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A shared decision-making communication training program for physicians treating fibromyalgia patients: Effects of a randomized controlled trial

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Abstract

Objective: Fibromyalgia syndrome (FMS) is a condition of chronic widespread pain that is difficult to control and is associated with strains in physician–patient interaction. Shared decision making (SDM) can be a potential solution to improve interaction. We evaluated the effects of an SDM intervention, including an SDM communication training program for physicians, in a randomized controlled trial with FMS patients. The main objective was to assess whether SDM improves the quality of physician–patient interaction from patients' perspective. **Methods:** Patients were randomized to either an SDM group or an information-only group. The SDM group was treated by physicians trained in SDM communication and had access to a computer-based information package; the information-only group received only the information package and was treated by standard physicians. All patients were offered the same evidence-based treatment options for FMS. Patients were assessed with questionnaires on physician–patient interaction (main outcome criteria) and decisional processes. Physicians filled out a questionnaire on interaction difficulties. Assessment took place immediately after the initial consultation. **Results:** Data from 85 FMS patients (44 in the SDM group and 41 in the information-only group) were analyzed. The mean age was 49.9 years (S.D.=10.2), and 91.8% of patients were female. The quality of physician–patient interaction was significantly higher in the SDM group than in the information-only group ($P<.001$). We found no differences in secondary outcome measures. **Conclusions:** SDM with FMS patients might be a possible means to achieve a positive quality of physician–patient interaction. A specific SDM communication training program teaches physicians to perform SDM and reduces frustration in patients.

Keywords: Chronic pain; Communication training; Fibromyalgia syndrome; Physician–patient interaction; Shared decision making; Randomized controlled trial

Introduction

In chronic pain conditions, the quality of physician–patient communication can facilitate or impede effective treatment [1–5]. Fibromyalgia syndrome (FMS) is a chronic, pervasive, painful condition that is difficult to control; attempts to treat the syndrome often lead to frustration and resignation on the part of the patient and the physician alike.

According to American College of Rheumatology (ACR) classification criteria, FMS is characterized by pain affecting the whole musculoskeletal system and by well-defined tender points [6]. Additionally, patients often present with various vegetative and functional symptoms such as sleep disturbance, fatigue, dizziness, cognitive dysfunction, recurrent headaches, and irritable bowel syndrome; comorbidity with anxiety and depression is high [7–10]. The prevalence of FMS is as high as 3.4% in European and North American countries, and women are seven to nine times more often afflicted than men [6,11,12]. The pathophysiological origins of FMS still remain widely unknown, and its etiology seems to be complex and multifactorial, involving somatic, psychological, and

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social components [13–15]. Unfortunately, there is as yet no cure available, so treatment options aim at alleviating symptoms [14].

Physician–patient interaction with FMS patients is often considered to be difficult [1–5]. Doctors characterize FMS patients as illness focused and demanding, and often find themselves in a dilemma due to the uncertainty inherent in FMS [4]. From patients' perspective, negative experiences during medical encounters include being met with skepticism and lack of comprehension; feeling rejected and ignored; and being belittled [1]. Friction in the patient–physician relationship is a common and frequently underestimated problem during FMS patients' consultations [5]. The inability to understand doctors' explanations and skepticism of the treatment can lead to an impaired physician–patient relationship and consequent dropout from treatment [16].

Given these therapeutic uncertainties and communication challenges, interactive principles inherent in "shared decision making" (SDM) may function as a model for more successful interactions between physicians and FMS patients.

SDM stresses the idea of partnership between physicians and patients when it comes to arriving at therapeutic choices in preference-sensitive decision situations. In physician–patient interaction, SDM bridges the gap between the assumption of exclusive responsibility for medical decisions, which is inherent in paternalistic approaches, and the concept of informed patient choice, which is inherent in approaches emphasizing patient autonomy [17–20]. Since the 1990s, the awareness of SDM in the general public and among practitioners has risen, apparently due to greater access to medical information, increasing trends in medical "consumerism," and a growing awareness of the patients' perspective [20].

An important element in SDM is the mutual exchange of information between doctor and patient. In an illness in which treatment options involve tradeoffs between the potential benefits and harm of therapy and uncertain outcomes, two kinds of knowledge are needed to manage an illness successfully: knowledge held by the physician, who is an expert in technical aspects of care, and knowledge held by the patient, who holds expert knowledge about one's unique circumstances (e.g., one's social situation, attitudes to risk, values, and preferences) [17,21,22]. When doctors consult according to SDM principles, they are careful to integrate their patients' perspective into the decision-making process. This requires certain key competencies, such as inviting patients explicitly into the decision-making process, checking patients' role preference, explaining the notion of medical equipoise and available options, checking patients' understanding, identifying and responding to any expectations and fears, and, finally, negotiating a treatment decision [19,23].

Several positive effects of treatment in accordance with SDM principles have been demonstrated in studies on chronic disease: It may have beneficial effects on clinical outcome as measured physiologically, psychologically, functionally, and subjectively [24–29]. SDM can also improve patients' satisfaction with their decisions and reduce their decisional conflicts [30].

To date, considerable attention has been devoted to the development and testing of SDM information materials for patients [31–33], but relatively little attention has been directed towards the systematic development and testing of ways to teach SDM transactional skills to physicians [30,34–36]. In spite of widespread agreement among physicians that patient preferences be considered when treatment decisions are made, skills to perform SDM are often lacking [20,37].

With interaction difficulties being obvious in FMS and with reasonable expectations that SDM might improve the situation, we found that it would be promising to implement an SDM intervention simultaneously focusing on FMS patients and their physicians.

The main objective of this study was to test whether the quality of physician–patient interaction from the patients' perspective could be improved by introducing principles of SDM to the physician–patient dyad in the management of FMS. We hypothesized that an intervention combining an information package for FMS patients with an SDM communication training program for physicians would lead to better physician–patient interaction when compared with a control group in which an information package was provided to patients but no special training was provided to physicians.

Methods

Study design

In a randomized controlled trial, we compared an SDM communication training group (hereafter referred to as SDM group for better readability) with an information-only group. All patients who were referred to the university's rheumatologic outpatient clinics for an initial consultation, with generalized muscle pain as main complaint, were asked for informed consent to participate in the study. A central coordination office ensured allocation concealment and carried out simple randomization of consenting patients either to the SDM group or to the information-only group by use of a random number generator. The waiting period for the first appointment for all patients was between 2 and 3 months, which is common for patients in this setting. By prescheduling consultations, we ensured an equal amount of treatment time for all patients.

Although cluster randomization of general practices would have been the favored allocation method, we chose individual randomization of patients due to reasons of feasibility: Since FMS is a rather rare disease, the average general practitioner in Germany takes care of only one or

two FMS patients. We anticipated that none of these doctors would have been willing to participate in our training for such few patients. Therefore, we moved our research to specialized clinics with a small number of doctors and a high number of relevant patients. For this situation, individual randomization of patients was the most valid design.

Patients were informed that the study involved testing different communication strategies, but they were blinded to the specific label of the study group to which they had been allocated. Blinding of physicians was not possible because the nature of the intervention demanded an active procedure. However, physicians were blinded with regard to evaluation strategies. To avoid experimental contamination in terms of information flow between SDM physicians and information-only physicians, the entire physician team of one of two outpatient clinics was assigned to the SDM communication training program, while the other team was not.

Physicians' adherence to protocol was ensured by audiotape recording of all consultations.

During the first consultation, all patients were offered the same evidence-based treatment options for FMS, as follows: physiotherapy, medication (antidepressants and analgesics), integrated group therapy for FMS patients [38], relaxation techniques, and exercise [9].

Assessment of all patients and their doctors with standardized questionnaires took place immediately after the first consultation (T_1).

The study was approved by the ethical board of the University of Heidelberg.

Participants and setting

Patients

Patient recruitment took place from January 2002 to January 2003 in two comparable rheumatologic outpatient clinics at the University of Heidelberg.

Inclusion criteria for all patients were as follows: a diagnosis of FMS according to ACR criteria [6], age between 18 and 70 years, and sufficient knowledge of the German language. Exclusion criteria were as follows: existence of serious psychiatric (e.g., major depressive disorder, psychosis) or somatic comorbidities (e.g., cancer, inflammatory diseases, systemic diseases) and failure to come to the first appointment. Patients were only included in the study if the diagnosis of FMS could be confirmed during the first consultation.

Physicians

The entire physician teams of both rheumatologic outpatient clinics of the University of Heidelberg participated in the study, with four physicians treating the SDM group and six physicians treating the information-only group. An SDM communication training program was administered to the four SDM physicians from October 2001 to December 2001. All 10 physicians specialized in internal medicine and were comparable with regard to their characteristics: SDM physicians had a mean age of 30.8 years (S.D.=2.3), 50% of them were female, and they had a mean length of working experience of 1.5 years (S.D.=0.3). Information-only group physicians had a mean age of 30.6 years (S.D.=3.5), 50% of them were female, and they had a mean length of working experience of 2.3 years (S.D.=1.1).

Interventions

Interventions consisted of two different modules targeting patients (Module I) and physicians (Module II). The two groups varied in the way in which they received Module II:

- The SDM communication training group (intervention group) received a complete SDM intervention combining both modules (information package and consultation with an SDM-trained physician).
- The information-only group (control group) only received the information package (Module I). Their consultation was carried out with a standard physician who had not been trained in SDM communication. This allowed us to control for the amount of attention patients received.

Module I: computer-based visualized information package on FMS

We developed and evaluated a computer-based visualized information package on FMS that informs about common symptoms, diagnosis, pathogenesis, treatment options, and prognosis. This information package has been described in detail in a separate paper [39]. It combines text information with diagrams, and short video sequences are used for additional illustration. It was designed in accordance with DISCERN criteria (the first standardized index of the quality of consumer health information) [40] and certified by Aktionsforum Gesundheitsinformationssystem (AFGIS, a German quality standard for medical Web sites on the Internet). All patients had access to the information tool during the first consultation before they discussed treatment with their physicians. A medical assistant introduced them to the computer-based information program and, if necessary, helped them to use it.

Module II: SDM communication training program for physicians

We enrolled physicians in a specific training program to ameliorate their patient-centered communication and interaction skills and to enable them to perform SDM. The training program consists of 12 sessions (1.5 h per session) and has been described elsewhere [41]. Its main focus is on practicing competencies needed for the SDM process [19,23,42] and on building a good working alliance with the patient. Interactive talks and role plays are used, and

instructional videos with standardized patients are analyzed to acquire the necessary competencies. Sensitivity to deliberate and unconscious signals of verbal and nonverbal communications is trained. Specific steps in SDM are practiced: inviting patients explicitly into the decision-making process, checking patients' role preference, explaining the notion of medical equipoise and available treatment options, checking patients' understanding and further need for information, identifying and responding to any expectations and fears, and, finally, negotiating a treatment decision.

Measures

Patients and their doctors were assessed with the following standardized questionnaires.

Primary outcome variable: quality of physician–patient interaction

The primary outcome variable was the quality of physician–patient interaction from the patients' perspective. It was assessed using the 14-item Questionnaire on Doctor–Patient Interaction (FAPI) [43], which was developed in a prestudy. All items focus on aspects of the physician–patient interaction, such as adequate imparting of information, involvement in medical decisions, and a feeling of being taken seriously by the physician. It features items such as "The physician's explanations were easily comprehensible to me" or "The physician asked about how my illness will affect my everyday life." All items are averaged to yield an overall score that ranges from a minimum of 1 (*lowest quality*) to a maximum of 5 (*highest quality*). The FAPI was validated with a sample of 147 patients from outpatient clinics for general internal medicine, diabetes, rheumatology, and pain. It shows good psychometric properties [i.e., high internal consistency (Cronbach's α=.96) and discriminative validity] as it is independent of doctors' rating of patient satisfaction (r=.12) and not biased by social desirability (r=−.06) [43]. One of the main advantages of the FAPI compared to other questionnaires on patient satisfaction is the absence of a ceiling effect. FAPI scores showed nearly normal distribution and, therefore, the FAPI is suitable for assessing improvement in the quality of physician–patient interaction.

Secondary outcome variables

Secondary outcome variables concerned the decision-making process and interaction difficulties from physicians' perspective.

To evaluate the results of the decision-making process, the one-dimensional Satisfaction With Decision (SWD) scale [44] and the Decisional Conflict Scale [45] (DCS) were applied. The SWD scale focuses on the results of the decision-making process, while the DCS examines aspects of the decision-making process itself.

All participating physicians completed the German version [46] of the Difficult Doctor Patient Relationship Questionnaire (DDPRQ) [47] to assess the quality of physician–patient interaction from the physicians' perspective. It addresses aspects of the physician–patient interaction that may cause unease and distress in the physician with a single scale.

Clinical variables

As clinical variables, we assessed pain intensity, functional capacity, depression, and general health status. Patients completed a visual analogue scale (VAS) on their typical and maximal levels of pain intensity during the 2 weeks before assessment, ranging from 0 (*no pain*) to 10 (*worst imaginable pain*); the Center for Epidemiological Studies Depression Scale (CES-D), German version [48]; the Hannover Functional Questionnaire (FFbH) [49]; and the first item of the 12-item Short Form (SF-12) [50] measuring general health status.

Statistical analysis

t tests for independent samples were calculated to compare the groups with regard to primary outcome variables (FAPI) and secondary outcome variables (SWD scale, DCS, and DDPRQ). *P* values of secondary outcome variables were adjusted for multiple comparisons using Bonferroni correction. All analyses were based on "intention to treat."

Sample size calculation

As noted above, the primary outcome variable was the quality of physician–patient interaction, as measured in terms of patients' scores on the FAPI. Based on the data of the FAPI prestudy, we expected an effect size of 0.625 to be a clinically relevant difference. For this effect size (with power=0.8 and α=.05), a *t* test for independent

Table 1
Socioeconomic characteristics of patients

	SDM group (n=44) [n (%)]	Information-only group (n=41) [n (%)]
Occupational situation		
Working full time or part time	21 (48.7)	19 (46.3)
Unemployed	7 (15.9)	7 (17.1)
Homemaker	7 (15.9)	8 (19.5)
Retired	7 (15.9)	7 (17.1)
Not specified	2 (4.6)	0
Marital status		
Unmarried	5 (11.4)	3 (7.3)
Married	31 (70.5)	21 (51.2)
Divorced/separated	7 (15.9)	14 (34.2)
Widowed	1 (2.3)	3 (7.3)
Not specified	0	0

Table 2
Baseline measures of patients' clinical variables

	SDM group (n=44) [mean (S.D.)]	Information-only group (n=41) [mean (S.D.)]
Pain intensity: typical pain (VAS)	6.4 (1.6)	6.0 (2.0)
Pain intensity: maximum pain (VAS)	8.5 (1.3)	8.8 (1.4)
Depression (CES-D)	21.6 (9.7)	22.2 (9.4)
General health status[a] (SF-12)	4.1 (0.7)	4.2 (0.7)
Functional capacity (FFbH)	67.8 (17.7)	63.7 (18.7)

[a] High values=low health status.

samples requires a sample size of 42 per group. Anticipating a dropout rate of 15%, we aimed at a sample size of 50 per group.

Results

Patients' characteristics

Of 164 eligible patients, 15 refused to participate, so 149 patients were randomized (n=76 to the SDM group and n=73 to the information-only group). In the SDM group, 14 patients cancelled the consultation, and 10 patients did not meet inclusion criteria. Therefore, 52 patients in the SDM group received the allocated intervention. After excluding eight patients due to missing questionnaires, data from the remaining 44 patients in the SDM group were analyzed.

In the information-only group, 11 patients cancelled the consultation, and 13 patients did not meet inclusion criteria, so 49 received the allocated intervention. After excluding eight patients due to missing questionnaires, data from 41 patients of the information-only group were analyzed.

We conducted a comparison of patients who did not fill out the complete set of questionnaires and analyzed the groups. This comparison revealed that, at baseline, non-participants did not significantly differ from participants in both groups with regard to their clinical (pain intensity, depression, functional capacity, and general health status) or sociodemographic characteristics (gender, marital status, and occupational situation).

Both analyzed groups had similar dropout rates and socioeconomic characteristics (Table 1). They consisted mainly of female patients (SDM group, 93.2%; information-only group, 90.2%) and were comparable in terms of mean age [SDM group, 49.5 years (S.D.=11.3); information-only group, 50.4 years (S.D.=8.8)] and work status.

Clinical variables

Clinically, these patients suffered from severe pain, with usual pain levels of approximately 6 (on a 0–10 scale) (Table 2). In both groups, the mean depression scores on the CES-D were approximately 22. The cutoff value on the CES-D indicating a clinically relevant level of depression is 17; in both study groups, the majority of patients fell above this cutoff point (61% and 68% for the SDM and information-only groups, respectively).

The functional capacity of these patients, as measured by the FFbH, was reduced in both study groups (67.8% and 63.7% for the SDM and information-only groups, respectively).

Primary outcome variable: quality of physician–patient interaction

There was a significant group difference in the patients' reported quality of physician–patient interaction (FAPI), which was the main outcome variable (Table 3). The SDM group judged the interaction with their doctors to be significantly better than did the information-only group (P<.001). The effect size was high, with d=0.75.

Secondary outcome variables

There were no significant group differences in patients' mean scores on the DCS or on the SWD scale, indicating that decisional conflicts and satisfaction with decisions were similar in both study groups.

Although SDM physicians tended to report lower ratings for difficulties in physician–patient relationship, as measured by the DDPRQ, this group difference did not reach significance (Table 4).

Discussion

This study was undertaken in consideration of substantial interaction difficulties between FMS patients and their physicians [1–5]. Its purpose was to investigate whether SDM communication training for physicians could improve this situation.

Table 3
Comparison of primary outcome variable: quality of physician–patient interaction from the patients' perspective (FAPI)

	SDM group	Information-only group	t test		Effect size (95% confidence interval)
			t	P	
Quality of physician–patient interaction (FAPI)[a]	4.2 (0.7)	3.5 (0.7)	4.15	<.001	0.75 (0.26, 1.24)

Table 4
Comparison of secondary outcome variables: from the patients' perspective (DCS and SWD scale) and from the physicians' perspective (DDPRQ)

	SDM group	Information-only group	*t* test		Effect size (95% confidence interval)
			t	*P*[a]	
SWD scale	4.2 (0.4)	4.0 (0.6)	1.56	.12	0.18 (−0.30, 0.67)
DCS	12.9 (4.3)	12.6 (3.4)	0.42	.67	0.26 (−0.23, 0.74)
DDPRQ	30.5 (6.9)	33.5 (9.8)	−1.57	.11	−0.33 (−0.81, 0.16)

[a] *P* values adjusted for multiple testing based on Bonferroni correction.

The results of the study corroborate our main hypothesis that an SDM intervention—consisting of a communication training program for physicians combined with an information package for patients—is a possible way of achieving a more successful interaction between FMS patients and their physicians.

FMS patients treated in the SDM communication training group judged the quality of their physician–patient interaction to be better compared with the information-only group, and this effect was stronger than expected (d=0.75). One consultation was already sufficient for the positive impact of the training to become evident to the patients. We expect the difference between the SDM group and the information-only group to be a specific effect of the communication training, since our design controlled for the attention patients received. It is known that the provision of information by a physician and the time spent with the patient can influence patients' satisfaction with consultation in a positive way [31–33,51]. Therefore, both groups received the information package, and equal consultation time was ensured.

We tried to control for confounders between both groups as much as possible. However, it cannot be ruled out that the difference we detected between both groups may have been influenced by membership in the cluster they were in (clinic) rather than by the intervention.

Still we assume that communication-trained doctors had gained interaction skills that were appreciated by their patients and that facilitated contact with their patients. The positive effects of physician communication training on their patients have already been shown in other studies [52–55], although not all communication training programs were effective in this regard. We could demonstrate that a communication training program with a special focus on SDM is a promising approach. During the training, doctors learned to consider their patients' individual needs and to meet their patients' expectations. These are elements assumed to contribute to a positive physician–patient interaction [23,51] and that are likely to foster a positive working alliance in the long run. We will assess the long-term effects of SDM communication training in follow-up evaluations.

None of the secondary outcome variables focusing on the decision-making process was significantly different for the SDM group and the information-only group.

Being treated by doctors with special SDM communication skills appeared to have no major additional beneficial effect on well-informed patients with regard to their decisional conflicts or their satisfaction with medical decisions. This might result from the low-risk nature of the decisions studied and from the fact that an information package is efficacious on its own, as has been shown in other studies [31–33]. However, there is no sufficient evidence in our study to decide on this.

It remains to be seen whether communication-trained doctors' support will become more important for patients in the long run when setbacks and failures in treatment have occurred and revisions of therapeutic strategies become necessary.

When comparing the physicians' appraisal of difficulties in the doctor–patient relationship, we could not find any significant difference between the physicians treating the SDM group and those treating the information-only group. However, mean scores show a tendency of SDM physicians to state less difficulties. Since our sample size was calculated for a high effect, it may be that the study is simply underpowered to test for this effect. It is likely that a larger number of patients are needed to identify an effect of the SDM training on physicians. However, this result clearly indicates that the effect of the training is stronger for patients than for physicians. So while SDM improves the communication experience for the patient, it does not necessarily have any effect on the physicians' distress in dealing with difficult FMS patients.

The results of the study should be interpreted in the light of some limitations. The first one is that patients were seen in a highly specialized university setting.

Although the socioeconomic characteristics and clinical data of the FMS patients in our study are comparable to those of other studies [6,11,56], they can be considered representative only of FMS samples in other tertiary care settings. It is known that the most difficult and most severely affected patients with the highest level of psychiatric comorbidity are usually seen in tertiary care settings such as ours [47,57]. So the patients included in our study may not be representative of FMS patients seen in general practice. Therefore, further studies in different settings are needed to allow the generalization of these results.

Another limitation of the study is related to dropouts and the possibility of bias associated with this. In our study, dropout was caused by systematic factors: one was postrandomization exclusion of patients for whom FMS could not be confirmed during the consultation; the others

were cancellation by the patient during the waiting period and incomplete questionnaires. It can be assumed that the treatment effect was not biased by this because attrition occurred similarly in both groups [58].

Finally, we were not able to analyze the influence of physicians' preexisting characteristics and attitudes or the influence of clinic specific differences on the effect of the training. It would have been interesting to learn more about the mechanisms linked to successful completion. As the small number of physicians involved in the study did not allow us to control for theses variables, we are now focusing on this topic in an ongoing study.

The central role of effective communication between doctors and patients in the treatment of chronic pain has been stated previously. Our findings emphasize that even highly elaborated and intensively reviewed educational measures for patients cannot compensate for the impact of doctors' communication abilities. However, these skills can be taught and should, therefore, be systematically incorporated into medical education programs.

Conclusion

The results of our study emphasize that FMS patients benefit from an SDM intervention that includes SDM communication training for their physicians.

When treated in accordance with the SDM concept, patients are significantly more satisfied with physician–patient interaction than are patients receiving only the information package. It will be important to investigate on follow-up whether there are any long-term benefits of SDM communication training.

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