

Education in health for individuals with chronic pain: clinical trial

Educação em saúde para indivíduos com dor crônica: ensaio clínico

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ABSTRACT

BACKGROUND AND OBJECTIVES: The use of socio-educational booklets is recommended for assisting in the control of chronic pain. However, the efficacy and safety of these light technologies have not yet been tested enough for widespread application, based on the model of scientific evidence. This study aimed to assess the effect of a health education program in individuals suffering from CP using the EducaDor booklet.

METHODS: Randomized clinical trial conducted with chronic pain patients from *Unidades Básicas de Saúde* (UBS – Primary Health Care Units) in Salvador, Bahia, Brazil. Assessments were performed using the Brief Pain Inventory (BPI), Visual Analog Scale of Pain (VAS-P) and World Health Organization Quality of Life instrument-Bref (WHOQoL-bref), before and after the intervention, for intra and intergroup analyses: Test Group (Booklet) and Control Group (Conventional Care). The contents of the EducaDor booklet were presented didactically in six meetings with an interval of one week between them.

RESULTS: The sample was composed of 10 individuals in each group (n = 20). In the Control Group, there was an increase in pain intensity (p=0.034), while the Test Group showed a reduction in pain intensity (p=0.015) and a lower level of interference in the physical, psychological, social relationships and environmental quality of life domains (p<0.05). In the intergroup comparisons, an improvement was observed in the domain of social relationships in the Test Group (p=0.015).

CONCLUSION: EducaDor booklet has been shown to be effective and safe for the education of patients suffering from CP by reducing pain intensity and improving patients' quality of life.

Keywords: Chronic pain, Clinical trial, Health education, Quality of life.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Recomenda-se a utilização de cartilhas socioeducativas para auxiliar no controle da dor crônica (DC). No entanto, a eficácia e a segurança dessas tecnologias leves foram pouco testadas para ampla aplicação, com base no modelo de evidências científicas. Este estudo teve como objetivo avaliar o efeito de um programa de educação em saúde em indivíduos com DC por meio da cartilha EducaDor.

MÉTODOS: Ensaio clínico randomizado realizado com indivíduos que apresentam DC em Unidades Básicas de Saúde (UBS) de Salvador, Bahia, Brasil. Os participantes foram submetidos à aplicação do Inventário Breve de Dor (BPI), Escala Analógica Visual (EAV) e do instrumento de Qualidade de Vida da Organização Mundial da Saúde - Bref (WHOQoL-bref), antes e após a intervenção, para análises intra e intergrupos: Grupo Teste (*booklet*) e Grupo Controle (cuidado convencional). O conteúdo da cartilha EducaDor foi apresentado didaticamente em seis encontros com intervalo de uma semana entre eles.

RESULTADOS: A amostra foi composta por 10 pessoas em cada grupo (n = 20). No Grupo Controle, houve aumento da intensidade da dor (p=0,034), enquanto o Grupo Teste apresentou redução da intensidade de dor (p=0,015) e menor nível de interferência nos domínios de qualidade de vida físico, psicológico, social e ambiental (p<0,05). Nas comparações intergrupos, observou-se melhora no domínio relações sociais no Grupo Teste (p=0,015).

CONCLUSÃO: A cartilha EducaDor mostrou-se eficaz e segura para a educação de pacientes com DC, por reduzir a intensidade da dor e melhorar a qualidade de vida dos pacientes.

Descritores: Dor crônica, Educação em saúde, Ensaio clínico, Qualidade de vida.

INTRODUCTION

Pain is a multidimensional phenomenon in which tissue lesions, adaptive biological responses and emotional, sociocultural and environmental aspects collaborate to generate its chronification^{1,2}. Chronic pain (CP) is defined by the International Association for the Study of Pain, Subcommittee on Taxonomy³, as pain that has persisted for a period longer than three months, and is considered a morbidity that generates high costs to the health system, and loss of quality of life for those affected by it⁴. CP is considered a public health problem, particularly in developing countries⁵. Due to its multifactorial nature, implementing health education programs is recommended, which have shown

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effects superior to those of other types of interventions, such as the isolated use of pharmacological treatments^{6,7}.

The use of booklets is common in the health education process, as they provide complementary information, favoring patients' autonomy and can be consulted several times, in addition to being easily replicated for work with communities⁸. By means of booklets, persons who suffer from CP, professionals and family members may acquire knowledge about the pain in question, thereby helping to minimize the symptoms and increase the efficacy of treatments. Consequently, the booklets must be self-explanatory and attractive, corresponding to the sociocultural context of the target public⁹. In addition, booklets can facilitate the learning process of undergraduate students in the health area, as well as assist in proposals for ongoing education for professionals working in pain control in a more dynamic way¹⁰.

In view of the previous considerations, researchers at the Bahiana School of Medicine and Public Health (EBMSP) and at the Federal University of Bahia (UFBA) developed in 2017 a booklet entitled "EducaDor"¹¹. This material was later validated in an ambulatory clinic specialized in pain¹². However, there is still a gap to be filled, relative to the assessment of its efficacy and safety. In continuation of this process, the aim of this study was to assess the effect of a health education program in individuals suffering from CP using the EducaDor booklet.

One of the strategies for dealing with CP is education. Educating people about what pain is, how is it processed in their bodies, what are its most common causes, risk factors and how to effectively prevent or treat pain can help to reduce its negative repercussions, control symptoms and optimize the use of health services^{5,13}. Although the best ways to educate on this topic are not fully known, several studies point to health education as an important pillar for the management of CP¹⁴.

What also needs to be considered is that CP influences a person's life not only in its physical aspect, but also affects social relationships. Therefore, one should think about carrying out group health education activities, since it's possible to learn from each other how to deal with chronic problems, such as CP. The group can be considered as an educational space, where the individual actively participates in the therapeutic process, while simultaneously increasing the support network¹⁵.

To meet this health education process, it's necessary to invest in professional qualification, as health professionals in this area may face difficulties, since their training is mostly based on biomedical knowledge that restricts their focus to biological factors. This can lead the professional to neglect real needs that could be explored by the knowledge offered by health technologies¹⁶. It is also important to reinforce multidisciplinary work and the creation of a bond between the health team and patients since comprehensive care is needed in CP¹⁷.

METHODS

A randomized clinical trial (RCT) conducted with individuals suffering from CP in a community assigned to the *Unidades Básicas de Saúde* (UBS – Primary Health Care Units) of Pituacu and Parque de Pituacu, Sanitary District Boca do Rio, Salvador,

Bahia, Brazil. Inclusion criteria were individuals reporting daily presence of pain throughout a period of at least six months, between the ages of 18 and 60 years, and literate. Exclusion criteria were pregnant women, people with difficulties in understanding the questionnaires, who were unable to attend the health unit for interviews and health education activities and with diseases affecting their quality of life.

To obtain sociodemographic and clinical data, a questionnaire and the following instruments were applied: Brief Pain Inventory (BPI) to assess intensity of pain and its interference in the daily life activities¹⁸; visual analog scale of pain (VAS-P)¹⁹; and WHOQoL-bref²⁰. Patients were responsible for providing the information.

Randomized clinical trial procedures

The RCT comprises five stages.

First Stage: Project presentation aimed at the professionals of the UBS' health teams.

Second Stage: People with a suitable profile according to the eligibility criteria were identified by the professionals of the health teams or approached in the waiting rooms of the UBS by the researchers responsible for data collection. After a week, people who agreed to participate in the study were recruited and signed the Free and Informed Consent Term (FICT).

Third Stage: The researchers applied the questionnaires with the participants in a UBS office, thus guaranteeing confidentiality and avoiding embarrassment for the interviewees.

Fourth Stage: After the interviews, another researcher conducted the sortition of participants to allocate them into two groups: Test Group (TG) and Control Group (CG). The TG received the booklet and participated in six meetings coordinated by the researcher in charge, with a duration of one hour, with weekly periodicity, for six consecutive weeks. At these meetings, the participants had the opportunity to have their doubts cleared up and discuss their problems with their peers, as a collective activity of shared experiences. The meetings were held at the UBS itself. In this group, work was done on the six domains of the EducaDor booklet, using the methodological strategies described in Table 1.

The CG Was not offered any additional intervention other than the usual care provided according to the service protocol. However, upon concluding the study, participants received the EducaDor booklet and were invited to participate in the six meetings.

Fifth Stage: In the week after the conclusion of the educational interventions, the participants were recalled in order to carry out the same procedures of assessment, as it had been performed, who were blinded to the group to which the patients were allocated. The independent variables of the research were the following: gender, age, educational level, time, and location of pain. The intensity of pain, and impact on quality of life were the dependent variables considered.

Sample

Considering a difference of three points to be detected on VAS-P and a standard deviation of three points for a level of significance of 1%, test power of 80% for a bicausal hypothesis, the need for

Table 1. Meetings' domains and methodological strategies used in the randomized clinical trial

Domains	Methodological strategy
What is pain?	To me, what is pain? All participants individually received paper and a pencil to make a drawing that represented how they perceived the pain or what pain was to them. After this, all participants individually, i.e., one by one, showed their poster, and proceeded with their presentation: name and their pain perception explanation. What is pain? Based on the presentations, the researcher presented the first domain of the booklet, bringing tags with the main phrases from the booklet.
Acute pain: useful pain.	The path of pain The researcher presented the "path of pain" by means of drawings, mediating the discussion and understanding of the concepts.
Chronic pain: persistent pain.	Differences between acute and chronic pain The researcher divided the group into two parts. One group conceptualized acute pain and the other, chronic pain. To do this, one group received the tag with the designation ACUTE PAIN and the other group, with the designation CHRONIC PAIN. In addition, tags were made available containing the characteristics of acute and chronic pain. One group created a panel with the characteristics of acute pain, and the other, a panel with the characteristics of chronic pain.
Living with pain	Numbers of pain – you are not alone The researcher presented the results of researchers showing the number of persons who live with chronic pain. How did the participants live with chronic pain? One by one, the participants reported the consequences brought by chronic pain to the lives of participants.

16 individuals with CP, per group (TG and CG) was identified, totaling a sample size of 32 individuals. To establish the groups, the application random.org, which generates random numbers, was used to allocate the research subjects: even numbers (TG), odd numbers (CG).

Researchers who applied data collection instruments were kept blinded to randomization and were not present at the UBS when health education activities were carried out. The researcher in charge of the randomization and implementation of the educational activities was denominated the "Coordinating Researcher".

The study protocol was carried out in compliance with all the recommendations of the Declaration of Helsinki and approved by the Committee on Ethics in Research Involving Human Beings of the Bahiana School of Medicine and Public Health, under Report No. 2.301.438 (CAAE 68160517.9.0000.5544). The research was previously authorized by the Municipal Secretary of Health of Salvador by means of Protocol No. 330/2017. Furthermore, the study was registered in the Brazilian Register of Clinical Trials, reference RBR6FYH2C. The questionnaires and other printed material used have been stored under the responsibility of the researchers.

Statistical analysis

Data collected in the pre- and post-tests in the two study groups were compared by means of the paired analysis for data before and after intervention and the non-paired analysis for comparison between the two groups. Nominal numbers are presented in absolute numbers and proportions and analysed regarding association among variables by the Chi-square test. Numerical data are presented by means of measures of central tendency and dispersion, and associations were verified by means of paired and non-paired Student's *t*-test, or Wilcoxon and Mann-Whitney tests, according to the normality of the data distribution. A confidence interval of 95% was adopted in all situations of statistical inference. Analyses were performed with the statistical package SPSS (Statistical Package for the Social Sciences) version 27.0 (21).

RESULTS

Considering the inclusion and exclusion criteria, 84 individuals were identified, complaining of daily or almost daily episodes of pain during a period of at least six months. These patients were invited to the first interview with the team of researchers. Of the 84 individuals who participated in the pre-test, 2 were excluded from the study, 1 due to death of the patient. The other person informed the decision of no longer wishing to participate, because the pain was associated with the diagnosis of *biliary lithiasis*, i.e., bile duct stones, solved after surgical intervention. Therefore, 82 subjects remained in the study and 45 were allocated to the TG and 37 to the CG.

Of the 45 subjects allocated to the TG, 12 participated in the meetings held by the Coordinating Researcher, 23 accepted the invitation, but did not appear at the meetings, and it was not possible to contact 10. Of the 12 individuals who participated in the meetings, 2 were excluded from the study: 1 because the person only participated in the first meeting, and 1 was not located for the post-test.

As for the CG, only 10 subjects participated in the two-time intervals, i.e., pre- and post-test application of the questionnaires, because, at the time of the post-test, 1 person was hospitalized, and it was not possible to contact 4 of them. The researchers decided not to contact the other 22, because there were only 10 people who effectively participated in the TG.

The period of collection was from October 2018 to December 2019. Therefore, the data collected were analysed based on the interviews with 10 subjects in the TG and 10 in the CG (Figure 1).

Sociodemographic and clinical characterization

The sample was composed of 10 individuals in the CG, and 10 in the TG, totaling 20 individuals. The mean age of the participants was 48.1±7.5 years old in the CG and 48.3±7.7 years old in the TG; and the body mass index (BMI) showed a mean of 29.8±4.9kg/m² and 29.1±3.7kg/m², respectively. After analysis of the sociodemographic and clinical characteristics, homogeneity between the groups was observed (Table 2).

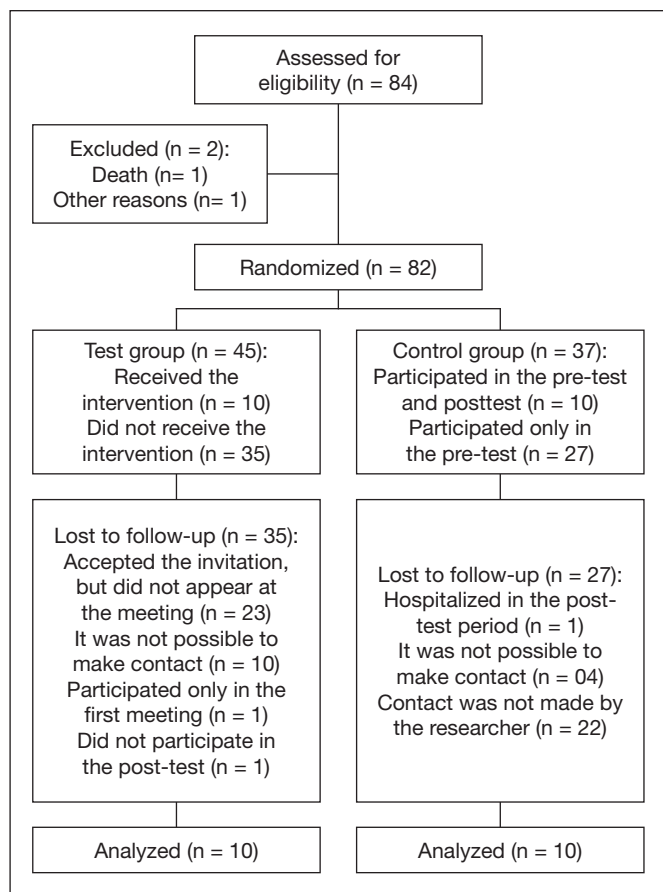


Figure 1. Flow diagram of the study's participants

Table 2. Sociodemographic characterization of the sample from an assigned UBS. Salvador, Bahia, Brazil

Variables	Control Group n (%)	Test Group n (%)	p-value
Gender			
Male	0 (0.0)	2 (20.0)	0.136
Female	10 (100.0)	8 (80.0)	
Marital Status			
Single	3 (30.0)	4 (40.0)	0.565
Married	6 (60.0)	6 (60.0)	
Divorced	1 (10.0)	0 (0.0)	
Race/Skin Color			
Yellow	0 (0.0)	2 (20.0)	0.264
Mulatto/or/Dark	6 (60.0)	6 (60.0)	
Black	4 (40.0)	2 (20.0)	
Smoker			
Yes	1 (10.0)	0 (0.0)	
No	5 (50.0)	9 (90.0)	0.139
Alcohol consumption			
No	8 (80.0)	7 (70.0)	0.659
Drink at weekends	2 (20.0)	2 (20.0)	
Once a month	0 (0.0)	1 (10.0)	

Continue...

Table 2. Sociodemographic characterization of the sample from an assigned UBS. Salvador, Bahia, Brazil – continuation

Variables	Control Group n (%)	Test Group n (%)	p-value
I Can Read			
Yes	10 (100.0)	10 (100.0)	Na
No	0 (0.0)	0 (0.0)	
I know how to write			
Yes	10 (100.0)	10 (100.0)	Na
No	0 (0.0)	0 (0.0)	
Years of Education*			0.206
5 - 9	4 (50.0)	3 (37.5)	
10 - 15	3 (37.5)	5 (62.5)	
>15	1 (12.5)	0 (0.0)	
Currently working			0.525
Yes	6 (60.0)	6 (60.0)	
No	2 (20.0)	3 (30.0)	
Student	1 (10.0)	0 (0.0)	
Retired	0 (0.0)	1 (10.0)	
Unemployed	1 (10.0)	0 (0.0)	
Family Members**			0.710
1 to 2 persons	3 (37.5)	3 (42.9)	
3 to 5 persons	5 (62.5)	4 (57.1)	
Responsibility for home			0.361
Only one resident	3 (30.0)	5 (50.0)	
More than one resident	7 (70.0)	5 (50.0)	
Head of the family			0.349
The respondent	2 (20.0)	5 (50.0)	
Spouse/Partner	7 (70.0)	4 (40.0)	
Mother	1 (10.0)	1 (10.0)	

	Mean (SD)	Min - Max	Mean (SD)	Min - Max	p-value
Age	48.1 (7.5)	32 - 59	48.3 (7.7)	37 - 58	0.954
Weight	76.2 (12.2)	60 - 98	77.1 (18.3)	50 - 114	0.903
Height	1.60 (0.1)	1.51 - 1.69	1.62 (0.1)	1.50 - 1.86	0.661
BMI	29.8 (4.9)	24.0 - 38.4	29.1 (3.7)	21.6 - 34.3	0.722

*Missing = 4; ** Missing = 5; SD = standard deviation; na = not applicable; BMI = body mass index.

Most individuals in the two study groups were female (100% in the CG and 80% in the TG), of self-reported dark color (60% in the two groups), non-smokers (50% in the CG and 90% in the TG) and did not consume alcohol (80% in the CG and 70% in the TG). Moreover, the sample was composed of individuals who could read and write (100% in the two groups) and were working at that time (60% in the two groups). The individuals complained of feeling pain for periods of time ranging between 5 and 10 years (60% in the CG, and 40% in the TG), in the night period (50% in the CG, and 90% in the TG), and, at the time of data collection, 70% of the individuals in the CG and 60% of the TG assessed their state of health as being good (Table 3).

Table 3. Clinical characterization of the sample from an assigned UBS. Salvador, Bahia, Brazil

Variables	Control Group n (%)	Test Group n (%)	p-value
Diseases diagnosed			
Diabetes mellitus	1 (10.0)	0 (0.0)	0.504
Renal disease/heart disease	0 (0.0)	1 (10.0)	
Systolic arterial hypertension	3 (30.0)	1 (10.0)	
Systolic arterial hypertension/ diabetes mellitus	1 (10.0)	1 (10.0)	
Uses drugs for disease*			
Yes	5 (100)	3 (75.0)	0.236
No	0 (0.0)	1 (25.0)	
Time of pain experience (years)			
< 5	3 (30.0)	4 (40.0)	0.645
5 to 10	6 (60.0)	4 (40.0)	
>10	1 (10.0)	2 (20.0)	
Is pain related to disease**			
Yes	1 (16.7)	2 (40.0)	0.387
No	5 (83.3)	3 (60.0)	
Time of day when pain is occurs more frequently			
Morning	1 (10.0)	1 (10.0)	0.162
Night	5 (50.0)	9 (90.0)	
Day	2 (20.0)	0 (0.0)	
At no specific time	2 (20.0)	0 (0.0)	
Assessment of health status			
Excellent	1 (10.0)	0 (0.0)	0.396
Very good	0 (0.0)	1 (10.0)	
Good	7 (70.0)	6 (60.0)	
Poor	1 (10.0)	3 (30.0)	
Very poor	1 (10.0)	0 (0.0)	

*Missing = 11; ** Missing = 9; an = not applicable

Effect of the intervention on pain intensity

Table 4 presents the pain intensity value at the times of assessment and reassessment of the individuals based on the BPI and VAS-P instruments. Regarding the BPI variables, an increase in pain intensity ($p=0.034$) could be observed in the CG individuals, and they complained of more intense pain at the time of reassessment ($p=0.011$). Furthermore, on reassessment, the individuals reported that the pain was interfering more intensely in the ability to walk, although this was not shown to be statistically significant. As to the TG, reduction in pain levels and less interference in daily life questions of the individuals were observed, and this was statistically significant in relation to the ability to walk ($p=0.041$).

Regarding the level of pain intensity, based on the categorized variables of VAS-P presented in median values, it was possible to visualize that the pain became more intense in the CG at the time of reassessment ($p=0.034$) in an intergroup comparison.

In table 5, the intergroup comparison is presented at the time intervals of assessment and reassessment of the individuals based on the BPI and VAS-P instruments. From the BPI variables it

Table 4. Intragroup comparison of pain intensity, based on variables of BPI and VAS-P, of the sample from an assigned UBS. Salvador, Bahia, Brazil

BPI	Control		p-value
	Before Median (P25-P75)	After Median (P25-P75)	
Categorized Intensity (zero to 10)	1.00 (0.00-2.00)	1.00 (1.00-2.00)	0.034
Value that shows how much pain you are feeling now	4.00 (0.00-7.00)	8.00 (5.00-9.00)	0.011
Interference of pain in general activity	5.50 (1.50-8.50)	5.00 (0.00-8.25)	0.646
Interference of pain in mood	5.50 (2.25-10.0)	5.50 (0.00-8.00)	0.540
Interference of pain in ability to walk	3.50 (0.00-7.25)	5.00 (0.00-8.25)	0.722
Interference of pain in work	5.00 (0.75-7.25)	5.00 (2.25-7.25)	0.758
Interference of pain in relationships with others	2.50 (0.00-7.50)	2.50 (0.00-5.50)	0.574
Interference of pain in sleep	7.00 (3.00-9.25)	6.00 (1.50-10.0)	0.758
Interference of pain in ability to appreciate life	4.00 (0.00-6.25)	1.50 (0.00-5.50)	0.672
BPI	Test		
Categorized Intensity (zero to 10)	1.00 (0.00-2.00)	0.00 (0.00-1.25)	0.102
Value that shows how much pain you are feeling now	5.00 (0.00-10.00)	2.00 (0.00-5.50)	0.120
Interference of pain in general activity	3.50 (0.00-9.25)	2.50 (0.00-5.25)	0.341
Interference of pain in mood	6.50 (0.00-9.75)	0.00 (0.00-3.25)	0.108
Interference of pain in ability to walk	4.00 (0.00-8.50)	0.50 (0.00-5.25)	0.041
Interference of pain in work	7.00 (0.00-10.00)	0.00 (0.00-9.00)	0.223
Interference of pain in relationships with others	4.00 (0.00-7.50)	0.00 (0.00-1.50)	0.149
Interference of pain in sleep	7.00 (0.00-9.25)	5.50 (0.00-10.00)	0.527
Interference of pain in ability to appreciate life	1.00 (0.00-8.50)	0.00 (0.00-5.50)	0.180
VAS-P (0 to 2)	Control		
	1.00 (0.00-2.00)	2.00 (1.00-2.00)	0.034
	Test		
	1.00 (0.00-2.00)	0.00 (0.00-1.25)	0.157

P25 = 25th Percentile; P75 = 75th Percentile.

Table 5. Intergroup comparison of pain intensity, based on variables of BPI and VAS-P, of the sample from an assigned UBS. Salvador, Bahia, Brazil

BPI	Before		After	
	Control Median (P25-P75)	Test Median (P25-P75)	Control Median (P25-P75)	Test Median (P25-P75)
Categorized Intensity (zero-10)	1.00 (0.00-2.00)	1.00 (0.00-2.00)	1.00 (1.00-2.00)	0.00 (0.00-1.25)
		1.000		0.009
Value that shows how much pain you are feeling now	4.00 (0.00-7.00)	5.00 (0.00-10.00)	8.00 (5.00-9.00)	2.00 (0.00-5.50)
		0.481		0.007
Interference of pain in general activity	5.50 (1.50-8.50)	3.50 (0.00-9.25)	5.00 (0.00-8.25)	2.50 (0.00-5.25)
		0.579		0.481
Interference of pain in mood	5.50 (2.25-10.0)	6.50 (0.00-9.75)	5.50 (0.00-8.00)	0.00 (0.00-3.25)
		0.796		0.218
Interference of pain in ability to walk	3.50 (0.00-7.25)	4.00 (0.00-8.50)	5.00 (0.00-8.25)	0.50 (0.00-5.25)
		0.912		0.190
Interference of pain in work	5.00 (0.75-7.25)	7.00 (0.00-10.00)	5.00 (2.25-7.25)	0.00 (0.00-9.00)
		0.529		0.579
Interference of pain in relationships with others	2.50 (0.00-7.50)	4.00 (0.00-7.50)	2.50 (0.00-5.50)	0.00 (0.00-1.50)
		0.842		0.143
Interference of pain in sleep	7.00 (3.00-9.25)	7.00 (0.00-9.25)	6.00 (1.50-10.0)	5.50 (0.00-10.00)
		0.853		0.684
Interference of pain in ability to appreciate life	4.00 (0.00-6.25)	1.00 (0.00-8.50)	1.50 (0.00-5.50)	0.00 (0.00-5.50)
		1.000		0.912
VAS-P (0 to 2)	1.00 (0.00-2.00)	1.00 (0.00-2.00)	2.00 (1.00-2.00)	0.00 (0.00-1.25)
		1.000		0.015

P25 = 25th Percentile; P75 = 75th Percentile.

was possible to observe that, after the six meetings, individuals in the TG had less intense pain than those in the CG ($p=0.009$). Moreover, the pain reported at the time was also less intense ($p=0.007$). In addition, it was observed that pain began to interfere less in all aspects of the lives of the individuals in the TG. As for the level of pain intensity, based on the categorized variables of VAS-P, presented in medians, in an intergroup comparison, it was possible to visualize that, after the intervention, the individuals in the TG had less pain than those in the CG ($p=0.015$).

Effect of the intervention on quality of life

The effect of the intervention on patients' quality of life was also tested. In the intragroup comparison after the results, it was possible to observe that the individuals in the CG considered their quality of life and health in general to be good, in both time intervals. However, in the TG, the quality of life was considered good, but the health was poor, and showed an improvement in the time interval after the intervention, when the categorized value increased from 1.0 to 1.5, but without statistical significance ($p>0.05$). Regarding the physical, psychological, social relationships and environmental domains, a discrete worsening was observed in the CG in the physical and environmental domains. In the TG, the physical domain was the only one in which no improvement was observed. However, there was no statistical significance in these analyses ($p>0.05$).

In the intergroup comparison and after the intervention it was possible to observe a statistically significant difference ($p=0.015$) between CG and TG in the social relationships' domain only.

DISCUSSION

This study sought to verify the effect of a health education program in individuals suffering from CP using the EducaDor booklet, in which reference is made to the intensity of pain and its repercussions on the participants' quality of life. The results pointed out the efficacy and safety of this light technology, which the health teams could immediately incorporate into the care they provide for people suffering from CP.

The sociodemographic characteristics of the sample showed a predominance of females with a low level of schooling. In the literature, a similar sociodemographic profile has also been found in previous studies²²⁻²⁴. The didactic approach adopted in the development of the EducaDor booklet¹¹ and its validation process¹², with the participation of those individuals affected by pain, who had a similar profile throughout all the stages of this study, are believed to have been fundamental for achieving the results obtained in the present RCT.

Populations who have received less attention from public policies and who are less educated in health also have a smaller chance of obtaining satisfactory results in different interventions, as shown by study²⁵. Therefore, if the effects were relevant for this sample, the belief is that they could be even more significant in people belonging to more favoured social classes, at both the educational and socioeconomic levels.

Pain intensity became worse in the CG, in both the BPI and VAS-P variables. Moreover, in the TG, it was observed that pain began to interfere less in relationships with others. Similar results

were found in studies assessing pain intensity before and after performing activities of education in health directed towards CP patients²⁶⁻²⁹.

Educational actions may develop positive changes in the behavior of individuals, reducing erroneous beliefs and broadening conscious attitudes towards the control of CP disturbances. The relief of symptoms by means of empowerment of the patients suffering from CP leads to hope and optimism that assist in their physical, emotional, and social recovery. As far as the quality of life is concerned, and although a trend towards improvement in the individuals of the TG in the present study was identified, this improvement was not proved from the statistical point of view. Apart from the chronic disease itself, other factors made it difficult for the impact on quality of life to be found relevant, since they involved losses of a personal, financial, and social nature³⁰. Previous studies have demonstrated that educational actions have improved the quality of life in CP patients in all the domains, except the physical domain²⁶⁻³¹. A hypothesis to explain this fact is that difficulties due to physical limitations may lead to social isolation, which was also observed in the present study³². Moreover, the time frame of six weeks between the initial and final assessments may have been insufficient to verify changes in the domains of quality of life, with the most perceivable effect being on the intensity of pain.

CP influences daily life and work activities and, consequently, this affects quality of life, because this is related to individual expectations. Therefore, although the design of the present study may have limited the assessment of the EducaDor booklet and its domains, the assessment of quality of life in future studies is recommended. However, without positive prognosis for cure, preventive actions in individuals with CP are fundamental for reducing functional incapacities that may arise from this condition of health and becoming ill^{33,34}.

During the data collection period, it was not possible to continue with the follow-up of 62 out of the 82 patients who performed the pre-tests. Notwithstanding the innumerable efforts made by the health teams and researchers, the losses to follow-up were inevitable. Populations with a low educational and socioeconomic level who suffer from CP have greater difficulties to remain in longitudinal studies, as observed in a previous study²⁶. These difficulties are probably even greater in residents of communities living with some level of danger, such as those of the present sample, due to being afraid of exposing themselves to this danger.

The low level of adherence to educational activities may have also been associated with the fact that the users of primary care still see attendance by the health service as an individual and curative action, in which drugs are the concrete alternative to meet their needs³⁵⁻³⁷. For the population to perceive the health system from a broader perspective, it's necessary, in the first place, for the professionals to believe in and bank on educational proposals, and these must be well planned and assessed.

The limited sample size prevented from verifying the efficacy of the other outcomes assessed, which suggests that further clinical trials should be developed to test the efficacy of the EducaDor booklet for the control of CP. Professional of primary health care should be trained to incorporate the socio-educational interven-

tions for the control of CP into their care programs/protocols. Regardless of the expressed limitations, the safety and efficacy demonstrated allows to suggest the EducaDor booklet wide application in services that attend to people suffering from CP.

CONCLUSION

This RCT aimed to assess the efficacy and safety of EducaDor booklet in health education of CP patients from primary health care units (UBS). The instruments used were the BPI, the VAS-P and the WHOQoL-bref. CP affects the participants' quality of life and social relationships, and this light technology is recommended for assisting in its control. Through the implementation of a health education program to a sample of 20 participants, it was found that the EducaDor booklet was shown to be effective and safe for the education of patients suffering from CP, by reducing the pain intensity and improving the quality of life. Despite the sample size, which will require further studies to prove the efficacy of the EducaDor booklet, it can be stated that these preliminary results are indicative of the importance to widely apply this kind of approach.

Beyond this main conclusion, another one needs to be highlighted, namely the capability to stabilize the level of pain, not allowing to increase. Moreover, it was clear that the use of light technologies, such as the EducaDor booklet, configures an important tool in adequate planning of the interventions in health, specifically in what related to CP. Although the results do not allow for conclusions about the instrument's impact on the control of CP in patients, the disclosure of the work design can contribute to similar studies, with adjustments that make data collection feasible. A smaller number of meetings, with condensed information, or carrying out the approaches through home visits, is suggested in future studies.

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AUTHORS' CONTRIBUTIONS

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Data Collection, Conceptualization, Project Management, Research, Methodology, Writing - Preparation of the original, Writing - Review and Editing, Software, Validation, Visualization

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