Clinical and humanistic impact of a minor ailment service in community pharmacy: a cluster randomised controlled trial

What is already known about this subject

Minor Ailment Services aim to treat minor ailments through community pharmacies. Quality standards need to be implemented to promote the safe and effective management of minor ailments in community pharmacies, also when patients request a product (self-medication) because less advice is offer from the pharmacist.

What this study adds

Patients with minor ailments are triaged and managed in a safe and effective way in community pharmacies using quality standards also facilitating appropriate self-selection of non-prescription medicines. Minor Ailment Services reinforce pharmacists' involvement with patient engagement.

Abstract

Aim

To evaluate the clinical and humanistic patient outcomes of a community pharmacy (CP) Minor Ailment Service (MAS) compared to usual pharmacist care (UC).

Methods

A cluster randomised controlled trial was conducted over six months in CP. The pharmacist-patient intervention consisted of a standardised consultation on a web-based program using co-developed protocols pharmacists' training, practice change facilitators and patients' educational material. Patients were followed up ten days after initial consultation. Primary outcomes were appropriate medical referral and changes to direct product request. Secondary outcomes were symptom resolution, reconsultation rates for the same ailment and health related quality of life (HRQoL).

Results

A total of 808 patients were recruited by 27 CP (323 MAS and 485 UC). Patients visiting MAS pharmacies had higher odds for being referred to the general practitioner (OR=2.343, CI95%=[1.146-4.792]); a higher increase in HRQoL (OR=1.026, CI95%=[1.002-1.051]) and higher number of reconsultation (OR=1.833, CI95%=[1.151-2.919]) compared to UC. No significant differences were observed for symptom resolution and modification of treatments with direct product requests.

Conclusions

Patients with minor ailments are triaged and managed in a safe and effective way in CP, facilitating appropriate self-selection of non-prescription medicines. MAS reinforce pharmacists' involvement with patient engagement.

Introduction

Minor ailments are defined as "common or self-limiting or uncomplicated conditions which may be diagnosed and managed without medical intervention"[1]. The primary method used by patients to manage minor ailments is self-care and self-medication. In many countries, community pharmacies (CPs) are an exclusive point of access for non-prescription medicines[2], with patients also requesting professional advice for symptoms considered minor ailments. Literature shows that additional assessment is conducted by pharmacists when patients ask advice for symptoms than when they request a product (self-medication)[3,4,5].

Government health policies and programs are implemented in some countries[6], actively promoting patient self-care using CP. These services are usually described as Minor Ailment Services (MAS), their major objectives are to increase engagement with patients and facilitate time for general practitioners (GPs) to care for more complex patients. International studies have demonstrated that MASs lead to high symptom-resolution[7], appropriate patients' triage[8,9], high patient satisfaction[10] and improved access to the health care system[11].

A high percentage[12] of CP activity is linked to minor ailment care, reflecting existing consumer usage and ease of access to CP. Existing protocols[13] specify that patients with minor ailments may receive self-care advice, non-prescription medicines or can be referred to other health practitioners. The literature reports referral rates of between 2.4-29% to the GP for patients presenting with minor ailments in CP[14,15]. A literature review[16] stated that when a protocol was used there was a high accuracy of identifying the ailment, with concordance rates between the pharmacist and a medical expert ranging from 70% to 97.5%. Inch et al[17] concluded that quality standards need to be implemented to promote the safe and effective management of minor ailments in CP.

The objective of this study was to evaluate the clinical and humanistic patient outcomes of a MAS, compared with usual care (UC) in CP.

Methods

Study design and setting

A cluster randomised controlled trial was conducted in CPs of Valencia (Spain) from December'17 to May'18. A co-design[18] was carried out between pharmacists, GPs, patients and representatives of local government to design the intervention (MAS).

The Pharmacist Association of Valencia provided CPs with study information via phone or email. CPs within the twenty-six municipalities agreed to participate. The municipalities were the clusters of the study to avoid contamination between groups. Municipalities were randomised through a sequence of computer-generated random numbers to the UC group and the MAS group with a ratio of 1:1. Due to the nature of the intervention, pharmacists could not be blinded.

Study outcomes and variables are included in Table 1.

Participants

Consecutive patients attending CPs were recruited. Eligible patients were those aged >16 years, or children >2 years accompanied by an adult, seeking care or requesting a medicine (direct product request) in CP for one of the minor ailments considered in the study.

Sample size calculation was based on the primary study outcomes. A 10% absolute increase in appropriate medical referral rate (85% to 95%)[19] and modification of direct product request (8% to 18%)[20,21] were estimated. The sample size was calculated with ≥0.9 power, type I error rate of 5%, equal allocation ratio and assuming an intra-cluster correlation of 0.01. The larger of the two-estimated sample size calculations was used to determine the overall sample size, of 726 patients (allowing for 10% dropout).

Intervention

The intervention is described using the TIDieR[22] template (Appendix 1). It included:

1. A standardised pharmacist–patient consultation[13] using:

- Co-developed management protocols for each specific symptom[23].
- Patient educational material.
- A web-based data collection software[24] that guided pharmacists including protocol flow and referral criteria (i.e. "red flag symptoms").

2. Practice change facilitators (PCF) made regular on-site visits to the participant CPs to identify and resolve barriers with service provision and check the fidelity of the intervention.

Educational training for MAS pharmacists was a twelve-hour training session delivered prior to the beginning of the trial. It covered service provision, good practice standards, service protocols, communication's skills with the patient and other health professionals, web-based software use, data collection and trial protocol. The control group documented their usual practice and attended a three-hour training on data collection procedures and patient recruitment.

Procedure

The study was approved by the University of Granada Ethics Committee (331/CEIH/2017) and Xátiva-Ontinyent Ethics Committee "Lluís Alcanyís". Pharmacists provided written consent to participate in the study. Patients or responsible adults (when the patient was under age) who met eligibility criteria were requested to give consent after being informed of the study.

The patient intervention was registered at the time of the consultation. The pharmacist recorded demographic variables and those related with the minor ailment. A researcher phoned patients ten days after the consultation. Research data was extracted from the web-based software.

Data analysis

Descriptive statistics were performed with continuous variables mean and standard deviation (SD) or median and percentiles depending whether the data was normally distributed using the Kolmogorov Smirnov test. Categorical variables were described as counts and percentages. Comparison of continuous variables between groups was undertaken using t-Student test and Kruskal-Wallis or Mann-Whitney (when skewed). Comparison of categorical variables was undertaken using Pearson's $\chi 2$ tests. Per-protocol analysis was undertaken; each patient was treated as per group assigned.

To determine the relationship between dependent variables (appropriate referral, modification of direct product request, symptom resolution, reconsultation rate and health related quality of life or HRQoL) and independent variables, multiple logistic regression was carried out, including all variables that achieved significant statistical in bivariate analysis and those of interest for the study. Also, the homoscedasticity of the model and the non-collinearity of the variables were checked. For linear regression the goodness of the model was verified using the Hosmer-Lemeshow co-efficient and the existence of interactions between the variables was explored. A linear regression model was constructed taking the changes in utility as a dependent variable. An intention to treat (ITT) analysis[25] was undertaken with the telephone non-responders considering the worst-case scenario. Multivariate logistic regression was used for ITT analysis to

evaluate symptom resolution and reconsultation rates. All analysis was made using software SPSS v26.0. A level of statistical significance $p<0.05$ was established.

Results

Twenty-seven CPs agreed to participate (13 MAS and 14 UC) with 42 pharmacists enrolled (20 MAS and 22 UC). A total of 808 patients were recruited (323 in MAS pharmacies and 485 in UC pharmacies) (Figure 1).

Most patients presented with upper respiratory tract symptoms (65.5%, n=529) (Table 2). Sixteen percent (n=134) were aged 65 years or over and 2.6% (n=21) were children between 2 and 12 years old. Significant differences were found in the type of consultation by gender, with males having a higher percentage of direct product request (34.6%, n=103 for males and 27.6% n=141 for females) rather than presenting with symptoms (65.4%, n=195 for males and 72.4% n=369 for females) (p=0.039).

Baseline HRQoL was statistically lower in the MAS group (Table 2). Patients visiting MAS with direct product requests had lower baseline HRQoL (0.86, SD=0.11) compared with UC patients (0.90, SD=0.12) (p=0.020).

ATC groups recommended by pharmacists were primarily from group R05 (cough and cold preparations), 47.3% in the MAS group and 50.9% in the UC group. Statistically significant differences were found, with a higher percentage of MAS patients receiving self-care recommendations (94.1%, n=304) compared with those receiving UC (72.8%, n=353) (p<0.001) (Appendix 2).

MAS pharmacists appropriately referred to GPs double the percentage of patients (7.4%) compared to UC pharmacists (3.9%), p=0.029 (Table 3). There were also a number of patients who presented with flu like symptoms that according to the protocols should have been referred but were not. When adjusting for baseline differences, patients visiting MAS pharmacies had higher probability of being referred to the GPs (OR=2.343, CI95%=[1.146-4.792]) (Table 5). Statistically significant differences were found for patients who reported longer symptom duration prior to the

pharmacy consultation, with a greater percentage of those patients being referred (OR=1.142, CI95%=[1.087-1.200]) (Appendix 2).

Thirty percent (n=244) of patients had a direct product request to self-medicate. MAS pharmacists modified a larger percentage of the products requested by the patient (11.4%) than UC pharmacists (4.5%) (p=0.041) (Table 3). However, when adjusting the model with baseline variables, no statistically significant differences were found (Table 5). Irrespectively of patients being consulted by either MAS or UC group, those with a direct product request who had already treated their symptoms had higher probability (OR=3.151) of having their request changed by the pharmacist (Appendix 2). There were patients who rejected pharmacists' recommendation for the change (6.6% in MAS group and 2.7% in UC group) but this was not statistical different (p=0.169).

No statistical differences in follow up rates between groups were found (64.7%, 523 out of the 808 patients) (Table 5).

Patients in MAS pharmacies had higher risk of having to consult for the same minor ailment at follow-up (OR=1.833, CI95%=[1.151-2.919]) (Table 4 and 5). This data excludes referred patients. Statistically significant differences were found in patients with longer duration of symptoms having a higher number of reconsultation rates (Appendix 2). No differences in reconsultation rates were found between groups when ITT analysis was carried out (Appendix 2).

Patients in the MAS group (OR=1.026, CI95%=[1.002-1.051]) had statistically significant greater improvements in HRQoL at follow up (Table 5).

Discussion

This was the first Spanish study to compare clinical and humanistic patient outcomes of MAS in CP. Patients characteristics were similar to previous studies[7,26]. Interestingly, few patients (8.4%) presented with symptoms for the first time, which is a smaller percentage than that reported previously (24.6%)[10]. Most participants presented with upper respiratory tract related symptoms, likely due to the study being undertaken during the winter season.

Results showed that MAS patients were more likely to be referred to GPs (OR=2.343), similarly to the study by Dineen et al[9]. Literature reports that referrals to another health care professional may vary from 1.4%[27] to 30%[8]. Variability may be due to a lack of national educational programs focussed on the implementation of educational programs to apply protocols for the management of minor ailments, lack of evidence that the protocols can lead to better clinical outcomes than UC, inherent practice variability or lack of protocol fidelity. UC pharmacists primarily referred patients due to duration of symptoms whilst MAS pharmacists also referred patients with suspected "red flag symptoms". There was a number of patients who presented with flu like symptoms and were not referred although MAS pharmacists were aware that these were referral symptoms according to protocols. The reason for the non-referral was a belief that treatment and management to be received by these patients would be similar to that of a GP. This lack of intervention fidelity should be emphasised in future training.

Prior to adjusting for baseline differences in variables, statistical differences were found for the modifications of direct product requests. However, when the model was adjusted, no statistical differences were found. In Spain, 6% of pharmacy turnover in 2019[28] was due to sale of non-prescription medicines (over 100 million units).

Extrapolating the study results to a national level, MAS pharmacists would have modified over ten million non-prescription medicine requests, facilitating appropriate self-medication. Patients rejected a number of recommendations to modify the medicines requested, suggesting that both patients' health education and pharmacists' intervention skills should be improved. It is important to emphasize communication's skills and behavioural techniques in future MAS training[29]. In agreement with Eikenhorst *et al*[5], more studies are needed to understand the impact of self-selection of medicines on patient safety.

No statistical difference was found for complete symptom resolution between groups. One could postulate that since minor ailments are self-limiting conditions, the time to resolution may be an appropriate indicator to use. Complete symptom resolution in both groups was 60.4% (n=316) similarly to other studies that found complete symptom resolution to be from 41% to 98%[9,10,19].

Reconsultation rates were significantly higher in MAS pharmacies. However, no differences were found when ITT analysis was carried. Similar data was showed in international, 2.4% to 23.4%[7].

At baseline, MAS patients had a statistically lower HRQOL. Adjusted change in HRQoL at follow up was statistically higher in the MAS arm compared to UC (OR=1.026). Minor ailments are self-limiting health problems that appear to have an impact in patients' daily life so patients' perception of their health status can change. New studies are needed to evaluate appropriateness of instruments to measure HRQOL when studying self-care[30].

Methodological limitations

It is important to note conditional referrals were not documented (when advice was provided to patients that if symptoms did not improve or worsened medical advice

should be sought). The study was powered to detect changes in primary outcomes not secondary outcomes such as symptom resolution. Lastly, the contribution of each component of the intervention for MAS is not clear (i.e. standardised consultation, training and practice change facilitator), as the study design did not allow for evaluation of each of the elements. However, it was clear from the informal qualitative feedback that having agreement on referral processes, technology platforms, documentation and the support of PCF were all highly regarded by MAS pharmacists.

Conclusions and practice implications

The overall findings demonstrated that patients are triaged and managed in a safe and effective way in CP through MAS. Pharmacists can perform clinically, appropriately acting as a triage point. Higher number of patients appropriate self-medicate with non-prescription medicines when attending MAS CPs. MAS reinforces the World Health Organisation policy for patient engagement and pharmacists' involvement. The availability of educational material as part of the MAS enhanced the delivery of non-pharmacological advice, potentially increasing the health literacy and actions of patients not only for the episodes of minor ailments consulted but also as a guide in the future. Results reinforce that most patients with minor ailments can be treated successfully in CP trough MAS. If these patients presented to other parts of the health care system, it would have great difficulty coping economically. The contribution of CP to primary health care should not be underestimated.

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Conflict of interest statement

The authors declare that they have no competing interests.

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Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

References

[1]. Jones R, White R, Armstrong D, Ashworth M, Peterset M. Managing acute illnesses: an enquiry into the quality of general practice in England. London: The King's Fund; 2010.

[2]. Porteous T, Ryan M, Bond C, Hannaford P. Preferences for self-care or professional advice for minor illness: a discrete choice experiment. Br J Gen Pract. 2006; 56:911-17.

[3]. Vella E, Azzopardi LM, Zarb-Adami M, Serracino-Inglott A. Development of protocols for the provision of headache and back-pain treatments in Maltese community pharmacies. Int J Pharm Pract. 2009;17:269–74. Doi: 10.1211/ijpp.17.05.0003.

[4]. Berger K, Eickhoff C, Schulz M. Counselling quality in community pharmacies: implementation of the pseudo customer methodology in Germany. J Clin Pharm Ther. 2005;30:45–57. Doi: 10.1111/j.1365-2710.2004.00611.

[5]. Eikenhorst L, Salema N, Anderson C. A systematic review in select countries of the role of the pharmacist in consultations and sales of non-prescription medicines in community pharmacy, Res Soc Admin Pharm. 2017;13:17–38. Doi: 10.1016/j.sapharm.2016.02.010.

[6]. Aly M, García-Cárdenas V, Williams K, Benrimoj SI. A review of international pharmacy-based minor ailment services and proposed service design model. RSAP. 2018;14(11):989-998. Doi: 10.1016/ j.sapharm.2017.12.004 PMID: 29444752

[7]. Paudyal V, Watson MC, Sach T, Porteous T, Bond CM, Wright DJ, et al. Are pharmacy-based minor ailment schemes a substitute for other service providers? A systematic review. Br J Gen Pract. 2013;63:472-81. Doi: 10.3399/bjgp13X669194.

[8]. Flint L, Rivers P. Evaluation of the Pharmacy First Scheme provided by the Central Derby Primary Care Trust. Derby: Central Derby PCT; 2003.

[9]. Dineen-Griffin S, Benrimoj SI, Rogers K, Williams KA, Garcia-Cardenas V. Cluster randomised controlled trial evaluating the clinical and humanistic impact of a pharmacist-led minor ailment service. BMJ Qual Saf. 2020;0:1–11. Doi: 10.1136/bmjqs-2019-010608.

[10]. Watson MC, Ferguson J, Barton GR, Maskrey V, Blyth A, Paudyal V, et al. A cohort study of influences, health outcomes and costs of patients' health-seeking behaviour for minor ailments from primary and emergency care settings. BMJ Open. 2014;5:e006261. Doi: 10.1136/bmjopen-2014-006261.

[11]. Rafferty E, Yaghoubi M, Taylor J, Farag M. Costs and savings associated with a pharmacists prescribing for minor ailments program in Saskatchewan. BMC. 2017;15:3. Doi: 10.1186/s12962-017-0066-7.

[12]. Prats R, Piera V, Pons L, Roig I. Estudio cuantitativo y cualitativo de la indicación farmacéutica en una Farmacia Comunitaria [Qualitative and quantitative study of a minor ailment service in community pharmacy]. Pharm Care Esp. 2012;14:2-10.

[13]. Pharmaceutical Care Forum in Community Pharmacy. Practical Guide to Pharmaceutical Care Services in Community Pharmacy. Madrid: General Pharmaceutical Council of Spain; 2019.

[14]. Baixauli-Fernández VJ, Barbero-González A, Salar-Ibáñez L. Las consultas de indicación farmacéutica en la Farmacia Comunitaria [Minor ailment consultations in community pharmacy]. Pharm Care Esp. 2005;7:54-61.

[15]. Salar Ibáñez L, Espejo Guerrero J, Gómez Martínez J, Prats Más R, Eyaralar Riera T, Barbero González A. Criterios de derivación a un servicio médico en 'I-VALOR' [Referral criteria to the general medical practitioner in "I-Valor"]. Farmacéuticos Comunitarios. 2006;8.

[16]. Curley L, Moody J, Gobarani R, Aspden T, Jensen M, McDonald M, et al. Is there potential for the future provision of triage services in community pharmacy? J Pharm Policy Pract. 2016;9 :29. Doi: 10.1186/s40545-016-0080-8.

[17]. Inch J, Porteous T, Maskrey V, Blyth A, Burr J, Cleland J, et al. It's not what you do it's the way that it's measured: quality assessment of minor ailment management in community pharmacies. Int J Pharm Pract. 2017;25:253-262. Doi: 10.1111/ijpp.12305

[18]. Amador-Fernández N, Benrimoj SI, Baixauli VJ, Climent MT, Colomer V, Esteban O, et al. Colaboración farmacéutico-médico en la elaboración de protocolos consensuados para el tratamiento de síntomas menores: programa 'INDICA+PRO' [Colaboration between pharmacists and general medical practitioners for the elaboration of agreed protocols for minor ailments: "INDICA+PRO" program]. Farmacéuticos Comunitarios. 2019;11:21-31. Ddoi: 10.5672/FC.2173-9218.(2019/Vol11).004.03.

[19]. Ocaña A. Efectividad del proceso estructurado de asesoramiento en síntomas menores frente al asesoramiento habitual en Farmacias Comunitarias españolas [Effectiveness of a structured process for the management of minor ailments compared to usual care in community pharmacy] [Doctoral Thesis]. Granada: University of Granada; 2011.

[20]. Paluch E, Jayawardena S, Wilson B, Farnsworth S. Consumer self-selection, safety, and compliance with a novel over-the-counter ibuprofen 600-mg immediate-release and extended-release tablet. JAPhA. 2016;56:397-404.

[21]. Eickhoff C, Hammerlein A, Griese N, Schulz M. Nature and frequency of drug-related problems in self-medication (over-the-counter drugs) in daily community pharmacy practice in Germany. Pharmacoepidemiology and drug safety. 2012;21:254-60.

[22]. De Barra M, Scott C, Johnston M, De Bruin M, Scott N, Matheson C, et al. Do pharmacy intervention reports adequately describe their interventions? A template for intervention description and replication analysis of reports included in a systematic review. BMJ Open. 2018;9:e025511. Doi: 10.1136/bmjopen-2018-025511.

[23]. Amador-Fernández N, Amariles P, Baixauli-Fernández VJ, Benrimoj SI, Climent-Catalá MT, Colomer-Molina V, et al. Protocolos de Indicación Farmacéutica y Criterios de Derivación al Médico en Síntomas Menores [Protocols for the minor ailment service and referral criteria for minor ailments]. Granada: Editorial Técnica Avicam; 2018.

[24]. Spanish Society of Community Pharmacy. SEFAC e_XPERT, software for the record of community pharmacy services. [Internet] [revised 19 sept 2020]. Available from: https://www.sefacexpert.org/

[25]. McCoy E. Understanding the Intention-to-treat Principle in Randomized Controlled Trials, Western Journal of Emergency Medicine. 2017;18:1075-78. Doi: 10.5811/westjem.2017.8.35985.

[26]. Ferrer-López I, Machuca M, Baena MI, Faus MJ, Martinez-Martinez F. Caracterización de la indicación farmacéutica en farmacias comunitarias de Sevilla capital (España). Estudio piloto [Characterisation of a minor ailment service in community pharmacies in Sevilla (Spain). Pilot study]. Ars pharm. 2007;8.

[27]. Mary Seacole Research Centre. The Pharmacy First Minor Ailments Scheme in Leicester. Leicester: Mary Seacole Research Centre: 2011.

[28]. IQVIA. Evolución del Mercado de la farmacia Española. Actualización datos diciembre 2019 [Evolution of Spanish community pharmacy market. December 2019 data]. [Internet] [revised 19 sept 2020]. Available from: https://statics-correofarmaceutico.uecdn.es/cms/sites/11/2020/01/informe-iqvia-diciembre.pdf

[29]. Watson MC, Bond CM, Grimshaw J, Johnston M. Factors predicting the guideline compliant supply (or non-supply) of non-prescription medicines in the community pharmacy setting. Br Med J. 2006;15:53–7. Doi: 10.1136/qshc.2005.014720.

[30]. Feng Y, Parkin D, Devlin NJ. Assessing the performance of the EQ-VAS in the NHS PROMs programme. Qual Life Res. 2014;23:977-89. Doi: 10.1007/s11136-013-0537-z.