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Effect of pharmaceutical pictograms on the textual comprehension of Prescription Medication Leaflets: A randomized controlled trial

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ABSTRACT

Introduction: Clear patient instructions are essential in pharmaceutical care. However, literature reveals a consistent gap between the readability of medication messages and population skills. This study aimed to assess the comprehension of information in three Prescription Medication Leaflets, with and without supplementary US Pharmacopeia (USP) pictograms, among Spanish adolescents completing secondary education.

Methods: We conducted a multicenter randomized controlled trial. From March to June 2022, 590 students were randomly assigned to read Prescription Medication Leaflets for ibuprofen, amoxicillin/clavulanic acid, and omeprazole, with or without USP pictograms. Comprehension was evaluated via questionnaire, alongside the European Health Literacy Survey short form, and sociodemographic data were collected. Mann-Whitney U and chi-square tests were used for analysis.

Results: Participant comprehension was significantly below the European standard, which requires at least 80 % readability for Prescription Medication Leaflets, even with pictograms. Pictograms, however, significantly enhanced comprehension across all medication package inserts ($p < 0.001$ for all comparisons), especially among students with higher health literacy. High health literacy was a statistically significant factor in comprehension only within the experimental group ($p = 0.005$; $p = 0.039$; $p = 0.004$).

Conclusion: The discouraging results highlight the imperative for innovation in medication labeling design, employing patient-centered approaches. USP pictograms have been shown to significantly enhance the reading comprehension of medication package inserts among the Spanish population.

1. Introduction

Medication is the primary means of treating diseases.[1,2] However, although largely preventable,[3] medication errors continue to significantly contribute to overall morbidity and mortality rates.[4] To address this, the World Health Organization (WHO) launched the Medication Without Harm initiative in 2017, aiming to reduce avoidable medication-related harm by 50 % within five years. Despite these efforts, global medication-related costs remain substantial, estimated at $42 billion annually.[5]

Effective communication is critical for ensuring treatment adherence and minimizing risks.[6] Clear and instructive written patient information is crucial for pharmaceutical care,[7] as ensuring that individuals comprehend health messages is an ethical imperative for public health institutions and healthcare professionals.[8] However, Patient Information Leaflets (PILs) provided by manufacturers with medications are often written at a high readability level.[9] Factors such as legibility, the prevalence of technical terms, and the length of the text create significant barriers to comprehension for end-users,[9,10] making it challenging for some readers to fully understand the information.

WHO[11] has identified unsafe medication practices and errors as leading contributors to preventable harm within healthcare systems. Pharmaceutical pictograms serve as visual aids that convey medication instructions, precautions, and warnings, thus reducing reliance on complex textual information.[12] Consequently, the WHO's Management Team on Research Priorities for Medication Safety[4] has prioritized the implementation of universally applicable pictograms as a preferred area of research to prevent medication-related problems.

The challenge for health professionals lies in modulating messages to facilitate understanding; if textual information is overly complex, it may fail to achieve its intended effect,[13] potentially leading to negative patient outcomes resulting from improper medication use or storage.[14] Therefore, healthcare materials should be designed with a patient-centered approach that accounts for the limited capacity of

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working memory.[15] The concept of working memory, introduced by Baddeley and Hitch,[16] describes the cognitive resource through which individuals actively manipulate and hold information for real-time processing.

Effective health communication must consider this limitation, as inadequate messaging can impair the understanding and recall of critical health information necessary for adopting recommended behaviors.[17] Pharmaceutical pictograms are standardized graphic images that help convey medication instructions, precautions, and/or warnings to patients and consumers,[12] reducing reliance on complex textual health information.[18]

Adequate Health Literacy (HL) is essential for patients to effectively understand, process, and apply medication-related information.[1,19] It is also widely accepted that educational level and HL are strongly correlated,[20] since basic general literacy skills (reading, writing, oral communication or numeracy skills) are necessary for improving an individual's degree of HL. It is reasonable to assume that citizens with low general literacy also have limited HL.[21] Secondary education, a common formative stage for all citizens, aims for its students to acquire all the skills needed to function effectively in various daily life activities, including the use of medications.[22] Therefore, this population group is a clear representation of the minimum HL skills of future generations.

Previous randomized controlled trials that evaluated the effect of pharmaceutical pictograms on the textual comprehension of printed medication instructions yielded mixed results. Some found statistically significant improvements in comprehension due to the inclusion of pharmaceutical pictograms,[23–27] such as Heyns et al.,[28] who observed partially significant effects, while Wolf et al.[29] found no significant differences in comprehension test results when pictograms were included. The limited number of trials identified and the inconsistency in their findings suggest that the inclusion of pharmaceutical pictograms to enhance reading comprehension in the field of pharmaceutical care is a strategy that requires further extensive research.

This study primarily aims to explore the effect of including US Pharmacopeia (USP) pictograms[12] on the comprehension of prescription medication PILs among students completing secondary education. The secondary aims were to explore the opinion on the inclusion of pictograms in the experimental group and to compare the perceived difficulty in comprehending the PILs between both groups.

2. Materials and methods

2.1. Study design and participants

A multicenter randomized controlled trial was conducted involving students completing their secondary education in the academic year 2021–2022 at all high schools in the city of Melilla, Spain. Convenience sampling was employed to recruit participants, with inclusion criteria limited to students completing their secondary education in the specified academic year. Exclusion criteria were applied only to individuals experiencing visual acuity difficulties preventing accurate perception of visual aids.

Approval for the study was obtained from the Granada University Ethics Committee (Approval No. 2320/CEIH/2021). Formal consent was obtained from the parents or legal guardians of the participating students, adhering to ethical guidelines and regulations set forth by the University of Granada regarding research involving human participants. Upon approval from school authorities, researchers and high school personnel approached eligible students in groups to explain the study objectives, procedures, and voluntary nature of participation. Students were given the opportunity to ask questions or seek clarification before deciding whether to participate. They were assured that participation status would not affect their academic standing or relationship with the high school.

According to data from the Ministry of Education and Vocational Training,[30] in the 2020–2021 academic year, 906 students matriculated in their final year of secondary education in Melilla. A minimum sample size of 486 individuals was determined for this study, based on a total population of 906,[30] a 95 % confidence level, a 5 % margin of error, an expected proportion of 50 %, and a 90 % power. However, additional resources allowed for an increase in the sample size to 612 participants. Of the 612 students invited to participate, 22 declined, resulting in a final sample of 590 students. Students were assigned to either the control or experimental group through alternate randomization based on their seating arrangement in the classroom, with the control group receiving original PILs for three prescription medications, and the experimental group receiving the same PILs supplemented with pictograms (Fig. 1).

2.2. Patients information Leaflets used

The three PILs used in the study were original documents provided by a primary care service, and were also available through the online medicines information center of the Spanish Agency of Medicines and Medical devices (CIMA, AEMPS).[31–33] The three medications were among the 15 most consumed generic medicines.[34]

2.3. Questionnaire

A questionnaire was used to assess the level of HL and comprehension of PILs, participants' perceived difficulty in comprehending PILs, and sociodemographic variables for both groups.

The questionnaire was presented in a simulated scenario where students were prescribed ibuprofen, amoxicillin/clavulanic acid, and omeprazole after a dental intervention. The students were given 30 min to answer the questions. The questionnaire was administered between March and June 2022.

Respondents were required to provide their answers in writing. To assess comprehension, European standards were applied, specifically following the European Commission's criterion outlined in Directive 92/27/EEC,[35] which mandates that PILs should be understood by at least 80 % of readers.

Our questionnaire was structured in 4 sections:

1. HL questionnaire: A short-form of the European HL Survey Questionnaire (HLS-EU-Q16).[36]

The validated Spanish version of the HLS-EU-Q16[36] was employed. This version is the short form of the HLS-EU-Q47,[37] which resulted from the selection of 16 items that evaluate self-reported difficulties in accessing, understanding, appraising, and applying information in healthcare decision-making and demonstrates high correlation with the original version ($r = 0.822$).[38] Responses to the questionnaire are collected using a Likert scale, allowing participants to express varying degrees of agreement or difficulty regarding each statement. This questionnaire is an easy-to-understand, cost- and time-effective instrument with good reliability and consistency.[37] Following Sørensen et al.[37] methodology in the European HL Survey with the extended version of the instrument, responses corresponding to "very easy", "quite easy", "quite difficult", and "very difficult" were assigned 4, 3, 2, and 1 points, respectively. The mean of the values obtained for all items was calculated to determine the General HL index as follows:

$$General\ HL\ Index = (mean - 1)^{*}\left(\frac{50}{3}\right)$$

From the results obtained, 4 levels of HL could be established: inadequate (0–25 points), problematic (>25–33 points), sufficient (>33–42 points) and excellent (>42–50 points). The inadequate and problematic HL ranges were grouped as Low HL, while the sufficient and excellent ranges as High HL, to dichotomize this parameter and simplify our analysis, following the approach utilized in previous studies.[39,40]

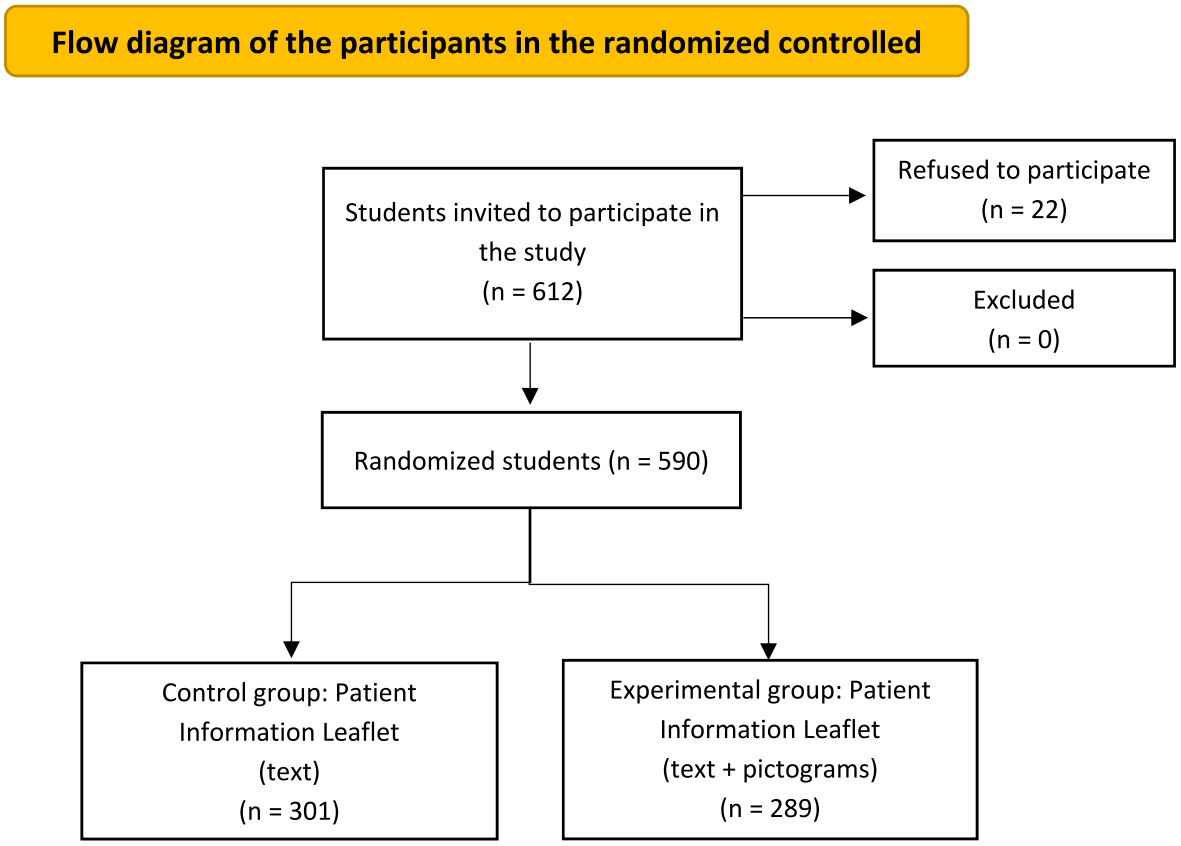

Fig. 1. Flow diagram of the participants in the randomized controlled trial.

2. Questions on the use of prescription medications.

Three basic questions about medication use were formulated based on PILs instructions to assess reading comprehension: a) "In relation to meals and according to the general recommendation, when would you take this medicine?" (referring to ibuprofen) b) "If you had to take the usual dose of the medication, when would you do it?" (referring to amoxicillin with clavulanic acid) c) "What is this medicine for?" (referring to omeprazole). Pictograms were intentionally selected and included to aid comprehension in the PILs of the experimental group. The comprehension test was conducted immediately after the participants read the PILs.

The pictograms used and their intended interpretation were as follows:

a) Take 1 h before meals

(*continued on next column*)

(*continued*)

b) Take 2 times a day with meals

c) For stomach/intestinal problems

3. Perceived difficulty and opinions on the usefulness of pharmaceutical pictograms for questions on the use of medications.

A Likert scale question was included to gauge the perceived difficulty of responding to the questions in both groups. Participants were asked to rate the difficulty level on a scale of four alternatives: "very difficult", "difficult", "easy", and "very easy". These responses were later dichotomized into high and low difficulty levels for analysis.

A survey of opinions on the usefulness of pharmaceutical pictograms was conducted among the experimental group using closed-ended responses on a Likert scale. Participants were asked to indicate their level

of agreement with statements using four alternatives: "strongly agree", "agree", "disagree", and "strongly disagree". These responses were later categorized into two variables: agreement and disagreement. The survey consisted of two questions: 1. "How much do you agree with the inclusion of pictograms for medication use?" and 2. "Do you find their application useful in this context?".

4. Questionnaire on sociodemographic variables of the study population.

This section of the questionnaire collected data on age, gender and cultural background. The variable cultural background was dichotomized into two categories: European and non-European.

2.4. Outcomes

The main outcome measure was comprehension, assessed specifically through response accuracy, which reflects participants' ability to provide correct answers to questions regarding medication use. For each question posed, participants were required to identify the relevant information in the text and write their responses. Responses were considered correct if they matched the wording of the prescription medication PILs instructions and incorrect if they did not. Responses that deviated from the exact language of the package inserts were evaluated for correctness, and final decisions were reached by consensus among the authors.

Secondary outcome measures included participants' perceived difficulty in comprehending the prescription medication PILs and their opinions on the utility of including supplementary pictograms in the PILs (only in the experimental group).

2.5. Statistical analysis

The Shapiro–Wilk normal distribution test was performed. Quantitative variables with normal distribution were presented as mean and standard deviation. Categoric variables were expressed as frequencies and percentages. A bivariate analysis of the data was performed using Pearson's or Fisher's chi-square tests (for categoric variables) or the Mann–Whitney U test (for quantitative variables). This analysis assessed differences in response accuracy between the control and experimental groups, examined associations between sociodemographic variables and HL with response accuracy, and investigated the relationship between perceived difficulty and response accuracy. A p-value <0.05 was considered to indicate significance. The magnitude of associations found to be significant was assessed by logistic regression analysis. All statistical analyses were performed in R Software v.4.1.1 (R Foundation for Statistical Computing, Vienna, Austria).

3. Results

3.1. Sample characteristics

Our participants ranged in age from 15 to 17 years old, and 46.27 % (n = 273) were male. The sample was characterized by marked cultural diversity, where the dominant cultural backgrounds were European and Berber, representing 57.29 % (n = 339) and 38.14 % (n = 225), respectively. A low degree of HL was observed in 54.58 % (n = 322) of the students, with an average score of 32.27 ± 6.60 points on a 50-points-scale (Supplementary Material A). Our randomization generated two comparable study groups with no significant HL or sociodemographic variable differences (Table 1).

3.2. Comparison of comprehension between the control and experimental groups

The minimum comprehension threshold required by the European Commission[35] of 80 % was only reached for the indication of omeprazole, and solely within our experimental group. Overall, the pictograms improved comprehension, as reflected in the higher percentage of correct responses. The mean percentage of correct answers in the control group was 41.97 %, while that of the experimental group was 68.51 %. The intervention resulted in significant beneficial effects on comprehension in the three questions posed ($p < 0.001$ for all comparisons) (Table 2). These effects were especially notable in the questions on antibiotic dosage and the indication of the proton pump inhibitor, where the odds of correct responses were 3.75 (95 % CI: 2.68–5.29) and 3.61 (95 % CI: 2.49–5.29) times higher, respectively (Supplementary Material B).

3.3. Association of sociodemographic variables and HL with comprehension in the experimental and control group

Age was a statistically significant factor in the first question within the control group. No significant association was found between the remaining sociodemographic variables or HL and the comprehension of the questions presented in the control group. A higher HL index proved to be a significant factor in obtaining more accurate answers for questions involving the application of supplementary pictograms ($p = 0.005$,

Table 1
Sociodemographic characteristics and Health Literacy of the participants. Statistical comparability between groups.

Variable	Control group				Experimental group				p	Total			
	n	(%)	Median	Range	n	(%)	Median	Range		n	(%)	Median	Range
Age	–	–	16	15–17	–	–	16	15–17	0.384[a]	–	–	16	15–17
Gender									0.964[b]				
Male	139	46.20	–	–	134	46.40	–	–		273	46.27	–	–
Female	162	53.80	–	–	155	53.60	–	–		317	53.73	–	–
Cultural background									0.071[c]				
European	173	57.50	–	–	165	57.10	–	–		339	57.29	–	–
Berber	120	39.90	–	–	105	36.30	–	–		225	38.14	–	–
Jewish	4	1.30	–	–	10	3.50	–	–		14	2.37	–	–
Romany	2	0.70	–	–	8	2.80	–	–		10	1.69	–	–
Arabic	0	0.00	–	–	1	0.30	–	–		1	0.17	–	–
Hindu	1	0.30	–	–	0	0.00	–	–		1	0.17	–	–
Health literacy									0.229[b]				
High	144	47.80	–	–	124	42.90	–	–		268	45.42	–	–
Low	157	52.20	–	–	165	57.10	–	–		322	54.58	–	–

[a] p-value for Mann-Whitney test.
[b] p-value for chi-square test.
[c] p-value for Fisher test.

Table 2
Response accuracy for questions related to medication usage in control (n = 301) and experimental (n = 289) groups.

Question	Question-related drug	Response accuracy (correct responses)				p[a]	OR	95 % CI
		Control group (text)		Experimental group (Text + Pictogram)				
		n	(%)	n	(%)			
1. In relation to meals and according to the general recommendation, when would you take it?	Ibuprofen	106	35.20	164	56.70	**<0.001**	**2.41**	**1.74–3.37**
2. If you had to take the usual dose of the medication, when would you do it?	Amoxicillin/Clavulanic acid	105	34.90	193	66.80	**<0.001**	**3.75**	**2.68–5.29**
3. What is this for?	Omeprazole	168	55.80	237	**82.00**	**<0.001**	**3.61**	**2.49–5.29**

[a] p-value for chi-square test.

p = 0.039, and p = 0.004 for questions 1, 2, and 3, respectively. Specifically, participants with higher HL levels were 1.97 times more likely to answer question 1 correctly, which asked about the timing of ibuprofen intake in relation to meals according to the general recommendation (95 % CI: 1.22–3.21), 1.70 times more likely to respond accurately to question 2, concerning antibiotic dosage timing (95 % CI: 1.03–2.84), and 2.64 times more likely to identify the indication of the proton pump inhibitor in question 3 (95 % CI: 1.37–5.38). No significant correlation was observed between the other sociodemographic variables and the comprehension of the questions presented in the experimental group (Table 3).

3.4. Comprehension and perceived difficulty in the control and experimental groups

In the control group, 53.80 % (n = 91) of the students rated the perceived difficulty of understanding the standard PILs as "difficult" or "very difficult". In contrast, this percentage decreased to 40.80 % (n = 121) in the experimental group. A low perceived difficulty was significantly associated with a higher likelihood of correct answers (p = 0.002), with students being 1.68 times more likely to answer correctly (OR = 1.68; 95 % CI, 1.22–2.34) (Table 4).

3.5. Opinion and usefulness of the inclusion of pictograms by students in the experimental group

After taking the test, 94.46 % (n = 273) of the experimental group stated that visual aids should be included in PILs. Additionally, 82.35 % (n = 238) of the experimental group mentioned that the visual aids were useful for text comprehension.

4. Discussion

It is evident that employing two methods to convey information is likely to be more successful than relying on a single method. However, a recent systematic review[41] has concluded that there is still limited research on the effectiveness of the strategy of combining pharmaceutical pictograms with textual information to promote the rational use of medicines. This study provides strong evidence of a consistent association between our pictogram intervention and improved comprehension. High HL also proved to be a statistically significant factor in the comprehension of PILs when accompanied by USP pharmaceutical pictograms.

The selected prescription medication PILs did not achieve the European Commission's minimum comprehension threshold of 80 %,[35] except for the indication of omeprazole in the experimental group. Based on the results obtained, a significant proportion of the population could be excluded from the benefits of medication if they had to rely on current prescription medication PILs, the primary regulated source of patient instruction in the Spanish context.[42] The disheartening findings highlight the urgent need for innovative, patient-centered strategies to make prescription medication PILs accessible for rational medication use across the population. Although validation of pharmaceutical pictograms with the target population is recommended,[43] we selected USP pictograms due to shared Western conventions. This lack of prior validation may be an important factor affecting the comprehension results in our study. Our results also indicate that in Spain, completing formal education does not ensure adequate HL skills for interpreting pharmaceutical information effectively.

Factors such as comprehensibility and design support the usefulness of medication labels and PILs.[9] Preventive health campaigns regarding behavioral guidelines rely on the correct understanding of the messages issued; thus, their legibility should be guaranteed for the entire population. Unfortunately, despite intense regulation,[42,44,45] presumed comprehensibility and the functional capacities of the target audience have been demonstrated to be misaligned.[1,9,18,46,47] To address this issue, Directive 92/27/ECC of the European Commission[35] defined the minimum contents that must be included in the PILs and ensured the inclusion of an explicit directive to read the inserts, and also declared that *"the package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately […]"*. Repeated user testing was implemented until 80 % of all consumers could use a medication successfully. However, prescription medication PILs appear to be regarded exclusively as a legal requirement that companies must fulfill to obtain authorization to market their medicinal products.[45] In practice, the wording and the terms used appear more aimed at the prescriber than at achieving compliance with the patient's right to information.

Consistent with previous similar studies,[24,25,27,48] including pharmaceutical pictograms significantly improved comprehension of PILs. Sweller's Cognitive Load Theory[49] could explain this strong association. This theory asserts that cognitive capacity is limited, and optimal performance is achieved when cognitive load is kept within certain limits. Therefore, if visual aids facilitate comprehension without increasing cognitive load, they could improve reading performance. However, according to previous studies,[41] pharmaceutical pictograms did not always show an improvement in textual comprehension.[28]

HL was only a significant factor for comprehension in the experimental group. These findings suggest that prior acquisition of health knowledge is crucial to render pharmaceutical pictograms more effective in enhancing comprehension. According to Piaget's theory,[50] learning is an active process in which individuals construct their understanding of the world based on the foundations of knowledge they have already acquired.

Among our participants, the incorporation of supplementary pharmaceutical pictograms alongside text would be widely embraced. Within our experimental group, 82.35 % found, based on their experience, that these supplementary visual aids were helpful in understanding the text, and 94.46 % opined that they should be included in PILs. European legal provisions in Directive 2001/83/EC[51] authorize the use

Table 3
Response accuracy by demographic variables and HL in control (n = 301) and experimental (n = 289) groups across medication usage questions.

Variable		Response accuracy (correct responses)																	
		Control group																	
		Question 1						Question 2						Question 3					
		n	%	Median	Range	p	OR (95 % IC)	n	%	Median	Range	p	OR (95 % IC)	n	%	Median	Range	P	OR (95 % IC)
Age		–	–	15	15–17	**0.015**[a]	**0.67 (0.46–0.95)**	–	–	15	15–17	0.260[a]	–	–	–	15	15–17	0.313[a]	–
Gender	Male	55	39.60	–	–	0.143[b]	–	41	29.50	–	–	0.070[b]	–	74	53.20	–	–	0.404[b]	–
	Female	51	31.50	–	–			64	39.5	–	–			94	58.00	–	–		
Cultural background	European	60	34.70	–	–	0.822[b]	–	65	37.60	–	–	0.255[b]	–	103	59.50	–	–	0.130[b]	–
	Non-European	46	35.90	–	–			40	31.20	–	–			65	50.80	–	–		
HL level	High	53	36.80	–	–	0.580[b]	–	52	36.10	–	–	0.669[b]	–	86	59.70	–	–	0.191[b]	–
	Low	53	33.80	–	–			53	33.80					82	52.20				

Variable		Response accuracy (correct responses)																	
		Experimental group																	
		Question 1						Question 2						Question 3					
		n	%	Median	Range	P	OR (95 % IC)	n	%	Median	Range	p	OR (95 % IC)	n	%	Median	Range	p	OR (95 % IC)
Age		–	–	16	15–17	0.351[a]	–	–	–	16	15–17	0.624[a]	–	–	–	16	15–17	0.682[a]	–
Gender	Male	71	53.00	–	–	0.237[b]	–	87	64.90	–	–	0.533[b]	–	112	83.60	–	–	0.517[b]	–
	Female	93	60.00	–	–			106	68.40	–	–			125	80.60	–	–		
Cultural background	European	90	54.50	–	–	0.383[b]	–	108	65.50	–	–	0.580[b]	–	136	82.40	–	–	0.831[b]	–
	Non-European	74	59.70	–	–			85	68.50	–	–			101	81.50	–	–		
HL level	High	82	66.10	–	–	**0.005**[b]	**1.97 (1.22–3.21)**	91	73.40	–	–	0.039[b]	**1.70 (1.03–2.84)**	111	89.50	–	–	**0.004**[b]	**2.64 (1.37–5.38)**
	Low	82	49.70	–	–			102	61.80	–	–			126	76.40	–	–		

HL: Health Literacy.
[a] p-value for Mann-Whitney test.
[b] p-value for chi-square test.

Table 4
Comparison of response accuracy by perceived difficulty in control (n = 301) and experimental (n = 289) groups.

		Response accuracy (correct responses)					
		Control group		Experimental group			
Perceived difficulty	n	(%)	n	(%)	p[a]	OR	95 % CI
Low	139	46.20	171	59.20	**0.002**	1.68	1.22–2.34
High	162	53.80	118	40.80		1	

Low: Easy-very easy.
High: Difficult-very difficult.
[a] p-value for chi-square test.

of images, pictograms and other graphics to facilitate comprehension, navigation and clarify or highlight key information without replacing the actual text. Finally, the perceived difficulty among our survey participants was lower in the experimental group. Simultaneously, a lower perceived difficulty showed a significant association with a higher number of correct answers (p = 0.002), making students 1.68 times more likely to respond accurately.

4.1. Strengths and limitations

This research achieved a large sample, enhancing statistical power (98 %) and the representativeness of the sociodemographic results. All participants in our study had the same educational level, facilitating result interpretation and external validity. Although non-probabilistic sampling was used, no significant differences emerged between control and experimental groups, reducing bias and ensuring internal validity. The multicenter design minimized selection bias, and conducting the study in a culturally diverse environment allowed examination of cultural factors. We used original PILs, preserving both macro- and micro-structural characteristics encountered by end-users in real-life scenarios. These characteristics potentially influence reading comprehension and the willingness to read, thus enhancing the significance of our findings. Finally, was assessed through both functional and general measures, providing a comprehensive perspective.

There are limitations to consider. The involvement of secondary students rather than patients may constrain the applicability of findings to clinical settings. Students' prior knowledge of the medications could have influenced responses, and their generally better health status compared to older adults may affect generalizability. Participation was voluntary, possibly introducing self-selection bias. Lastly, the study did not evaluate recall or adherence, and the alternating assignment method, combined with the lack of blinding, may introduce bias.

4.2. Practical implications

This research highlights the importance of addressing HL from two distinct angles.[52] Firstly, current Spanish medication PILs do not align well with the functional competencies of future users. There is a need for innovative designs that consider the actual competencies of the population and minimize the cognitive demands placed on patients. Secondly, these findings may prompt reflections on whether the pharmacist's educational role should also extend to educational institutions, in line with their social responsibility. This reconsideration would allow us to preemptively address a future public health issue, such as the widespread inappropriate use of medications. The lack of involvement of healthcare professionals in secondary education programs could be a plausible explanation for our results.

Despite the effectiveness of supplementary pictograms as facilitators of understanding, this strategy was not sufficient to achieve acceptable results. The significant influence of cultural background and HL levels underscores the need to consider these variables when designing future educational interventions. The significant findings of this research could encourage decision-makers to reconsider current PILs, incorporating pharmaceutical pictograms to enhance comprehension and, consequently, medication use.

Healthcare providers and policymakers should promote the effective use of pharmaceutical pictograms to integrate them into standard practice in real-world settings in Spain. Incorporating basic content on medications and health into formal education curricula—delivered by pharmacists with a focus on understanding these pictograms—could significantly advance their effective and widespread use. Additionally, community pharmacies could incorporate pharmaceutical pictograms into their daily practice as more accessible educational materials for patients with specific needs. Furthermore, health authorities could encourage the systematic inclusion of pictograms in medical prescriptions and PILs.

In summary, continued research is essential to gain a deeper understanding of these dynamics and to design more effective interventions in the fields of HL and medication information comprehension.

5. Conclusions

The inclusion of USP pictograms significantly improved the comprehension of PILs, and this trend was particularly relevant among participants with higher HL. Perceived difficulty in comprehension of PILs in the experimental group was lower compared to the control group, suggesting that the inclusion of visual aids may alleviate reading comprehension difficulties. Additionally, the majority of participants in the experimental group indicated the usefulness of visual aids in comprehending the text after their experience.

The results of this study demonstrate the significant benefits of incorporating visual aids, such as USP pictograms, into PILs to enhance medication comprehension among individuals completing formal education in the Spanish population. These findings underscore the importance of employing innovative strategies in health communication to empower individuals with the necessary information to make informed decisions and promote the rational use of medicines.

CRediT authorship contribution statement

Francisco Javier Ferreira-Alfaya: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Yasmin Cura:** Writing – review & editing, Formal analysis, Data curation. **María José Zarzuelo-Romero:** Supervision.

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Declaration of interest

None.

Appendix A. Supplementary data

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