

Evaluation of a pharmaceutical service for managing minor ailments

Submission date 15/04/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/06/2024	Condition category Other	<input checked="" type="checkbox"/> Individual participant data

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
namador@sefac.org

Contact information

Type(s)

Scientific

Contact name

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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, Xàtiva-Ontinyent Ethics Committee "Lluís Alcanyís" (Hospital Lluís Alcanyís, ctra Xàtiva-Alzira km 2, 46800 Xàtiva, Spain; +34 (0)962 28 93 00; comitebioetica_dsxo@gva.es), ref: not applicable

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

See additional file ISRCTN17235323_PIS (added 01/06/2021)

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2017

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

Age group

Mixed

Sex

Both

Target number of participants

726

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'Elia
L'Elia
Spain
46183

Study participating centre
Community pharmacies in Vilamarxant
Vilamarxant
Spain
46191

Study participating centre
Community pharmacies in Aldaia
Aldaia
Spain
46960

Study participating centre
Community pharmacies in Buñol
Buñol
Spain
46360

Study participating centre
Community pharmacies in Chiva
Chiva
Spain
46370

Study participating centre
Community pharmacies in Godella
Godella
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 Xàtiva (Valencia, Spain)

Xàtiva

Spain

46800

Sponsor information

Organisation

Spanish Society of Community Pharmacy

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Sponsor type

Research organisation

Website

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Organisation

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Sponsor type

Research organisation

Website

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Funder(s)**Funder type**

Research organisation

Funder Name

Spanish Society of Community Pharmacy

Funder Name

Results and Publications

Publication and dissemination plan

Further results publications are planned:

- 1. Clinical and humanistic impact of a minor ailment service in community pharmacy: a cluster randomised controlled trial
- 2. A cost-utility analysis alongside a cluster-randomised trial evaluating a minor ailment service compared to usual care in community pharmacy

Intention to publish date

01/01/2021

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
Participant information sheet			01/06/2021	No	Yes
Protocol file	version v1.0	01/01/2017	01/06/2021	No	No
Results article	outcome measure data	25/10/2022	26/10/2022	Yes	No
Dataset			24/06/2024	No	No
Results article	Cost utility analysis	20/11/2024	24/06/2024	Yes	No