

ORIGINAL ARTICLE

Enhancing Adherence and Satisfaction with Disease-Modifying Therapies in Multiple Sclerosis Through Pharmacist-Led Interventions: Interventional Study

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Abstract

Background: Pharmacists are essential in treating MS. Pharmacists' involvement and patient consultation may improve patient adherence and satisfaction.

Aim: To evaluate the influence of pharmacist-led interventions (PLI) on medication adherence and satisfaction in patients with multiple sclerosis receiving disease-modifying therapies (DMTs).

Methods: This study was conducted on patients with relapsing-remitting multiple sclerosis who were receiving DMTs and attended a neurological consultant clinic in the medical city of Baghdad. It was a pre-post-intervention study. Each patient underwent two educational sessions: the first session took place at the beginning of the study, after completing the Arabic version of the treatment satisfaction questionnaire for medication (TSQM-14item) and the Arabic version of the Morisky, Green, and Levine (MGL-4item) medication adherence scales. The second session occurred one month later. The duration of each session ranged from 30 to 45 minutes, during which the patients received educational counselling. Each patient was provided with a formal Arabic pamphlet. This pamphlet contained medical information about the disease and treatment. Subsequently, after two months, the patient completed the identical questionnaires once again.

Results: The participants' average age was 30.64±8.54. PLI had a substantial positive effect on adherence levels, but it did not have a significant impact on medication satisfaction. Significant variations in the educational level and type of treatment were only observed in the changes in treatment satisfaction scores. The degree of response to PLI was not correlated with sociodemographic factors.

Conclusion: The implementation of an educational intervention led by a clinical pharmacist can enhance the adherence of patients with multiple sclerosis; however, the change in treatment satisfaction scores was only a minimal change.

Keywords: Disease modifying therapy, Multiple sclerosis, Clinical Pharmacist Led-Intervention, treatment satisfaction and adherence.

1. INTRODUCTION

Multiple sclerosis (MS) is an autoimmune disease defined as a demyelinating nervous system ailment [1]. A number of disease-modifying therapies (DMTs) have become available, making MS a treatable disease. These compounds target the inflammatory response in MS. They work by decreasing the chances of relapse, decreasing the chances of new lesion formation seen on MRI of the CNS and by slowing the accumulation of disability [2]. The World Health Organization considers poor drug adherence to be a severe concern worldwide [3]. Maintaining MS patients' adherence to therapy is typically tricky, yet it is critical to their survival and health-related quality of life [4]. In several studies, adherent patients expressed increased satisfaction with disease-modifying therapies (DMTs) in terms of convenience and effectiveness [5–8]. Therefore, promoting high patient satisfaction is desirable to achieve the best clinical results [9]. In addition, dissatisfaction with therapy has a particularly negative impact on adherence among MS patients [9]. Pharmacists play an essential role in treating MS [10,11]. Pharmacists also act as drug information experts, conducting medication utilization assessments and providing advice on prescription selection and dose [12]. They also work with other healthcare experts to improve patient outcomes. Patient education and understanding of effective drug use, which leads to positive treatment results and illness control, may encourage patients to adhere to their medications [13–15]. Pharmacists' involvement and patient consultation may improve patient awareness of administered medications and satisfaction [16]. Many studies have been undertaken to evaluate the advantages of pharmacist-led intervention (PLI) for patients in neurology

clinics worldwide [17–20]. Numerous studies have also been conducted to evaluate treatment satisfaction and adherence, as well as the relationship between these two characteristics in MS patients [5,21,30,22–29]. Many studies have been undertaken in Iraq to determine the efficacy of pharmacist-led interventions and interprofessional collaboration (a physician-pharmacist partnership) in a variety of medical diseases. The pharmacist's role proved beneficial and valuable in these investigations [31–36]. To increase pharmacist involvement in this field (PLI), we can extend the positive findings from these studies to other diseases; in this study, the application is to patients with MS.

There had been no previous study in Iraq to explore the impact of a PLI on medication satisfaction and adherence among adult patients with MS.

Accordingly, this study aimed to evaluate the efficacy of pharmacist-led intervention (PLI) on medication satisfaction and adherence of patients with multiple sclerosis who were taking disease-modifying therapies (DMTs).

2. METHOD

2.1. Study Design and Study Population

This was a pre-post-intervention study on a convenient sample of MS patients diagnosed by specialists with RRMS and receiving DMTs who attended a neurological consultant clinic in the medical city of Baghdad between November 2023 and March 2024.

2.2. Inclusion Criteria

- Patients with relapsing-remitting multiple sclerosis.
- Patients who had taken DMTs for at least six months (to ensure the effectiveness and response of the drug) but no more than two years.

- Patient 18 years and older.
- Patients must accept participation in the study and remain in contact with the author.

2.3.Exclusion Criteria

- Patients who had hearing, speech, or cognitive deficits that would impair understanding of the questions and receiving the education.
- Women who were pregnant or breastfeeding (These cases may affect relapse or type of treatment).
- MS patients who had been diagnosed with other types of MS.
- Patients providing incomplete information during the completion of the questionnaire also were excluded from the study.

2.4.Data Collection and Pharmaceutical Counseling Sessions

The data related to the study were collected using a data collection sheet designed for the study's purpose. For each patient involved in the research, the following information was recorded:

1-Demographic characteristics: age, gender, social status, educational level, residency.

2-MS-related variables: duration of disease, duration of current treatment, and current medications used for MS.

A reference pamphlet translated into a formal Arabic language was given to each patient.

Five PhD-holding faculty members in the Department of Clinical Pharmacy, College of Pharmacy, University of Baghdad's scientific committee examined and evaluated the pamphlet. The translated version of the pamphlet was validated using the face validation procedure by five academic faculty members in a pharmacy college at the University of Baghdad who held a PhD

degree in clinical pharmacy. The face validation led to acceptance and approval of the translation process after some suggestions to change some terms to be more understandable by Iraqi patients.

The pamphlet contained the following medical information:

- (1) Information on DMTs and MS.
- (2) The purpose of DMTs;
- (3) The prevention and management of adverse drug reactions;
- (4) Dietary and nonpharmacological advice;
- (5) Cautions and drug interactions with DMTs.

After determining the baseline levels of adherence and satisfaction, each participating patient received an educational pamphlet.

Firstly, the baseline level of satisfaction and adherence were determined by asking patients to complete the structured questionnaire (a convenience sampling method was used to recruit the patients). After that, the patients received face-to-face pharmaceutical counseling.

Each patient received two counseling sessions: the first at baseline and the second after a month. Each session lasted for approximately 30-45 minutes. In addition, the researcher kept full contact with patients via mobile phone (if the author needed any information regarding the study or any patient needed an inquiry or questions regarding the pamphlet or the instructions that were conducted in the two sessions), and patients could chat with the clinical pharmacists during all the periods.

After two months, the researcher asked the patient to refill the same questionnaires to determine the degree of improvement in satisfaction and adherence.

The counselling session included the following information:

(1) Information about MS and its symptoms.

(2) Information about the drug that the patient used (importance, route of administration, adverse effects, and how to

reduce/ prevent them)

(3) Counseling about adherence and how to prevent intentional nonadherence.

The study timeline is presented in the figure.

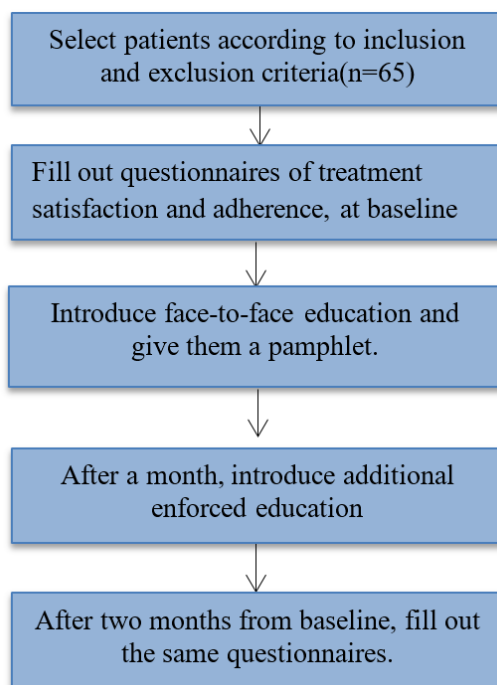


Figure1:The study timeline

2.5.Study instruments

The demographic and clinical characteristic data were collected using a datasheet. After that, the following study instruments were used:

2.5.1. The face validation Arabic version of the Treatment Satisfaction Questionnaire for Medication (TSQM version 1.4).

A face-validated (by a panel of experts of five PhD-holding faculty members in the Department of Clinical Pharmacy, College of Pharmacy, University of Baghdad scientific committee) Arabic version of the Questionnaire about TSQM was created. The face validation led to acceptance and approval of the translation process after some

suggestions to change some terms to be more understandable by Iraqi patients [37].

The TSQM Version 1.4 is a 14-item, verified, and psychometrically sound instrument with four scales. The four scales of the TSQM are the effectiveness scale (questions 1 through 3), the side effects scale (questions 4 through 8), the convenience scale (questions 9 through 11), and the global satisfaction scale (questions 12 through 14). [37].

A Likert-type scale of 5 or 7 points was used to measure the responses, except item 4 on the side effects subscale, which inquired if there were any side effects. If the participant did not report any side effects, items 5 through 8 in the side effects subscale were not

asked, and the total score for this subscale was automatically tallied as a maximum of 100. Each of the subscales received a score between 0 and 100, with higher scores indicating more patient satisfaction with medication [37,38]. The sum of the scores of each subscale minus the number of questions in that subscale was divided by the maximum score minus the minimum score of that subscale multiplied by 100 [39].

2.5.2. Arabic version of The Morisky, Green and Levine (MGL) Medication Adherence Scale [40].

The scale has four questions with a "Yes" = 0 and "No" = 1 score system. The items are added together to produce a score range from 0 to 4. The sum of "Yes" responses provides a composite measure of nonadherence. Higher scores suggest higher levels of adherence, and the overall patient scores can be divided into three categories: high levels of adherence (no items replied "yes"), moderate levels of adherence (one to two items responded "yes"), and poor levels of adherence (three to four items answered "yes") [40,41].

2.6. Statistical Analysis

The statistical package for the social sciences software SPSS (version 26.0) was used to analyze all the data. Continuous variables were expressed in mean $\pm$ standard deviation, while categorical variables were expressed as number and frequency. A Shapiro–Wilk test was used to test the normality of the results. The test showed normally distributed data (P value > 0.05). A paired t -test and Wilcoxon signed ranks test were used to compare the changes before and after the clinical pharmacist intervention. Mann-Whitney test, independent t -test,

Kruskal Wallis test, and one-way ANOVA were used to compare the differences between demographic data groups. The Spearman correlation coefficient was used to find if there was a correlation between the change in the scores of both scales. A probability less than 0.05 was considered significant.

3. RESULTS

Eighty patients with RRMS were enrolled in the study, and sixty-five of these patients ultimately completed it. The response rate was 81.25%. Fifteen of them continuously received phone counselling, and the rest of the patients did not contact the researcher. In the second session, they were assured that the pamphlet and information were clear and understandable.

Regarding the follow-up questionnaire (TSQM-14 items), the internal consistency (Cronbach's alpha coefficient) used to assess instrument reliability was estimated at 0.80. The scale has effectively achieved convergent validity in all aspects. Additionally, the pamphlet was screened by neurologists. Neurologists who read the pamphlet reported that it would minimize their burden and increase patients' awareness about their disease and treatment, leading to increased adherence.

The mean age of the participants was 30.64 ± 8.54 years. As shown in Table 1, most patients were female, married, had high levels of education, resided in Baghdad, and had natalizumab and interferon beta as their current treatments. We took only four types of treatments already available in the clinic where the study took place, and the other types of DMTs are not available.

Table 1. Demographic and clinical characteristics.

Variable		No.		%
Age	(18-29)	33		50.76
	(30-39)	23		35.38
	(40-49)	5		7.69
	(50-59)	4		6.15
Sex	Male	Married	12	18.46
		Unmarried	8	12.30
	Female	Married	26	40.00
		Unmarried	19	29.23
Educational level	Primary	7		10.76
	Middle	9		13.84
	High	15		23.07
	University	34		52.30
Residency	Baghdad	46		70.76
	Other provinces	19		29.23
Treatment	Interferon beta	20		30.76
	Fingolimod	5		7.69
	Natalizumab	35		53.84
	Rituximab	5		7.69

No.: Number, %: Percentage.

In this study, a score ≥ 75 was considered to be high satisfaction [42]. Patient satisfaction only slightly increased after PLI, and the side effect scale had more satisfaction

(69.23% and 73.84%) before and after the study, respectively, among other scales of TSQM, as in Table 2.

Table2. TSQM-14item (number and percentage of patients before and after Pharmacist-led Intervention)

TSQM-14item	Before PLI				After PLI			
	Patients with scores ≥ 75		Patients with scores < 75		Patients with scores ≥ 75		Patients with scores < 75	
	No.	%	No.	%	No.	%	No.	%
Effectiveness scale	24	36.92	41	63.07	28	43.07	37	56.92
Side effect scale	45	69.23	20	30.76	48	73.84	17	26.15
Convenience scale	20	30.76	45	69.23	20	30.76	45	69.23
Global satisfaction scale	27	41.53	38	58.46	29	44.61	36	55.38

No.: Number, %: Percentage, PLI: Pharmacist Led-Intervention

The clinical pharmacist's intervention resulted in a non-significant effect in all four

scales of TSQM (P value > 0.05), as shown in Table 3.

Table 3. Scores of all scales and items of the TSQM-14item before and after the study.

TSQM-14item scale	Before PLI	After PLI	P*
	Median(IQR)	Median(IQR)	
Effectiveness scale	67(30.5)	67(33)	0.74
Side effect scale	100(37)	100(31)	0.90
Convenience scale	67(22)	61(25)	0.11
Global satisfaction scale	64(32)	64(32.5)	0.42

*: Within group comparison (before versus after study scores), Wilcoxon signed ranks test, **P**: P value, **PLI**: Pharmacist Led-Intervention, **IQR**: Interquartile Range.

In this study, most patients (40 and 21) already had high and moderate levels of adherence, respectively, and only four patients had poor adherence before the study (Table 4).

As shown in Table 4, the number of

patients with a high level of adherence increases after PLI from 40 to 53, and the number of patients with moderate and poor levels of adherence decreases to only 10 and 2, respectively, after PLI.

Table 4. MGL-4items Medication Adherence scale (levels of adherence before and after Pharmacist-led Intervention).

(MGL)-4item Medication Adherence scale	Before PLI		After PLI	
	No.	%	No.	%
High level of adherence	40	61.53	53	81.53
Moderate level of adherence	21	32.30	10	15.38
Poor level of adherence	4	6.15	2	3.07

No.: Number, **%:** Percentage, **PLI**: Pharmacist Led-Intervention.

Regardless of the patients with a high level of adherence, the clinical pharmacist's intervention significantly improved adherence levels (P value<0.05) (Table 5).

The median adherence scores before and after PLI are equal to 4 because most patients' scores are equal to 4 (high level of adherence).

Table 5. Scores of Adherence levels of (MGL)-4 item medication adherence scale before and after the study.

(MGL)-4item Medication adherence scale	Median(IQR) before PLI	Median(IQR) after PLI	P*
Level of adherence	4(1)	4(0)	0.000 [#]

* Within group comparison (before versus after study scores), Wilcoxon signed ranks test, **P**: P value

[#] P value less than 0.05 considered significant, **IQR**: Interquartile Range, **PLI** Pharmacist intervention.

The changes in scores before and after the intervention in the TSQM scale had significant differences in the type of treatment and educational level of the

patients (P value<0.05), as shown in Table 6.

There were also non-significant differences in other demographic data groups (P value > 0.05) (Table 6).

Table6. Changes in scores of TSQM between before and after Pharmacist-led Intervention and their relation to demographic data groups.

TSQM	Mean(SD)	Demographic data		Mean(SD)	P*
Change in scores	0.98(11.89)	Age	(18-29)	0.50(12.04)	0.632
			(30-39)	2.02(13.52)	
			(40-49)	1.05(3.45)	
			(50-59)	7.16(5.58)	
		Sex	Male	1.82(17.57)	0.707
			Female	0.60(8.48)	
		Social status	Married	2.64(11.81)	0.183
			Unmarried	1.36(11.82)	
		Educational level	Primary	9.25(9.15)	0.043 [#]
			Middle	4.52(15.86)	
			High	3.26(8.78)	
			University	3.01(11.24)	
		Treatment	Natalizumab	0.425(8.77)	0.030 [#]
			Interferon beta	2.58(14.42)	
			Fingolimod	13.75(15.59)	
			Rituximab	6.40(8.46)	
		Duration of treatment	=or<1year	2.75(12.92)	0.317
			>1year	0.27(11.11)	

*Within group comparison (changes between after and before versus demographic data groups), Independent t test and one-way ANOVA, **P**: P value, [#] P value less than 0.05 considered significant. **PLI**. Pharmacist Led-Intervention. **SD**.Standard deviation.

Changes in scores on the MGL-4item medication adherence scale before and after pharmacist intervention showed non-significant differences in all demographic data groups (P value>0.05), Table 7.

The median of the change in scores

between before and after PLI and the change of these scores in all demographic data groups is equal to 0 because the most value of change in scores is equal to 0. The mean rank was used for these values.

Table7. Changes in scores of MGL-Medication adherence scale between before and after Pharmacist-led Intervention and their relation to demographic data groups.

MGL	Mean Rank	Demographic data		Mean Rank	P*
Change in scores	33	Age	(18-29)	35.53	0.205
			(30-39)	32.57	
			(40-49)	19.50	
			(50-59)	31.50	
		Sex	Male	37.40	0.133
			Female	31.04	
		Social status	Married	31.84	0.482
			Unmarried	34.63	
		Educational level	Primary	39	0.489
			Middle	33.95	
			High	36	
			University	30.34	
		Treatment	Natalizumab	30	0.239
			Interferon beta	34.70	
			Fingolimod	44.20	
			Rituximab	36	
		Duration of treatment	=or<1year	32.41	0.792
			>1year	33.42	

*: Within group comparison (changes between after and before versus demographic data groups), Mann-Whitney test and Kruskal Wallis test, **P**: P value, **PLI**: Pharmacist Led-Intervention.

4. DISCUSSION

In this study, the scales of TSQM (effectiveness, side effect, convenience, and global satisfaction) were non-significantly affected by clinical pharmacist intervention (P value>0.05). This result may be attributed to a short period of intervention. Patients who participated in the current study had scores of satisfaction that only slightly changed after the study; 35 patients in this study had natalizumab as the current treatment, and patients using this treatment more satisfied than another type of DMTs. Studies in 2014 by Glanz *et al.* [21]. and in 2018 by Yahya *et al.* [29]. proved this. For patients using interferon beta, the primary reason for not increasing or changing satisfaction scores was the inconvenience of administering the dose as injectable. This was proven in the

study in 2017 by Fernández *et al.* [22]. The second reason was the side effects of this drug; most patients reported side effects when using interferon beta, as in the study by Eagle *et al.* [24]. In 2017, the proportion of patients reporting a side effect was higher for injectables than orals and infusion. Clinical pharmacists do not significantly reduce these problems. Although the patient was taught how to avoid or reduce side effects according to the treatment used, most patients followed these tips. Only a few of them decreased side effects such as how to inject subcutaneously, redness and swelling at the injection site, and fever that occurs due to this type of treatment being home administered. Patients using fingolimod and rituximab who were enrolled in this study were small in number and not highly affected by satisfaction score changes.

In other ways, the adherence levels were significantly affected by PLI (P value<0.05); the patients with low and moderate levels of adherence changed their levels to moderate and high, respectively.

Improved adherence to treatment by educating the patient about the importance of taking the dose on time to get better results. This group of patients stopped treatment as soon as the symptoms of the disease decreased and they felt better or when the symptoms of the disease became severe. They would stop treatment by saying that the treatment was not working and also because of the side effects of the drug when they worsened. It was previously mentioned that education was provided about reducing the side effects. PLI reduced all these reasons for non-adherence.

In addition, the change in scores of TSQM was significantly different in relation to the educational levels of the patients and the type of treatment, which slightly increases satisfaction scores among these groups after intervention, as compared to other demographic data groups. In the change of scores of the adherence scale, there was a non-significant difference between demographic data groups. This means all patients received educational advice regarding adherence at the same level. In the current study, despite the fact that satisfaction was unaffected but adherence improved following the intervention, clinical pharmacists brought benefits to patients with multiple sclerosis, as in numerous previous studies[17–20] , by educating them about treatment and how to deal with side effects to reduce problems and increase satisfaction and adherence to treatment.

There were no similar studies on pharmacist interventions for MS in Iraq or Arab countries. There were studies on other

diseases in Iraq [31–36] , and the results were positive. Therefore, there was encouragement in such a study in Iraq to teach and educate patients with multiple sclerosis to improve their disease and to increase the role of the pharmacist in educating and treating those patients.

But despite the improved adherence and unaffected satisfaction, longer follow-up studies were still required to further educate the MS patients and also for other chronic diseases.

In Iraq, pharmacists receive hospital training while in college and counsel patients on treatment options. Mohammed *et al* [43] conducted a qualitative survey at different hospitals in Baghdad, Iraq, in 2022 to identify recent graduates' perceptions of the benefits and factors influencing the quality of hospital training courses for pharmacy students. As a result, the hospital training course efficiently prepared the graduate pharmacist for future work in hospitals.

Despite significant problems during the first year of the program, most participants were optimistic about the future of PharmD in Iraq and continued to believe so. We may capitalize on this trend by including the teaching programs used in our study for pharmacists, which may serve as a source of enhancing patient medication satisfaction and adherence. Patients responded positively to the counselling sessions and the pamphlet designed for our study.

Furthermore, neurologists who read the pamphlet stated that it would minimize their burden while increasing patients' knowledge of their ailment and treatment, resulting in higher adherence. This has helped MS patients improve their medication satisfaction and quality of life by teaching them how to self-inject and manage their therapy at home. In addition, any non-

pharmacological instructions concerning disease and treatment were also mentioned in the sessions and pamphlet. As a result, this study's findings will help policymakers, Ministry of Health planners, doctors, health care providers, and others design effective plans and interventions to increase patient adherence and satisfaction with their medication.

5. LIMITATIONS

The study's main limitations were the limited sample size, the short study duration, and the single-centre design despite the fact

that patients were recruited from various governorates. The researcher needed help with scheduling the meeting date with the patient due to differing protocols about the timing of treatment administration.

6. CONCLUSION

A clinical pharmacist-led educational intervention may improve multiple sclerosis patients' adherence. Additionally, treatment satisfaction was only a minimum change in scores that was not considered significant. Longer follow-up studies are needed to find if treatment satisfaction improves.

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تعزيز الالتزام والرضا عن العلاجات المعدلة للمرض في مرض التصلب المتعدد من خلال التدخلات التي يقودها الصيدالة: دراسة تداخلية

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الملخص

الخلفية والاهداف : الصيدالة ضروريون في علاج التصلب المتعدد. قد يؤدي إشراك الصيدالة واستشارتهم للمرضى الى تحسين التزام المريض ورضاه. **الهدف:** تقييم تأثير التدخلات التي يقودها الصيدلي على الالتزام بالأدوية والرضا لدى مرضى التصلب المتعدد الذين يتلقون العلاجات المعدلة للمرض.

منهجية الدراسة : أجريت هذه الدراسة على مرضى التصلب المتعدد الانتكاسي المتكرر الذين يتلقون العلاجات المعدلة للمرض وحضروا الى العيادة الاستشارية العصبية في مدينة الطب في بغداد. كانت دراسة ما قبل وبعد التدخل ، خضع كل مريض لجلستين تعليميتين: الجلسة الأولى كانت في بداية الدراسة، بعد استكمال النسخة العربية من استبيان الرضا عن الدواء (TSQM-14item) والنسخة العربية من مقاييس الالتزام بالأدوية لموريكي وغرين وليفين (MGL-4item)، و الجلسة الثانية كانت بعد شهر واحد. تراوحت مدة كل جلسة من 30 الى 45 دقيقة، تلقى خلالها المرضى الاستشارة التعليمية. تم تزويد كل مريض بكتيب رسمي باللغة العربية. يحتوي هذا الكتيب على معلومات طبية حول المرض والعلاج. بعد ذلك، بعد شهرين، ملئ المريض نفس الاستبيانات مرة أخرى.

النتائج: متوسط عمر المشاركين هو $8,54 \pm 30,64$. كان لتدخل الصيدلي السريري تأثير إيجابي كبير على مستويات الالتزام، لكنه لم يكن له تأثير كبير على الرضا عن الدواء. لوحظت اختلافات كبيرة في المستوى التعليمي ونوع العلاج فقط في التغييرات في درجات الرضا عن العلاج واما باقي العوامل الاجتماعية والديموغرافية لم تكن لها استجابة بتدخل الصيدلي. **الاستنتاجات:** يمكن أن يؤدي تنفيذ التدخل التعليمي بقيادة الصيدلي السريري الى تعزيز التزام المرضى المصابين بالتصلب المتعدد، ومع ذلك، فإن التغيير في درجات الرضا عن العلاج ليس سوى تغيير طفيف.

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