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ORIGINAL RESEARCH

Evaluating the Impact of a Training Program in Shared Decision-Making for Neurologists Treating People with Migraine

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ABSTRACT

Introduction: Migraine symptoms vary significantly between patients and within the same patient. Currently, an increasing number of therapeutic options are available for symptomatic and preventive treatment. Guidelines encourage physicians to use shared decision-making (SDM) in their practice, listening to patients' treatment preferences in order to select the most suitable and effective therapy. Although training for healthcare professionals could increase their awareness of SDM, results concerning its effectiveness are inconclusive. This study aimed to analyze the impact of a training activity to promote SDM in the context of migraine care. This was addressed by evaluating the impact on patients' decisional conflict (main objective), patient-physician relationship, neurologists' perceptions of the training and patient's perception of SDM.

Methods: A multicenter observational study was conducted in four highly specialized headache units. The participating neurologists received SDM training targeting people with migraine in clinical practice to provide techniques and tools to optimize physician-patient interactions and encourage patient involve-

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ment in SDM. The study was set up in three consecutive phases: control phase, in which neurologists were blind to the training activity and performed the consultation with the control group under routine clinical practice; training phase, when the same neurologists participated in the SDM training; and SDM phase, in which these neurologists performed the consultation with the intervention group after the training. Patients in both groups with a change of treatment assessment during the visit completed the Decisional conflict scale (DCS) after the consultation to measure the patient's decisional conflict. Also, patients answered the patient-doctor relationship questionnaire (CREM-P) and the 9-item Shared Decision-Making Questionnaire (SDM-Q-9). The mean ± SD scores obtained from the study questionnaires were calculated for both groups and compared to determine whether there were significant differences ($p < 0.05$).

Results: A total of 180 migraine patients (86.7% female, mean age of 38.5 ± 12.3 years) were included, of which 128 required a migraine treatment change assessment during the consultation (control group, $n = 68$; intervention group, $n = 60$). A low decisional conflict was found without significant differences between the intervention (25.6 ± 23.4) and control group (22.1 ± 17.9; $p = 0.5597$). No significant differences in the CREM-P and SDM-Q-9 scores were observed between groups. Physicians were satisfied with the training and showed greater agreement with the clarity, quality and selection of the contents. Moreover, physicians felt confident communicating with patients after the training, and they applied the techniques and SDM strategies learned.

Conclusion: SDM is a model currently being actively used in clinical practice for headache consultation, with high patient involvement in the process. This SDM training, while useful from the physician's perspective, may be more effective at other levels of care where there is still room for optimization of patient involvement in decision-making.

Keywords: Migraine; Headache; Shared decision-making; Decisional conflict; Training activity; Spanish

Key Summary Points

Why carry out this study?

Guidelines encourage physicians to use shared decision-making (SDM) in their practice, listening to patients' treatment preferences in order to select the most suitable and effective therapy

The evaluation of SDM training should consider different levels: reaction, learning, behavior and results. We used Kirkpatrick's model, which considers these levels, to evaluate training for physicians responsible for the management of migraine patients

What was learned from this study?

In highly specialized headache clinics, SDM is being actively used in practice to involve the patient in migraine care. Our findings highlight the low decisional conflict of the patients included in the study, and no differences were found between patients before and after the training addressed to physicians

Even though SDM training was useful from a physician's perspective, its impact on patient involvement in decision-making may be greater at other levels of care

INTRODUCTION

Migraine is a highly prevalent neurologic disorder affecting around 8–13% of the general population worldwide [1–3], especially young women [4], with similar prevalence rates in the Spanish population [3, 5, 6].

It is characterized by recurrent severe headaches that are often incapacitating and usually accompanied by a myriad of symptoms such as photophobia, nausea and/or vomiting [7]. This symptomatology makes migraine one of the

leading causes of years lived with disability in individuals under 50 years of age worldwide [4]. Apart from being prevalent and sometimes highly incapacitating, this disorder is quite heterogeneous among patients, meaning that migraine attacks and symptoms vary significantly between patients and even in the same patient over time. Thus, selecting the most suitable and effective therapy for each migraine patient may be challenging for physicians.

Furthermore, the therapeutic options available to treat acute episodes and prevent them have increased in recent years, and the treatment must be tailored to the characteristics and needs of each patient [8]. Therefore, current guidelines encourage physicians to listen to patients' treatment preferences and use shared decision-making (SDM) in their practice [9, 10]. The process of SDM is a joint procedure in which healthcare professionals (HCPs) share information with patients and jointly assess the therapeutic options available to decide on care. To date, SDM is not widely implemented in routine care: various studies indicate that the communication between HCPs and migraine patients is often insufficient, and HCPs pay little attention to patients' treatment preferences in clinical practice [11–13]. These findings are particularly relevant since the active participation of migraine patients in their treatment decisions apparently contributes to better control of the disease [14]. Thus, there is an urgent need to involve patients in their care and promote SDM among HCPs to optimize migraine care.

Different strategies have been published to promote SDM in HCPs [15, 16]. Among these strategies is HCP training in SDM, including specific training, case studies, role play or group discussion [15]. These formative activities have been shown to raise HCPs' awareness of the importance of SDM. However, results are inconclusive as to which type of training is most effective to promote SDM [15, 17, 18]. Likewise, the strategies to evaluate HCP training vary greatly among studies [16].

In the present observational study, we aimed to analyze the impact of a training activity targeting neurologists specialized in headache, "Conversations in Motion in Migraine and Other Headaches," to promote SDM in the context of migraine care. For our assessment, we applied Kirkpatrick's four-level model, the most well-established model for training evaluations [18, 19].

METHODS

We conducted this multicenter observational study between September 2020 and October 2021 to analyze the impact of the SDM training activity targeting neurologists.

To perform this analysis, we applied Kirkpatrick's model consisting of measuring the impact of the training on four levels: (1) reaction, (2) learning, (3) behavior and (4) results. The level 4 evaluation consisted of evaluating the results training on the ultimate beneficiaries, namely the patients. To do so, we used the Decisional Conflict Scale (DCS) tool [20], which assesses the decisional conflict that patients might experience regarding healthcare decisions. Since the evidence shows that greater patient involvement in SDM decreases their decisional conflict level [21–23], we hypothesized that patients whose physicians had participated in the intervention would exhibit a lower level of decisional conflict than those whose doctors had not. Thus, our main objective was to assess the impact of the training on patients' decisional conflict (level 4). Other objectives were to evaluate the impact of the training on the patient-physician relationship (part of level 4 assessment), to assess neurologists' perceptions of the training (which comprised the assessment at levels 1, 2 and 3), to assess the patients' perception of SDM (degree of involvement) (part of the assessment of level 3) and to analyze patients' self-confidence and willingness to participate in SDM.

The physicians who specialized in migraines and other headaches worked in four highly specialized headache management outpatient units at public hospitals in Spain: Hospital Clínico Universitario de Valladolid, Hospital Clínico Universitario Lozano Blesa, Hospital Clínico San Carlos and Hospital Universitario Fundación Jiménez Díaz.

The study was set up in three consecutive phases. In the first phase (control phase), neurologists were blind to the training activity and performed the consultation under routine clinical practice. This blinding consisted of the neurologists being unaware of the study design and objective and being invited to participate by other colleagues in the first phase for the collection of descriptive information from their patients. In the second phase (training phase), the same neurologists participated in the training; in the third phase (SDM phase), these neurologists performed the consultation after the SDM training (Fig. 1).

This study was conducted according to the Declaration of Helsinki, and the study protocol was approved by the Research Ethics Committees of the Hospital Clínico Universitario de Valladolid (Valladolid) (code: EPA 20-326). All the study subjects gave their informed consent to participate in the study.

Study Intervention and Participants

The neurologists who participated in the first phase (n = 5) were invited to the online intervention training "Conversations in Motion" in April 2021. This educational intervention was developed targeting people with migraine or other headaches in clinical practice. Its overall objectives were to provide techniques and tools to optimize physician-patient interactions and encourage patient involvement in SDM. The course contained four training modules: module 1, Shared decision making; module 2, Empathy and trust; module 3, Efficiency in practice; module 4, Medication adherence. Each module included lectures, case studies, role play or group discussion. The training lasted approximately 2 h, and all the participating neurologists had previously received pre-read material for each module. The session was led and delivered by headache specialist neurologists with years of experience in patient management and shared decision making.

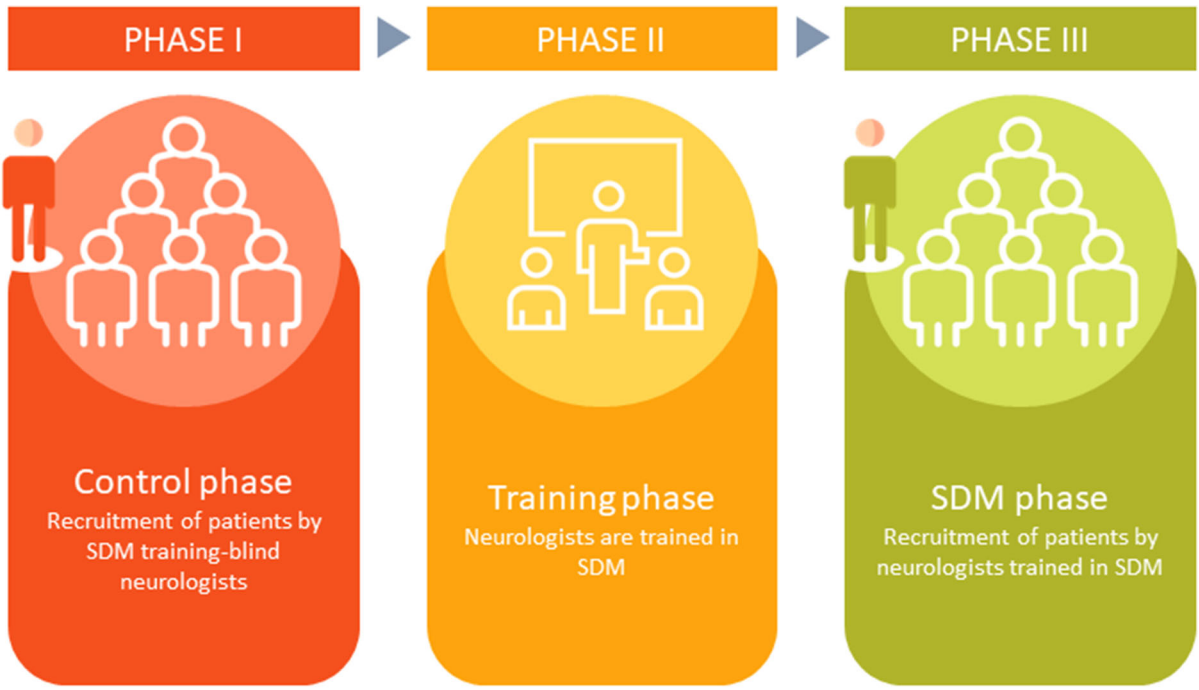

Fig. 1 Study design and intervention

The neurologists recruited patients in the control group (between September 2020 and April 2021) unaware of the training they would receive. Then, they recruited other patients in the intervention group after training (between May 2021 and October 2021). Patients were recruited on a consecutive sampling basis according to their attendance at the consultation, if they were ≥ 18 years with migraine diagnosis, were undergoing acute and/or preventive pharmacological treatment or might require it in the physician's opinion, and were able to participate in shared decision making and to understand and answer the questions in the questionnaires according to the researcher's criteria. Inclusion in the study was irrespective of whether they were new patients or under follow-up. Patients were excluded if they were participating in another clinical study on migraine, were receiving botulinum toxin or nerve blocking treatment, or decided to withdraw their participation during the study. All patients who met the inclusion criteria were informed about the study purpose and procedures and signed a written consent before inclusion.

Study Outcomes

Figure 2 shows which outcomes were recorded and data collection time points during the study phases.

Patients were invited to answer an online questionnaire before (all patients) and after participating in the neurologist visit (only patients for whom an assessment was made for a change of pharmacological treatment during consultation). At the same time, neurologists collected patients' socio-demographic (age, gender, education level) and clinical variables (type of migraine, time since diagnosis, number of previous treatment failures, assessment for a change of pharmacological treatment and decision after assessment) during the visits. The change of treatment evaluation included any assessment by the practitioner of the need for a change of drug, change of dose or dosage, introduction of a new drug, change to a new drug or discontinuation of current treatment. Also, neurologists were invited to answer an online survey after their participation in the training intervention.

Patients' Questionnaire

The patients' questionnaire comprised two parts: one to be filled in before the visit (part A) and the other to be filled in after the visit (only by patients for whom a change of pharmacological treatment was evaluated) (part B).

Part A of the questionnaire consisted of two scales: the 11-item Decision Self-Efficacy Scale (DSES), which assessed patient's self-confidence in making informed decisions (final scores range from 0 to 100, with 100 being the highest level of patients' self-confidence in SDM) [24], and an ad-hoc questionnaire which assessed patients' preferences regarding models of SDM (patients were asked to select 1 model out of 5; Supplementary Table 1). This questionnaire was developed based on the preferences and vignettes outlined by Solari et al. [25].

Part B comprised three scales: the DCS, which was first adapted and validated by our group in a previous study [26] and consists of 16 items to assess the decisional conflict that patients might experience during SDM (final scores ranged from 0 to 100, 100 being the highest decisional conflict) [20]; the patient-doctor relationship questionnaire (CREM-P, for its Spanish acronym *Cuestionario de relaciones medico-paciente*) consisting of 13 items that evaluated the quality of the patient-physician relationship, 1 being the highest quality of relationship and 6 the lowest [27]; the 9-item Shared Decision-Making Questionnaire (SDM-Q-9), which evaluates the degree of patient involvement in the shared decision-making process (total scores range from 0 to 100, 100 being the highest level of patient involvement in SDM) [28, 29]. To use these validated questionnaires, the appropriate permissions were requested and acquired from the developers where necessary.

Neurologists' Questionnaire

The neurologists' ad-hoc questionnaire had three sections: "Introduction," satisfaction with the training (8 items), "Methods," acquired

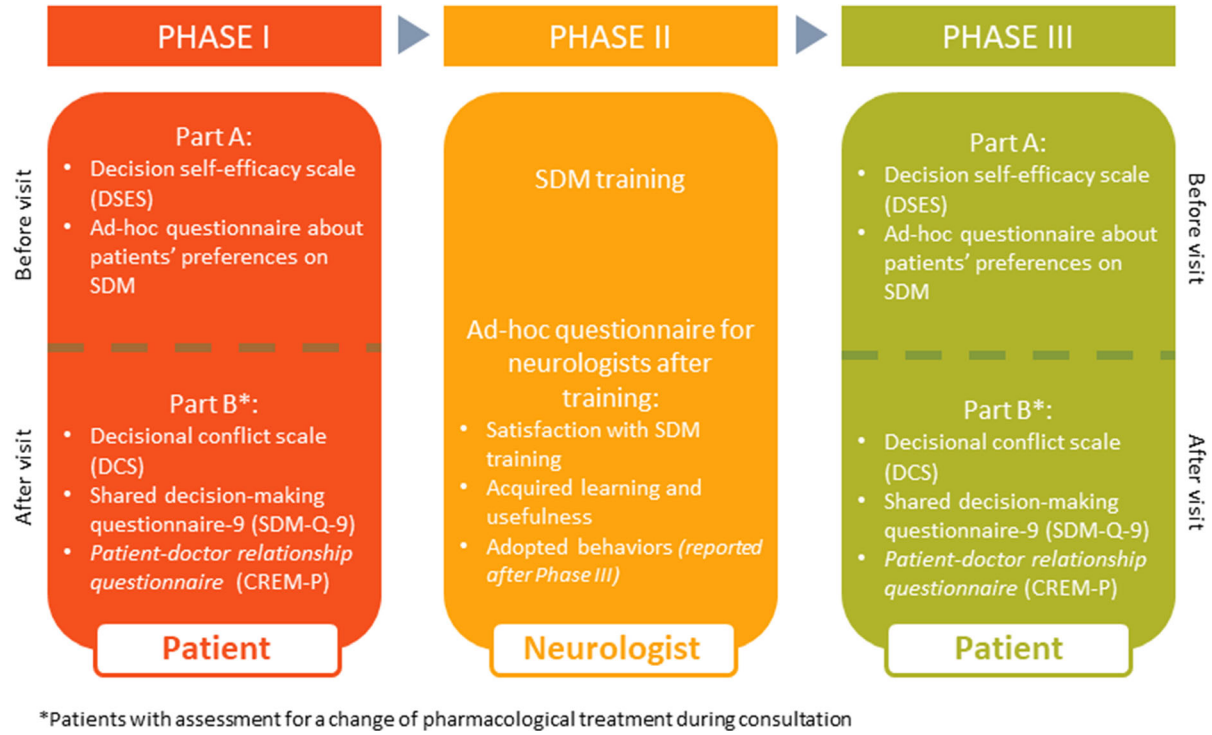

Fig. 2 Study variables and data collection time points

learning and its usefulness (10 items); "Results," adopted behaviors (4 items). Neurologists were asked to score each statement from 0 to 4 (0 = totally disagree and 4 = totally agree). Neurologists completed "Introduction" and "Methods" after the training (Supplementary Table 2) and "Results" after the recruitment of the intervention group (Supplementary Table 3).

Study Analysis

Sample Size

The migraine patients' sample was estimated in accordance with our study hypothesis, which proposed that the decisional conflict of patients recruited post-intervention would be significantly lower than that of those recruited pre-intervention.

Accordingly, we determined that a minimum sample of 132 (66 in each of the control and the intervention groups) was necessary to detect an effect size of 0.4 standard deviation (minimal clinically meaningful difference) on the DCS between groups [20]. This sample size provides a 90% power and a one-sided confidence level of 95%. The minimum sample size amounted to 146 patients (73 per group) when 10% losses were considered.

Descriptive Analysis

For the descriptive analysis, qualitative variables were estimated using absolute and relative frequencies, whereas quantitative variables were calculated by measures of central tendency and dispersion (mean, standard deviation [SD], percentile, maximum and minimum).

Analysis by Objectives

Main Objective: Impact of Training on Patients' Decisional Conflict (Level 4) To answer the study's main objective, the mean score and standard deviation (± SD) of the DCS for control and intervention groups were calculated. These scores were compared to determine if there were statistically significant differences ($p < 0.05$) using the Wilcoxon rank test for non-normal distributions. In addition, a

multiple linear regression was performed to identify the determinants of the decisional conflict where the independent variable was the overall DCS score, and the dependent variables were patients' socio-demographic and clinical variables and the group they belonged to (control and intervention).

Secondary Objective: Impact of the Training on the Patient-Physician Relationship (Part of the Level 4 Assessment) The impact of SDM training on the physician-patient relationship was evaluated as part of the level 4 assessment. The mean (± SD) scores obtained from the CREM-P were calculated from both groups and compared to determine whether there were significant differences ($p < 0.05$). For this purpose, Student's *t*-test or the equivalent nonparametric test was used if the data did not follow a normal distribution. Additionally, a correlation analysis was performed between the results of the DCS and CREM-P.

Secondary Objective: Neurologists' Perceptions of the Training (Levels 1, 2 and 3) To establish the neurologists' satisfaction with the training (level 1), the mean (± SD) of the sum of the scores of all 8 items was estimated (scale 0–32). Additionally, the answers to each item were grouped into the following categories: disagree (0 and 1 points), neither agree nor disagree (2) and agree (3 and 4), and the frequencies of patients' answers were estimated. To estimate the learning acquired and its usefulness (level 2) and the behaviors adopted (level 3), the frequencies of patients' answers to "disagree," "neither agree nor disagree" and "agree" were estimated for each item.

Secondary Objective: Impact of the Training on the Patients' Perception of SDM (Part of the Assessment of Level 3) The impact of SDM training on patients' degree of involvement in SDM was evaluated as part of the level 3 assessment. The mean (± SD) scores of the SDM-Q-9 questionnaire were calculated for both groups and compared to determine whether there were significant differences ($p < 0.05$). For this purpose, Student's *t*-test or the equivalent nonparametric test was used if the data did not follow a normal distribution.

Secondary Objective: Patients' Self-confidence and Willingness to Participate in SDM To determine patients' self-confidence in decision-making, the mean (± SD) was estimated from the answers given by all patients to the DSES. In addition, the frequency of responses to each option was estimated to determine patients' desired degree of involvement in SDM.

The data analysis was performed using the STATA version 14 statistical software package. Results were considered statistically significant for all the statistical tests when $p < 0.05$.

RESULTS

Patient Characteristics

A total of 180 migraine patients from the four participating centers comprised the final sample. Most (86.7%) were female with a mean age of 38.5 ± 12.3 years. Figure 3 shows the distribution of the patients included in each group (control and intervention) and within each group, those who participated in a treatment change evaluation in their visit and those who did not.

Of the 180 patients included in the study, 145 underwent a treatment change evaluation during their visits. During the DCS validation analysis (results detailed by Guerrero-Peral et al. [26]), 17 patients gave inconsistent answers to the different study questionnaires, with high scores for all of them (DCS > 80, SDM-Q-9 > 80, and DSES > 70), attributed to a lack of attention and comprehension of the questionnaires. Therefore, they were considered missing data, resulting in 128 patients for the evaluation of the study's primary objective ($n = 68$ in the control and $n = 60$ in the intervention group). Table 1 shows the details of the overall study population ($N = 180$) and patients analyzed with treatment change evaluation ($N = 128$).

In more than 80% of patients in both groups, there was a drug change or the addition of a new drug to current therapy as a result of the treatment change assessment.

Main Objective: Impact of Training on Patients' Decisional Conflict (Level 4)

Overall, patients (n = 128) presented a low decisional conflict with a mean score of 23.7 ± 20.6 for DCS. No significant difference was seen regarding the DCS scores between the intervention group (25.6 ± 23.4) and the control group (22.1 ± 17.9; p = 0.5597) (Fig. 4).

Regarding the determinants of decisional conflict, the multiple regression showed that only educational level affected the DCS score (p = 0.041) with a coefficient of − 8.065, indicating that patients with higher education had a lower decisional conflict than those with a basic educational level (21.2 ± 17.3 vs. 29.3 ± 25.9). Although age and the number of previous treatment failures between the groups showed significant differences (Table 1), they were not factors affecting decisional conflict.

Secondary Objectives

Impact of the Training on the Patient-Physician Relationship (Part of the Assessment of Level 4)

Overall, patients (n = 128) rated their relationship with doctors very positively, with a mean score of 5.3 ± 0.8 on the CREM-P questionnaire (6 = best relationship possible). As for the DCS, no significant differences in the CREM-P scores were observed between the intervention group (5.3 ± 0.8) and the control group (5.3 ± 0.8; p = 0.768). In addition, the correlation analysis between CREM-P and DCS scores showed an inverse and moderate correlation for both intervention (− 0.4286) and control (− 0.4811) groups.

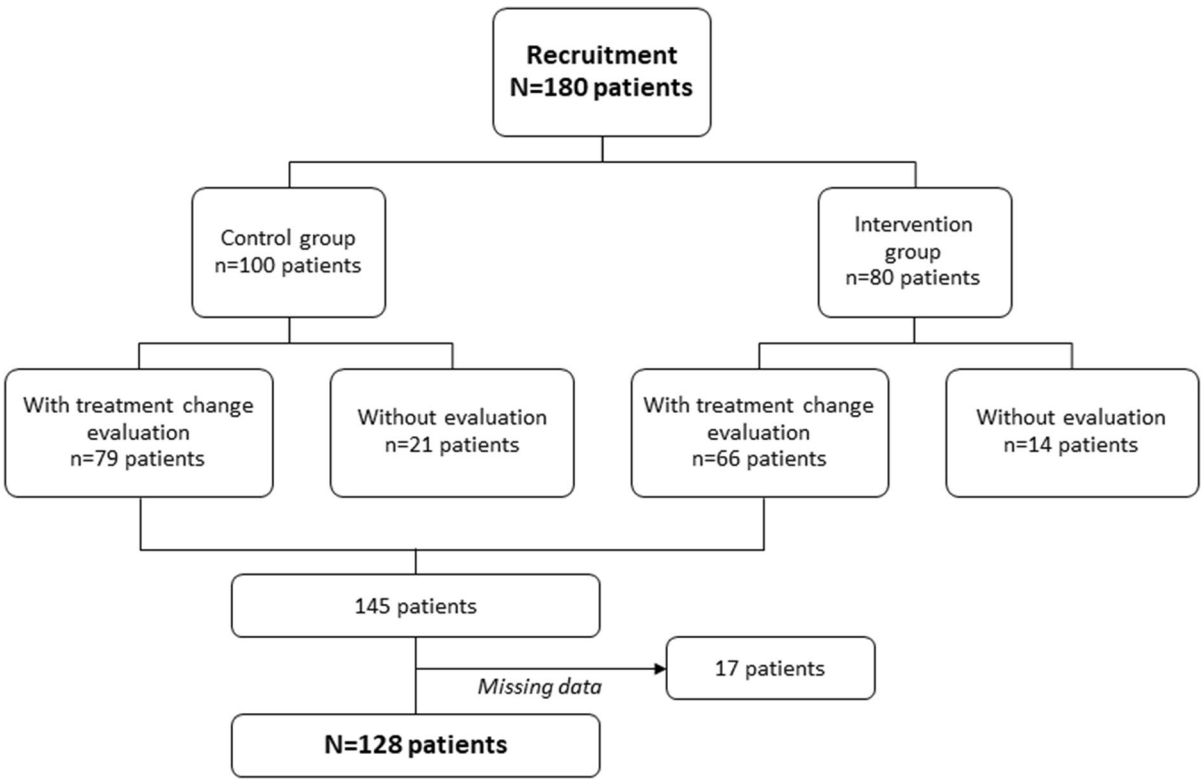

Fig. 3 Distribution of patients in groups and according to whether a change of pharmacological treatment was evaluated during the visit

Table 1 Socio-demographic and clinical characteristics of the study population

Characteristics		Overall study population (N = 180)	Population with treatment change evaluation (N = 128)	Control group (N = 68)	Intervention group (N = 60)	Control vs. intervention p value
Age, mean (SD)		38.5 (12.3)	39.0 (12.4)	36.7 (12.8)	41.6 (11.6)	**0.016***
Gender, %	Male	13.30	14.70	14.70	11.70	0.613
	Female	86.70	85.30	85.30	88.30	
Education level, %	Primary education	6.10	7.00	7.40	6.70	0.626
	Secondary education	25.60	24.20	25.00	23.30	
	Vocational training	26.70	22.70	26.50	18.30	
	University or higher education	41.70	46.10	41.20	51.70	
Time since diagnosis, years, mean (SD)		14.7 (13.8)	14.3 (13.8)	15.4 (14.2)	13.2 (13.2)	0.377
Type of migraine, %	Low-frequency episodic migraine (4–7 HDs/month)	41.10	39.10	41.20	36.70	
	High-frequency episodic migraine (8–14 HDs/month)	27.20	32.00	32.40	31.70	
	Chronic migraine (≥ 15 HDs/month)	31.70	28.90	26.50	31.70	0.791
Number of previous treatment failures, %	Without failure	45.00	50.00	39.70	61.70	**0.023***
	1–2 failures	28.90	32.80	35.30	30.00	
	≥ 3 failures	26.10	17.20	25.00	8.30	

*Statistically significant

Secondary Objective: Neurologists' Perceptions of the Training (Levels 1, 2 and 3)

All five neurologists participating in recruitment and training responded to the ad hoc questionnaire.

Overall, physicians were satisfied with the training (level 1) with a mean of 22.8 ± 6.7 points (with a scale of 0–32; higher values indicate greater satisfaction). Among the questions evaluated, physicians showed greater agreement with the clarity of the presentation

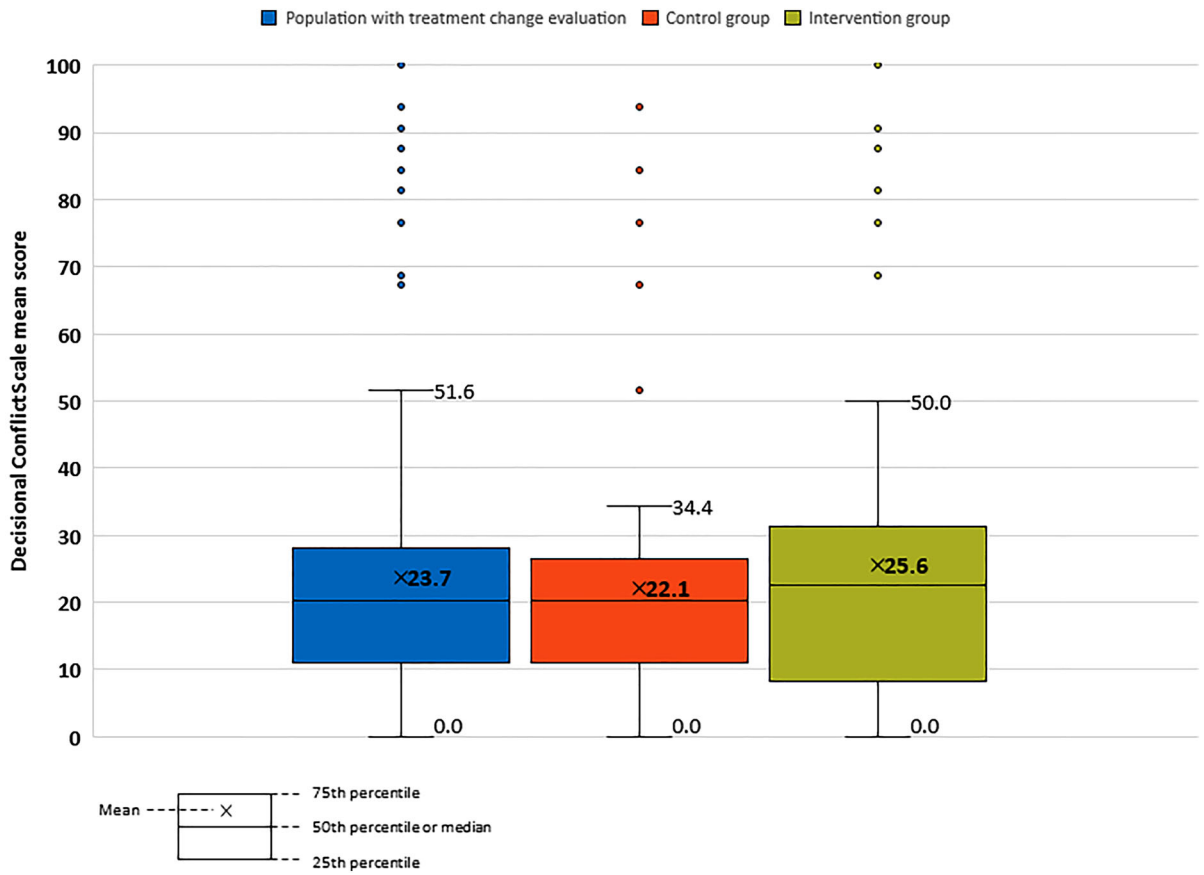

Fig. 4 Decisional conflict scale scores for all patients with treatment change evaluation (N = 128), patients in the control group (N = 68) and patients in the intervention group (N = 60)

(100% agreed) and with the quality and choice of the contents (80% agreed) (Supplementary Fig. 1). However, their agreement was not so strong on the content depth (40% agreed) or duration of the training (40% agreed). In addition, most physicians agreed that the training had enabled them to acquire new knowledge and skills related to SDM and found it useful for their practice (level 2) (Supplementary Fig. 2). However, their level of agreement was lower when asked if the course had increased their motivation to communicate with their patients (40% agreed). As for the behaviors adopted (level 3), all physicians agreed that they felt confident communicating with patients after the training. Similarly, most of them agreed that they had applied the techniques and SDM strategies learned in their clinical practice (80% agreed) (Supplementary Fig. 3).

Impact of the Training on the Patients' Perception of SDM (Part of the Level 3 Assessment)

Overall, patients' (n = 128) degree of involvement in the SDM process was substantial, with a mean score of 79.0 ± 19.4 (100 = highest involvement measured by the SDM-Q-9 questionnaire). In this case, there were also no significant differences between groups, with a mean score of 77.8 ± 21.7 for the intervention group and a mean of 80.1 ± 17.3 for the control group (p = 0.752).

Patients' Self-confidence and Willingness to Participate in SDM

The degree of confidence in making therapeutic decisions was high among the whole sample (N = 180), with a mean of 81.1 ± 14.0 in the DSES (100 = highest degree of confidence). Also,

most patients (93.3%) expressed their wish to discuss the therapeutic options with their clinicians, and 43.9% considered it appropriate to make the final decision about their treatment jointly with their physicians.

DISCUSSION

This study aimed to evaluate the impact of a training activity targeting healthcare professionals involved in the management of headaches "Conversations in Motion in migraine and other headaches" to promote SDM in the context of migraine care. To perform this assessment, we applied the most well-established method for this type of evaluation, namely the Kirkpatrick's model [18, 19], based on a four-level evaluation: (1) reaction, (2) learning, (3) behavior and (4) results. Our main objective focused on level 4 assessment by measuring the impact of training on patients' decisional conflict.

In this respect, we did not observe significant differences in decisional conflict between those patients in the intervention group and those in the control group, suggesting that the training neurologists received did not ultimately impact the patients' decisional conflict or other aspects of the SDM process. Our results could be explained by the fact that the study involved highly specialized units, where patients are managed with an exceptional degree of awareness of their disease and where professionals are highly qualified. The lack of impact on patients' decisional conflict resulting from a decisional support intervention due to excellence in the clinical approach of specialized units has previously been highlighted in another study [30].

Patients in our study also demonstrated great involvement in the SDM process. Most of them wished to discuss the therapeutic options with the physician, and almost half also expressed their willingness to make therapeutic decisions together with their physician; this is reflected in their low decisional conflict values, which are lower than those reported for other patients [31–33]. We hypothesized that a reduction in an already low conflict would be difficult to detect. Proof of this is that we detected a slight floor effect of the DCS scores in a previous validation study. This effect might mean that the DCS has a lower ability to discriminate between patients with lower scores (low decisional conflict); therefore, an eventual decrease in patients' decisional conflict might be difficult to detect. The fact that we did not observe an apparent effect of the intervention on the patients' decisional conflict is not new and was also observed in other studies with breast cancer patients [34]. When we evaluated the possible determinants for the decisional conflict, we found that it was only affected by educational level, being higher in patients with lower educational levels. Patients' educational background and health literacy have already been identified as one of the most important elements to consider in patients' readiness for SDM [35]. Thus, our results support the idea that patients with a lower educational level have higher decisional conflict and are less prepared for SDM in practice, which should be considered by physicians when implementing SDM tools.

Regarding the decisional conflict, we obtained similar results when evaluating the influence of the intervention on other aspects of SDM, such as patients' degree of involvement in the SDM process through the SDM-Q-9 questionnaire or on the patient-physician relationship measured by the CREM-P. In those cases, the population also displayed ample involvement, high-quality relationships with their doctors and no significant differences between groups. The explanation for this may be similar to that for decisional conflict since the score for migraine patients regarding SDM involvement (around 80 points) was higher than that obtained in other populations [36, 37]. As with the DCS, the ability of SDM-Q-9 to capture improvements in the SDM process was limited given the consistently high scores obtained from our patients. In any case, results in other studies prove that educational interventions for professionals do not significantly impact patients' SDM-Q-9 scores, as in our study [36, 37].

Although we could not confirm the efficacy of the intervention on patients, we did corroborate the intervention's impact on its direct recipients, i.e., the neurologists, at three

different levels. First, neurologists were generally satisfied with the training, being unanimous on the clarity of the presentation and mostly satisfied with the appropriateness of the contents (level 1—reaction). Second, neurologists agreed that the training had enabled them to acquire new knowledge and skills related to SDM (level 2—learning). Third, physicians agreed that the training had enabled them to involve the patient more in SDM, and they felt confident with their communication skills with patients and with the implementation of SDM in their practice (level 3—behavior). The latter point suggests that the neurologists implemented the strategies learned during the course with patients in the intervention group, although no differences were found in this group of patients concerning the control group. These results were in line with other evaluations of SDM courses for other medical specialists and supported the implementation of these programs: specialists were in general satisfied with these interventions [38–42]; they acknowledged that these interventions increased their knowledge [43–45]; they considered that training had made them more competent in SDM [44, 46] and in communication skills with patients [42, 47–50] and had taught them to use consultation time more appropriately [41].

This study presents some limitations which should be mentioned. First, the patients included in the group and the intervention group were different. In this regard, we believe our approach was appropriate since we evaluated training aimed at professionals rather than a decision-making tool aimed at patients. Also, it was not feasible to evaluate the impact of the intervention on two different treatment change processes for the same patients since this does not frequently occur in clinical practice. In any case, we ensured that the groups' characteristics were similar in terms of age, gender and experience with the disease. Second, another potential limitation of the study is that it did not consider other conditioning factors of decisional conflict such as anxiety and depression, which are common conditions in the migraine population [51] and could have an impact on shared decision-making [52]. Third, one of the major disadvantages of the research using online questionnaires and electronic patient-reported measures is that there could potentially be a 'digital divide' since older people or those with no access to electronic infrastructure could be not included [53]. Nevertheless, migraine is a chronic disease mainly affecting adults whose usual age range is not a problem for the use of new technologies. In our case, the mean age of the study population was 38.5 (12.3) years. Even so, considering that these problems could occur, electronic devices were available for patients before and after the consultation to complete the questionnaires in the waiting room and assistant staff of the consultation gave support to the patients whenever necessary. Fourth, the professionals who participated in the training were physicians involved in highly specialized clinics in the management of headache patients, and they may not represent all those who attend migraine patients, such as non-headache neurologists or primary care physicians. The latter are often the gateway to the healthcare system for these patients, and they are normally responsible for their diagnosis and follow-up. In addition, we hypothesized that the inclusion of these neurologists may have contributed to the fact that there were no differences between the control and intervention groups since these specialists have more experience than others in communicating and engaging with migraine patients in their care and therapy decisions. Further studies should investigate the impact that this training has on other levels of care or specialization and involving a larger sample of professionals, which would allow us to hone in on the results perceived by the physician.

Notwithstanding, the study has important strengths. Among them, we highlight that we used the most established evaluation, i.e., the Kirkpatrick's model [18, 19], which has proven to be useful for the design and analysis of strategies in the evaluation of SDM training for healthcare professionals [16]. Therefore, we consider our evaluation methodology robust, especially knowing that these evaluations have not generally addressed all assessment levels or do not do so following an established methodology [16]. Another strength of this study is that we evaluated the SDM process from different

perspectives, such as the decisional conflict, degree of patient involvement in the DCS, patient self-confidence and relationship between the physician and patient. In this respect, our results have enabled us to better characterize patients with migraine in terms of their involvement in the SDM process.

CONCLUSIONS

Our results show that SDM is currently a model that is actively used in clinical practice in the context of headache consultation, but there is still room for improvement. The model of patient-physician collaboration and SDM should be adjusted according to patient's preferences, and evaluation should consider the results obtained with the treatment together with the physician's and patient's perception of the process.

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Compliance with Ethics Guidelines. This study complies with the Declaration of Helsinki

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request. Lilly provides access to all individual participant data collected during the study, after anonymization, with the exception of pharmacokinetic or genetic data. Data are available to request 6 months after the primary publication acceptance. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data-sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at www.vivli.org.

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