.es) or Noelia Amador Fernández (namador@sefac.org). Data shared would be the information recorded at the patient's consultation (Excel file), this data is anonymised. This information is already available and it will be until 5 years after the study ended (31/05/2023). Consent was obtained from patients or responsible adults (when patients were between 2 and 16 years of age). Data was extracted already anonymised from the website used by participant pharmacists to record consultations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/12/2019	04/05/2021	Yes	No
Results article	outcome measure data	25/10/2022	26/10/2022	Yes	No
Results article	Cost utility analysis	20/11/2024	24/06/2024	Yes	No
Dataset			24/06/2024	No	No
Participant information sheet			01/06/2021	No	Yes
Protocol file	version v1.0	01/01/2017	01/06/2021	No	No