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Artículos originales

Patient participation in research projects in Community Pharmacies: An exploratory study

Estudio exploratorio de la participación en proyectos de investigación en Farmacias Comunitarias

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Resumen

Introducción: En los últimos años ha habido un incremento de la participación de farmacias comunitarias en proyectos de investigación. El reclutamiento de pacientes juega un papel clave en el éxito de las investigaciones. Se han identificado barreras y facilitadores que promueven dicho reclutamiento por parte de los farmacéuticos, pero poco es sabido sobre la influencia de factores relacionados con los proyectos de investigación. El objetivo de este trabajo es observar la participación en diferentes investigaciones llevadas a cabo en farmacias comunitarias e identificar las variables propias de los estudios que puedan estar asociadas con la participación.

Método: Se realizó un estudio multicéntrico experimental en 12 farmacias comunitarias que formaron parte de 4 proyectos de investigación. Se registró el número de pacientes que aceptaron/rechazaron participar. Se recogieron variables relacionadas con el estudio ofrecido y las farmacias. Se realizó un análisis bivariante mediante la prueba Chi-Cuadrado de Pearson y un análisis de los riesgos.

Resultados: La participación total fue del 90,44 % (n=558). El tipo de estudio (OR=2,64; 95 %IC=1,47-4,75; transversal vs pragmático), el tipo de medida aplicada (OR=2,47; 95 %IC=1,43-4,36), la aplicación de zona de atención personalizada (ZAP) (OR=2,49; 95 %IC=1,44-4,39), y la solicitud de datos personales (OR=2,53; 95 %CI=1,47-4,42) mostraron asociación con la participación en los PI (p<0,05).

Conclusiones: La participación por parte de los pacientes en proyectos de investigación es elevado y parece depender de factores propios del estudio aplicado.

Palabras clave: Participación del paciente; Farmacia Comunitaria; Sujetos de investigación.

Abstract

Introduction: Over the last years there has been an increase in community pharmacy participation in research projects. Patient recruitment plays a key role in the research project success. Pharmacists' barriers and enablers of recruitment have been identified, but little is known about the influence of research project-related factors. The aim of this paper is to explore patient participation in different studies conducted in community pharmacies and to identify study-specific factors that may be associated with it.

Method: An experimental multicenter study was performed in 12 community pharmacies participating in 4 research projects. The number of patients who accepted/refused to participate was recorded. Variables related to each offered study and the project were collected. A bivariate analysis using Pearson's Chi-Square test and a risk analysis were performed.

Results: Participation rate was 90.44 % (n=558). Study type (OR=2.64; 95 % CI=1.47-4.75; cross-sectional vs pragmatic), the type of measurement applied (OR=2.47; 95 % CI=1.43-4.36), the use of a personalized care area (PCA) (OR=2.49; 95 % CI=1.44-4.39), and personal data request (OR=2.53; 95 %CI=1.47-4.42) showed association with participation in the RP (p<0.05).

Conclusions: Patient participation in research projects is high and appears to rely on study-specific factors.

Keywords: Patient participation; Community pharmacy; Research subjects.

Highlights

Due to the high number of clinical trials and research projects in the hospital and clinical settings, the variables affecting subjects' willingness to participate in these research projects have been studied. Until now, the focus has been on investigating the factors influencing patient and professional recruitment more than participation based on study factors. Unfortunately, the number of research studies in community pharmacies is not as high. There is very limited information regarding research and the conduct of research projects in community pharmacies in Spain.

This study identifies the characteristics of research projects that seem to be associated with patient participation in community pharmacies. Based on the results obtained, variables inherent to the studies are identified that should be considered when designing research in community pharmacies, as well as aspects to be taken into account for the design of future research.

Introduction

Research in community pharmacies has experienced a surge in recent years, evidenced by a marked increase in participation in research projects (RPs)[1,2].

Community pharmacy emerges as an ideal setting for the implementation of pharmaceutical care services and for conducting research studies[3,4]. Community pharmacists are healthcare professionals who are accessible to the public, regularly interact with patients to whom they dispense medications, and are often the first or, in many cases, the only health professional consulted by the patient[5]. However, various barriers impede the development of pharmaceutical care services and RPs in community pharmacies as a routine practice[6–8]. Key barriers identified in previous studies include lack of time, remuneration, or training in research[7]. Sometimes, fear of patient rejection plays a crucial role in RPs conducted in community pharmacies. Previous studies assessing pharmacists' perspectives towards their regular practice have identified a negative perception of the patients' willingness to spend more time than usual in the pharmacy. Pharmacists believe that patients do not want to waste time in the establishment[6,8].

A low participation rate in RPs increases the risk of biases and raises the likelihood that the sample is not representative of the general population, thereby increasing the incidence of Type II errors[9,10].

Within this conceptual framework, it seems pertinent to explore patients' willingness to participate in RPs in pharmacies and to identify potential factors involved in patient participation in projects carried out in community pharmacies. This will help to elucidate possible reasons that may lead to patient refusal to participate. With this information, studies can be designed with more favorable characteristics to enhance participation rates.

The aim of this study is to observe participation in various RPs conducted in community pharmacies and to identify study-specific variables that may be related to participation.

Methods

Desing and participants

A multicenter observational study was conducted, which included data collected from 4 RPs carried out in 12 community pharmacies that agreed to participate, between January 2018 and April 2021 in Salamanca (Spain).

Measurements

The total number of patients who were offered participation in the studies was counted and categorized as "Participates" and "Does Not Participate".

We collected the type of location (setting) of the pharmacy offering participation (rural or urban), the study being offered, the design of the research, the estimated average time required from the patient to complete the study, and the location within the pharmacy where it was conducted (PCA or non-PCA) were collected. The method of measurements (instrumental or questionnaire) was also recorded. 'Instrumental' was defined as all measurements that required the use of a device in addition to a questionnaire (blood pressure monitor, scale, height measure, caliper, etc.). Additionally, it was recorded whether the study required the signing of personal data protection forms.

Analysis

A descriptive analysis of frequencies and percentages was carried out for qualitative variables.

Subsequently, the groups of Participating and Non-Participating patients were compared using a bivariate analysis with Pearson's Chi-square test and a risk analysis, with a 95% confidence interval.

Results

The characteristics of the included studies are shown in Table 1. Of the total participating pharmacies, 6 (50%) were located in an urban setting.

Table 1. Description of the Included Research Projects.

Project	#1	#2	#3	#4
Estimated time required	>10 min	10 min	>10 min	£10 min
Measurements	Instrumental	Questionnaire	Questionnaire	Instrumental
Design	Cross-Sectional	Cross-Sectional	Pragmatic	Longitudinal
Location	PCA	No PCA	No PCA	PCA
Personal data collection	No	No	Yes	Yes
No. of Pharmacies	12	3	2	3
Sample size	293	85	178	61
Participates/ Does Not Participate (%)	279 (95,2) / 14 (4,8)	75 (88,2) / 10 (11,8)	151(84,8) / 27 (15,2)	53 (86,9) / 8 (13,1)
Duration	6 months	3 months	6 months	3 months

PCA: Personalized Care Area

A total of 617 patients were included, of whom 558 (90.44 %) agreed to participate, and 59 (9.56%) declined participation. The results of the bivariate analysis are presented in Table 2.

A significant association was found between the application of instrumental measures (OR=2.47; 95 % CI=1.43-4.36; p=0.001), PCA (OR=2.49; 95 % CI=1.44-4.39; p=0.001), cross-sectional study design (OR=2.64; 95 % CI=1.47-4.75; vs. pragmatic) and not requesting personal data (OR=2.53; 95 % CI=1.47-4.42; p=0.001) in relation to patient participation.

The time required to conduct the study (p=0.193) and the location of the pharmacy (p=0.675) were not statistically significant factors.

Table 2. Bivariate Analysis.

	Sample	Participating N (%)	Does Not Participate N (%)	p-value*	OR	(CI=95%)
Total	617	558(90,44)	59(9,56)	-	-	-
Study Design Pragmatic Cross-Sectional Longitudinal	178 378 61	151(84,8) 354(93,7) 53(85,9)	27(15,2) 24(6,3) 8(13,1)	0,003	1 2,64 1,18	(1,47-4,75) (0,53-2,94)
Measurement Questionnaire Instrumental	263 354	226(85,9) 332(93,8)	37(14,1) 22(6,2)	0,001	1 2,47	(1,43-4,36)
Time Required ≤10 minutes >10 minutes	146 471	128(87,7) 430(91,3)	18(12,3) 41(8,7)	0,193	-	-
Setting Urban Rural	379 238	341(90,0) 217(91,2)	38(10,0) 21(8,8)	0,675	-	-
Location No PCA PCA	262 355	225(85,9) 333(93,8)	37(14,1) 22(6,2)	0,001	1 2,49	(1,44-4,39)
Personal Data Yes No	239 378	204(85,4) 354(93,7)	35(14,6) 24(6,3)	0,001	1 2,53	(1,47-4,42)

SD: Standard Deviation; PCA: Personalized Care Zone; OR: Odd Ratio; CI: Confidence Interval. *Chi-Squared test. α=0,05

Discussion

To the best of our knowledge, this is the first compilation of data from different RPs to analyze participation in community pharmacies from Spain. The participation rate in the RPs was 90.44 %, reflecting a high willingness to participate among patients.

Cross-sectional studies have shown higher participation rates (p-value=0.003). This might be due to their requirement of only a single visit, unlike other designs. Additionally, this visit often occurs when the patient goes to their regular dispensing service at the community pharmacy. Contrary to what was suggested by Arfken et al.[11], patient follow-ups has led to decreased participation. This could be because the measurements in the included cross-sectional studies were taken advantage of the patient's visit to the community pharmacy, whereas follow-up involves more active participation from the patient, requiring them to return to the community pharmacy (Study #2) or respond to telephone calls (Study #3). This aligns with other authors' propositions that when a study demands more from the patient, participation decreases[12]. It's important to note that half of the RPs included in our study (n=4), were cross-sectional studies, accounting for 61.3 % (n=378) of the total patient sample, which could have influenced the results obtained.

We found that RPs employing instrumental measurements have higher participation rates than those using only questionnaires (OR=2.47; 95 % CI=1.43-4.36; p=0.001). Other authors have also noted that

the use of the terms 'survey' or 'questionnaire' reduces both participation and the proportion of participants[13]. Utilizing instruments beyond questionnaires may be perceived as a reward by the patient. This approach has been shown to increase participation in previous studies[13,14].

Conducting RPs in the PCA appears to increase participation (OR=2.49; 95 % CI=1.44-4.39; p=0.001). In Spain, many tasks in the community pharmacy are carried out at the counter. Among these tasks can be the administration of questionnaires for RPs. However, conducting these RPs in the PCA may provide a more private environment and, therefore, be more suitable for data collection.

RPs that did not require the signing of a document for personal data collection showed higher participation than those that did (OR=2.53; 95 % CI=1.47-4.42; p=0.001). This could be due to patient reluctance, firstly, to provide personal data, and secondly, to sign a document. This situation has been previously documented[12]. This potential barrier could be better addressed by improving the explanation of the RPs and the importance of the Personal Data Protection Form to patients. The pharmacist's behavior during interactions with patients is one of the factors that predisposes to active participation, both in RPs and in daily community pharmacies activities (medication dispensing and monitoring)[15].

The time required from the patient to conduct the RP was not associated with the observed participation rate (p-value=0.193), even though this variable was one of the main barriers perceived by pharmacists when recruiting patients[6–8]. According to the data obtained, it seems that this claim is more of a perception from the pharmacist's perspective rather than an accurate reflection of the patients' actual willingness to participate. As previously seen, patient recruitment for RPs in community pharmacies depends more on the pharmacist's disposition than on the patients themselves[16].

The primary limitation of our study is that we have focused only on the study design as an influencing factor in patient participation in RPs. There are other variables related to the pharmacist and the patient that should be considered[17]. Another point to note is that this study did not record the presence or absence of a minimum recruitment requirement, a characteristic of studies that can generate a higher patient recruitment rate [17].

Conclusion

Patient participation in RPs conducted in community pharmacies is high. We can affirm that community pharmacies are a good place for the collection of RPs data.

Participation seems to depend on specific factors of the study such as the design, the use of measurement instruments, the area in which it is carried out, and the documentation requested from the patient. Apparently, the time required from the patient to participate in the study is not a factor that influences participation.

It would be interesting for future work to conduct a comprehensive analysis that also considers factors specific to the pharmacist and the patients.

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