Analysis and improvement of therapeutic adherence at a community pharmacy in Ourense

Laura León-Rodríguez[1,2,3], Lara Fernández-Puga[2], Xavier Martínez-Casal[1,4], Kevin González-González[2], Mª Teresa Rodríguez-Rodríguez[2], José Antonio Fornos-Pérez[1,3,5], N. Floro Andrés-Rodríguez[1,3]

1. Doctor of pharmacy. 2. Community pharmacist in Ourense. 3. Berbés Research and Teaching Group. 4. Pharmacist specializing in Hospital Pharmacy, Pharmacy Department of the Cee Public Hospital (La Coruña). 5. Community pharmacist in Cangas do Morrazo (Pontevedra).

ABSTRACT

Objectives: To evaluate the therapeutic adherence of patients with prevalent pathologies, identifying related factors. To quantify improvement in adherence achieved through professional pharmaceutical services (PPS). To establish satisfaction with the service.

Methods: Design: Phase 1: a single-center, descriptive, longitudinal study carried out between 3/18 and 4/10/2019. Phase 2: Quasi-experimental study with no control group, with educational intervention and PPS, medication use review (MUR) and Personalized Dosage System (PDS), October-November/2019.

Subjects: Elderly patients with dyslipidemia, high blood pressure or diabetes, who went to the pharmacy and agreed to participate. For the second phase, patients who were non-adherent in the first phase were selected.

Variables: adherence (measured with the Morisky-Green test), satisfaction with the service. Demographic variables.

Results: Phase 1: 101 patients, mean age 69 years. 50.5% male. The proportion of non-adherents was 55.4% 40 (71.4%) at some point forgot to take their medication. Adherence was not related to sex, age, companionship status, number of pathologies or level of education (p > 0.05).

Phase 2: MUR: The percentage of non-adherents decreased to 67%. PDS: Nine of the 10 patients were adherent at the end of the study. One patient was non-adherent due to sporadically forgetting to take the medication.

100% of the satisfaction survey respondents were "very satisfied," and would continue to visit the pharmacy and recommend it.

Conclusions: Iadherence to treatment was low, less than 50%. No relationship was found with the factors analyzed.

Conducting an MUR and PDS improves adherence. The degree of satisfaction was 100%. All patients wanted to continue with the service.

INTRODUCTION

The increase in life expectancy coupled with aging has led to an increase in the number of chronic diseases, which is associated with an increase in the prescription and consumption of drugs for the treatment and prevention of these diseases. For these reasons it is common to find numerous patients with various pathologies in the community pharmacy. Polymedication is often associated with decreased adherence to treatment, which is also influenced by the fact that many patients do not take their medication correctly for various reasons such as forgetting, lack of understanding of the dosage, difficulties managing devices, etc. (1).

Lack of adherence is a problem for both the patient and the healthcare system. Regarding the patient, it causes a lack of clinical improvement and a lower quality of life and it results in a higher number of admissions and higher expenditure (2).

It is the responsibility of the community pharmacist to ensure that patients, when collecting their medication, know exactly what they need to take it for and how to take it, thus avoiding drug-related problems (DRP) that lead to negative medication outcomes (MRI) (3).

Currently, the professional activities of the pharmacist are considered to be oriented toward the provision of professional pharmaceutical services (PPS) (4,5). PPS are divided into two groups, depending on whether they are aimed at improving the drug use process, or whether they are aimed at improving drug treatment outcomes. The former includes the specific therapeutic adherence service, or the medication use review (MUR) service (5,6), which includes an assessment of the patient's degree of adherence. It consists of the pharmacist, along with the patient and the caregiver, completing a structured review of their knowledge and use of their medications, offering advice on correct use and ensuring that the patient understands what they are taking, how they should take it, what they are taking it for and how long they should take it for (7).

Personalized dosing systems (PDS) are one of the most widely used tools to improve adherence in chronic elderly patients on polymedication and/or have difficulties taking their medication. These are post-dispensing reconditioning systems, in which the pharmacist prepares the patient's medication according to the guidelines of the prescribing physician authorized by Royal Decree Law 9/2011 (8) and documented in the community pharmacy Good Practice Document of the General Council of Official Pharmaceutical Associations (9).

The municipality of Ourense (Galicia) has a population of 107,597, with an average age of 46.79 years; those over 65 years make up 25.2% of the total (10). The average life expectancy in Ourense is 82.3 years (10). The most common pathologies are high blood pressure (HBP), with a prevalence of 13.7% in the population between the ages of 45 and 64 and 30.8% in those over the age of 65, whereas 17.0% of the population between the ages of 45 and 64, and 32.2% of those over the age of 65 suffer from dyslipidemia. Diabetes mellitus (DM) affects 7.5% of the population of Ourense (11). In addition, 39.3% are overweight and 11.3% are obese. It is a sedentary population—31% acknowledge that they do not do any kind of physical exercise (11).

According to a large national study on adherence by the Monitoring Center for Treatment Adherence (OAT), the percentage of compliance in chronic diseases does not reach 50%. The pathologies where less adherence was found were: Cardiovascular disease with 56.8% non-compliance, diabetes with 54.0% and hypertension with 53.5%. Its cost was estimated at EUR 11,250 million per year (12). This is thus an enormous health, social and economic problem, in which the community pharmacy can play a major role due to its proximity and access to the patient and the continuity of care it provides. It is not limited by prior appointments and even in times of pandemic the population continues to go there in person.

The aim of this work is to ascertain the degree of adherence in patients with hypertension, dyslipidemia and/or diabetes who attend a community pharmacy in Ourense, and to evaluate the impact of the MUR and the use of PDS on the improvement of adherence in these patients.

OBJECTIVES

General
- To analyze treatment adherence and evaluate its improvement through the provision of professional pharmaceutical services.

Specific
- To evaluate the treatment adherence of patients with some kind of prevalent pathology.
- To identify related factors.
- To quantify improvement in the adherence to treatment achieved.
- To check patient satisfaction with these services.

MATERIALS AND METHODS

Design
The work consisted of two parts. The first was a single-center, descriptive, cross-sectional study at a community pharmacy in Ourense between March 18 and April 10, 2019. The second part was a quasi-experimental study without a control group, with educational intervention and with PPS conducted in the same pharmacy in October and November 2019 (figure 1).
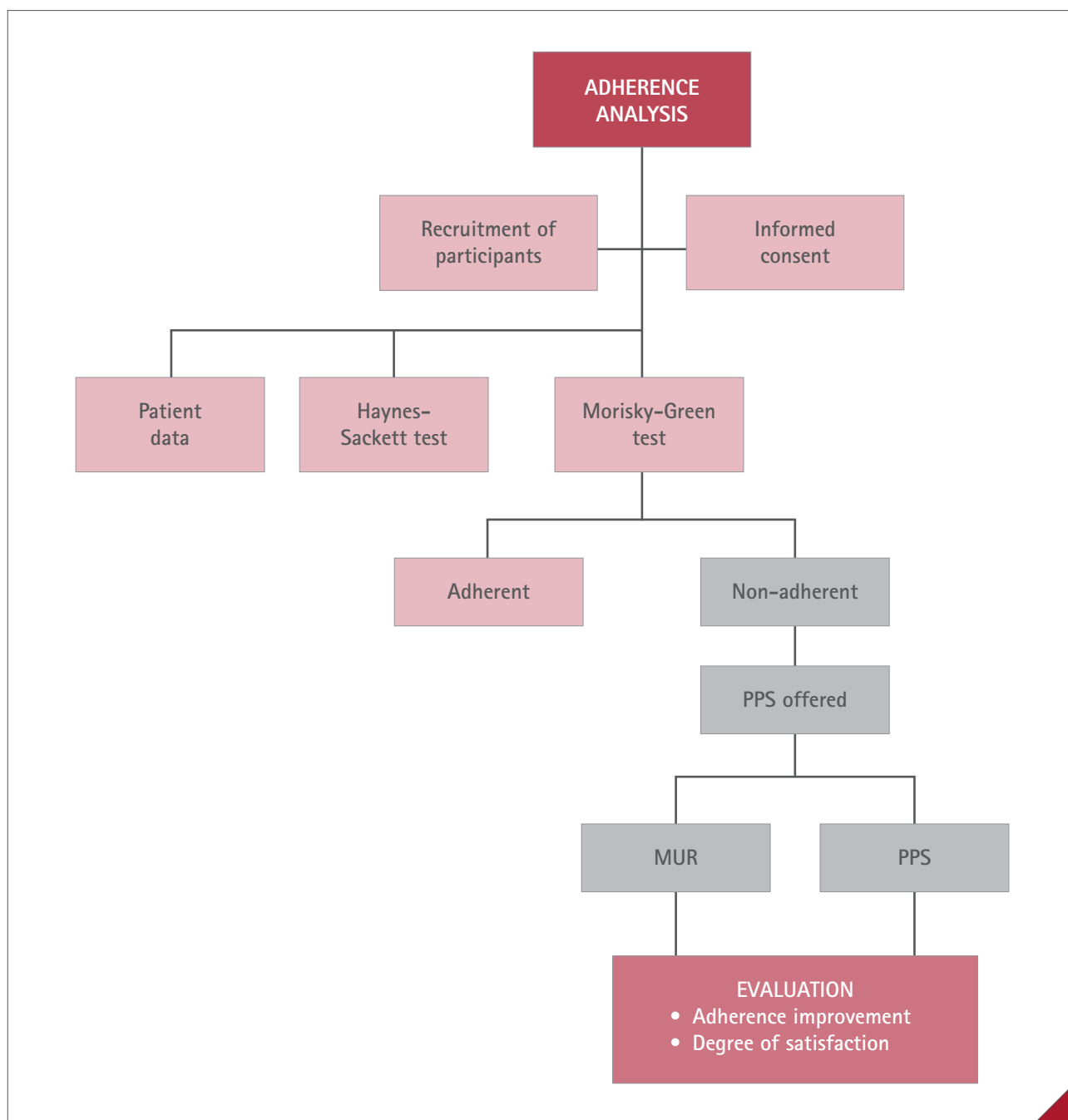
Figure 1 Study design

Subjects

For the first part of the study, all older patients with dyslipidemia, hypertension, or diabetes who attended the pharmacy during the study period and agreed to participate were selected. The second part included patients from the pharmacy between 40 and 95 years of age, with dyslipidemia, high blood pressure or diabetes, who had been non-adherent in the previous adherence study.

Exclusion criteria

Refusal to participate.

Variables

Main variables

Adherence (% adherents), Haynes-Sackett test (13) and Morisky-Green test (14,15). Patients who failed any of the four questions were considered non-adherent. Degree of satisfaction with the service: ad hoc questionnaire, Likert scale, based on the Armando scale (16) **(figure 2)**.

Secondary variables

Sex, age, level of education, living alone, number of medications, smoking, physical exercise.

The times I went to the pharmacy to receive their services	Completely disagree	Disagree	Neither agree nor disagree	Agree	Very much in agree-ment
The staff showed interest in collaborating with me in managing my medications					
The time spent by the staff was sufficient					
They were friendly during the service					
I received the right information about how to use my medications					
They gave me the right information about how to use my medications					
They made me feel confident when giving me their recommendations					
As a result of the services provided by the pharmacy	**Completely disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Very much in agree-ment**
I learned more about the medicines I use					
I would continue to visit this pharmacy for their professional services					
I would recommend to my family or friends to go to this pharmacy for these services					
I am satisfied with the services received					

Figure 2 Satisfaction questionnaire used in the study

Procedure

According to criteria based on the type of non-adherence and difficulty that each patient had in failing to adhere to their treatment, the patients were referred to the different professional services. Patients who had problems or doubts as to the dosage, indication or duration of treatment were referred to MUR and patients with difficulties managing their medication were transferred to PDS: manuals that were prepared entirely by an accredited pharmacist, responsible for the PDS service, at both the healthcare and technical levels, and supervised by another pharmacist, were used.

These systems have the advantage of being more economical and the disadvantage of requiring more preparation time and staff (17). The DPS were prepared weekly and collected by the patient or caregiver once a week. When the previous week's blister was delivered, it was checked whether all the medication had been taken or if any were left unused. The medication that was unused was monitoried through collection of the blister packs. After eight weeks, adherence was reevaluated and the satisfaction questionnaire was given.

The Patient Information, Informed Consent and Data Record Sheet are presented in the Appendices.

Sample size

For an accuracy of 10.0% in the asymptotically normal approximation for a 95% bilateral confidence interval, assuming that the proportion is 50.0%, and that the pharmacy-related population was estimated at 28,500 people (those attending the nearby medical center), 96 patients needed to be included. For the second part, due to the system of inclusion of patients in the study (from the previous evaluation), the sample size calculation was not made.

Statistical analysis

Quantitative variables are expressed as mean (m) ± standard deviation (SD), and qualitative variables as percentages. The Microsoft Excel® 2011 office suite and the IBM SPSS Statistics® version 20.0 (IBM Corporation®) statistical package for Mac® were used for data collection, exploitation, and analysis. For quantitative variables with normal distribution, the t-study of independent samples and single-factor Anova (>2 classes) were used. For categorical variables the Pearson Chi-square was used. In the case of non-parametric quantitative variables for unrelated samples, Zkolmogorov-Smirnov was used. The Pearson Chi-squared test was used for categorical variables in unrelated samples. A statistical significance level of $p < 0.05$ was considered, establishing the value of the differences obtained with their confidence interval at 95%.

Ethical issues

In all cases, in line with the ethical principles of the Helsinki Declaration in force and Organic Law 3/2018, of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights, the autonomy of the participants in the study was respected. The data was recorded anonymously in a table. Patients were previously provided with relevant information and informed consent was collected in all cases.

RESULTS

Determining adherence to treatment

In the first part of the study, 110 patients were asked to participate. Nine of them decided not to accept due to lack of time, so the number of participants was 101. The average age was 69. Of those that did, 28.7% (29) were 40–64 years of age; 32.7% (33) were 65–74; 29.7% (30) were 75–84 and 8.9% (9) were over 85 years. And 50.5% were male. In all 31.7% (32) presented one of the pathologies to be studied, 52.5% (53) two pathologies and 15.8% (16) all three. Table 1 presents the different pathologies according to the age range. Of these 6.9% (7) were smokers, 29.7% (30) recognized that they did almost no physical activity, 50.5% (51) reported physical activity of 6–10 hours per week and 19.8% (20) 11–20 hours.

According to Haynes-Sackett's indirect self-communication method of compliance, 99% of the patients surveyed responded with no difficulty taking their medications. According to the Morisky-Green test, the proportion of adherents was 44.6% (45 patients).

Of the 56 patients (55.4%) who were not adherent to treatment, 40 (71.4%) acknowledged having forgotten to take their medication to treat the disease. Of the total 39.6% (37) were non-adherent due to forgetting to take their medication, while the remaining 15.8% (16) of the patients were non-adherent for other reasons.

Table 1 Prevalence of the different pathologies grouped by patient age

Pathologies	40–64 years n (%)	65–74 years n (%)	75–84 years n (%)	>85 years n (%)	Total n (%)
DM	3 (75.0)	1 (25.0)	0	0	4 (100)
HBP	8 (47.1)	2 (11.8)	7 (41.2)	0	17 (100)
Dyslipidemia	7 (58.3)	1 (8.3)	2 (16.7)	2 (16.7)	12 (100)
Dyslipidemia+HBP	6 (16.2)	17 (46.0)	10 (27.0)	4 (10.8)	37 (100)
HBP+DM	1 (11.1)	0	6 (66.7)	2 (22.2)	9 (100)
Dyslipidemia+DM	1 (14.3)	3 (42.9)	3 (42.9)	0	7 (100)
Dyslipidemia+DM+HBP	3 (20.0)	9 (60.0)	2 (13.3)	1 (6.7)	15 (100)
Total	29 (28.7)	33 (32.67)	30 (29.71)	9 (8.9)	101 (100)

DM: diabetes mellitus; HBP: high blood pressure.

Table 2 Results for each item of the Morisky-Green test

	Yes n (%)	No n (%)
Have you ever forgotten to take your medication to treat your disease?	39 (38.6)	62 (61.4)
Do you take your medications at the prescribed times?	71 (70.3)	30 (29.7)
Do you stop taking the medication when you feel well?	1 (1.0)	100 (99.0)
Have you ever stopped taking your medications or taken less if they make you feel unwell?	0 (0.0)	101 (100)

Table 2 presents the results for each item of the Morisky-Green test.

The degree of adherence was not directly related to sex, age, companionship, number of pathologies, level of education, smoking or the patients' physical activity (p>0.05) (Table 3).

Improved adhesion through PPS

In the second part of the work, non-adherent patients were referred to one of the professional pharmaceutical services, 40 patients considered that they did not need it and did not continue, six non-adherent patients were referred to the MUR and 10 were referred to personalized dosing systems following the criteria described in the methodology.

Table 3 Relationship of treatment adherence to sociodemographic and clinical factors

Factors	Adherents n (%)	Non-adherents n (%)	Total n (%)	p-value
Smoking				
Non-smoker	42 (41.6)	52 (51.5)	94 (93.1)	0.925*
Smoker	3 (3.0)	4 (4.0)	7 (6.9)	
Sex				
Female	23 (22.7)	27 (26.7)	45 (44.6)	0.772*
Male	22 (21.8)	29 (28.7)	56 (55.5)	
Companion				
Lives alone	5 (5.0)	13 (12.9)	18 (17.8)	0.114*
Lives with companion	40 (39.6)	43 (42.6)	83 (82.2)	
No. of pathologies				
1	14 (13.9)	18 (17.8)	32 (31.7)	0.988**
2	24 (23.8)	29 (28.7)	53 (52.5)	
3	7 (6.9)	9 (8.9)	16 (15.8)	
Age				
40-64 years	14 (13.9)	15 (14.9)	29 (28.7)	0.505**
65-74 years	17 (16.8)	16 (15.8)	33 (32.7)	
75-84 years	10 (9.9)	20 (19.8)	30 (29.7)	
>85 years	4 (4.0)	5 (5.0)	9 (8.9)	
Level of education				
Primary	20 (19.8)	21 (20.8)	41 (40.6)	0.774**
Secondary	21 (20.8)	29 (28.7)	50 (49.5)	
Tertiary	4 (4.0)	6 (5.9)	10 (9.9)	
Level of activity				
Low (0–5 hr/week)	11 (10.9)	19 (18.8)	30 (29.7)	0.57**
Medium (6–10 hr/week)	24 (23.8)	27 (26.7)	51 (50.5)	
High (11–20 hr/week)	10 (9.9)	10 (9.9)	20 (19.8)	

* Pearson Chi-squared test.
** One-way analysis of variance Anova test.

Of the patients referred to MUR, the percentage of non-adherent patients decreased from 100% to 66.7% (four still sometimes forgot to take the medication).

Nine of the 10 patients were adherent at the end of the study. Only one patient was non-adherent due to sporadically forgetting to take a medication.

All the blister packs that the patients returned to the pharmacy came with the medication taken. In all 90% of patients (9) collected the medication on the correct date, but one (10%) systematically collected it two days late, as that patient forgot to take the medication as many as two times.

The satisfaction surveys results showed that 100% were "very much in agreement" with all the questions asked, the patients stating that they were very satisfied with the services received, and as a result of which they learned to better understand the medication, they would continue to visit the pharmacy and recommend it to family and friends.

DISCUSSION

Adherence analysis

Drug adherence varied according to the test used. With the Haynes-Sackett test it was 99% and with the Morisky-Green it was 44.6 %, in line with other published studies (12,18,19). The differences between the two are due to each addressing a different aspect of adherence assessment. The Haynes-Sackett test is sometimes used to make the patient being interviewed more comfortable when responding to the other test (20), as its usefulness is limited by its low sensitivity. The Morisky-Green test measures adherence from the person's behavior toward taking medication (21). In our case it indicates that forgetting is the main cause of non-adherence.

The study is based on collecting information from the patients themselves and it should be noted that the results obtained in this study were obtained by applying indirect methods of self-reported compliance, which have the disadvantage of overestimating adherence, as there is a possibility that the patient may exaggerate, forget details about taking their medication or think that they are taking the treatment correctly, but not actually doing so (involuntary non-adherence) (15).

Another limitation of the study was the small sample size that participated in the second part, which was determined by it being a single-center study, determined by the number of patients who agreed to participate, as the vast majority felt that they did not need the service offered. Effort should be made to raise awareness of the PPS that the community pharmacy can make available to patients.

In our study, 23 of the 45 people with adherence to treatment were women and 22 were men, and the statistical test indicates that both sexes behaved the same with regard to taking medication, coinciding with some studies (1,22) but not with others which show greater adherence in the female sex than in the male (23) or vice versa (19).

Neither were there significant differences in age in our sample, as described by Leites-Docío et al. (22), but in contrast to other studies which found significant differences with better adherence found at older ages with treatment in diabetic and hypertensive patients (24,25).

While in other studies (19) adherence decreases with low levels of education, in our study it had no affect, the same as is described by Leites-Docio et al. (22), which could be due to a different questionnaire being used to measure adherence.

Another factor evaluated was whether living alone or with company may influence adherence to treatment. This factor was chosen as it is often a caregiver or family member who collects the medication and reminds the patient to take their medication. In our study, living alone or not was not a statistically significant factor in adherence. In addition, no relationship was found between the number of pathologies and adherence. This factor is variable and our findings were consistent with some studies (20,22) and not with others (1,19,26).

As we have seen, there is no consistency between the various studies on the possible relationship between the factors that are supposed to have an influence on therapeutic adherence and the results of the questionnaires that evaluate it. Methodological or environmental differences may explain this disparity in the results.

Improved treatment adherence

In the second phase of the study, regardless of the PPS provided, the improvement in adherence was remarkable. This clearly indicates that, even at the modest level of a single community pharmacy, which, as we find in other studies reviewed, the intervention of the pharmacist, through various methods, significantly improves patient pharmacotherapeutic compliance, either through specific follow-up with educational intervention (27), MUR (28) or other intervention models (29–31).

The fact that there is a very high number of non-adherent patients, as demonstrated in the study, showed that the professional services offered by some pharmacies are a very important tool for both patients and the Public Administration as its widespread use would reduce the healthcare costs associated with the misuse of medications, especially the high social and economic cost involved with the lack of adherence (32).

Patient satisfaction was very high, consistent with other PPS studies (33). While this is a small sample, the study

showed that there is considerable improvement in the process of using the drugs, which will undoubtedly have an impact on attaining better health results. In any case, communication with the doctor facilitates the provision of the service and more rational use of the medication.

We therefore believe, and in view of the high degree of satisfaction obtained through the provision of the PPS implemented to improve adherence, that extending it to a significant number of community pharmacies to the extent that the circumstances of each permit, would provide an excellent tool for improving the use of treatments and thus the health of the patients who collect their medication from these pharmacies.

CONCLUSIONS

Patients at the pharmacy where the study was conducted have a low degree of treatment adherence, less than 50%. No statistically significant relationship was found with the factors analyzed. Actions aimed at improving adherence are needed.

Despite the small sample size, we believe that MUR and PDS result in a significant improvement in treatment adherence. The effectiveness appears to be greater in the case of PDS.

Satisfaction was 100% and all patients wanted to continue with the service.

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APPENDICES

Appendix 1. Patient information document

ANALYSIS OF ADHERENCE TO PHARMACOTHERAPEUTIC TREATMENT
IN POLYMEDICATED PATIENTS FROM A COMMUNITY PHARMACY IN OURENSEE

What is going to be done?

In this project the research team will use three questionnaires to conduct a study of adherence to pharmacotherapeutic treatment for patients with hypertension, diabetes and/or hypercholesterolemia, to ascertain aspects of the patients and of the pharmacy and for the pharmacy to be able to collaborate in improving treatments and health.

I have read this document;

....

SIGNATURE, NAME AND SURNAMES

Ourense, on .... of .... 20............

Appendix 2. Document of consent to participate in a research project

ANALYSIS OF ADHERENCE TO PHARMACOTHERAPEUTIC TREATMENT
IN POLYMEDICATED PATIENTS FROM A COMMUNITY PHARMACY IN OURENSE

Mr./Ms. ....

With ID no..

Freely and voluntarily declares:

- That I have been sufficiently informed of the objective of the study.
- That I agree to participate in it voluntarily throughout the entire process.
- That I have been informed that the data collected in this study will be treated confidentially, applying the current legislation for the protection of personal data (Organic Law 15/2999, December 13) and any other that may be applicable.
- That, while always safeguarding my right to privacy, I accept that the data derived from my participation can be used for scientific purposes.
- Any important findings that may be a major risk to my health will be reported to me immediately.
- I understand that my personal data will not be used for other studies without my consent.
- I understand that I can withdraw from the study at any time, without having to give explanations and without this having an impact on my medical care.

I therefore agree and consent to the detailed study being carried out with the necessary assistance with the appropriate qualification and specialization.

The person concerned

....
SIGNATURE

Ourense, on .... of .... 20............

Appendix 3. Patient data collection sheet

Pharmacy: Mª Teresa Rodríguez Rodríguez	**Date:**
Age:	**Sex:**
Do you live alone? ○ Yes ○ No	**No. of children:**
Civil status: ○ Unmarried ○ Married ○ Separated ○ Widowed	**Education:** ○ No education ○ Secondary ○ Primary ○ University

Lifestyle	
	Current number of hours
Weekly physical activity	

Tobacco consumption: ○ Smoker (no. of cigarettes ..../day)   ○ Ex-smoker (time............../years)   ○ Non-smoker

Pathologies		
Diabetes ○ Yes ○ No	**High blood pressure** ○ Yes ○ No	**Hyperlipidemia** ○ Yes ○ No
Treatment initiated ○ Yes ○ No **Controlled** ○ Yes ○ No	**Treatment initiated** ○ Yes ○ No **Controlled** ○ Yes ○ No	**Treatment initiated** ○ Yes ○ No **Controlled** ○ Yes ○ No

Medication	
Do you remember the year you were diagnosed? ○ Diabetes: .... ○ High blood pressure: .... ○ Hypertriglyceridemia:	**What drug(s) were you prescribed?**
In what year did you start treatment?	**Who prescribed your treatment?** ○ General practitioner ○ Specialist ○ Other (specify who)
Have you been told how long you should take the medicine? ○ Yes ○ No	**Who?** ○ Doctor ○ Pharmacist ○ Other
Has it been explained to you how to use it? ○ Yes ○ No	**How many times a day do you take medications?** ○ 1 ○ 2 ○ 3 ○ 4 or more

Do you take other medications? Indicate which	
Medication	**Dose**