The Effect of Disease Management Education Provided to Women with Rheumatoid Arthritis on Quality of Life, Anxiety, and Depression: A Randomized Controlled Study

Romatoid Artritli Kadınlara Verilen Hastalık Yönetimi Eğitiminin Yaşam Kalitesi, Anksiyete ve Depresyon Üzerine Etkisi: Randomize Kontrollü Bir Çalışma

[1]Irem YILDIZ CILENGIROGLU, [1]Serap ÜNSAR

[1]Trakya University, Faculty of Health Sciences, Department of Internal Medicine Nursing, Balkan Campus, Edirne, Türkiye

Irem Yildiz Cilengiroglu: https://orcid.org/0000-0001-8276-0158
Serap Unsar: https://orcid.org/0000-0001-7723-8816

ABSTRACT

Objective: The aim of this randomized controlled trial is to investigate the effect of education of disease management on quality of life, anxiety and depression in women with rheumatoid arthritis.

Materials and Methods: The study included 66 women with rheumatoid arthritis at a university hospital in Türkiye. Data were obtained via "Rheumatoid Arthritis Quality of Life Scale", "Health Assessment Questionnaire", and "Hospital Anxiety Depression Scale".

Results: A significant difference was found between the intervention group's mean scores on the "Rheumatoid Arthritis Quality of Life Scale" at baseline and third month (p <0.05). Significant correlations were found between the intervention group's Rheumatoid Arthritis Quality of Life Scale scores and the sociodemographic and disease-related characteristics such as education level and having arthritis-related deformities (p <0.05).

Conclusions: The findings obtained in this study showed that education is an effective method to increase the quality of life of women with rheumatoid arthritis. Individual disease management training provided by rheumatology nurses to women with Rheumatoid Arthritis is considered to improve quality of life. Therefore, women with rheumatoid arthritis are recommended to receive psychosocial support in managing their disease and symptoms.

Keywords: Anxiety, depression, quality of life, rheumatoid arthritis, women

ÖZ

Amaç: Bu randomize kontrollü araştırma, Romatoid Artritli kadınlara hastalık yönetimine ilişkin verilen eğitimin yaşam kalitesi, anksiyete ve depresyon üzerine etkilerini belirlemek amacıyla planlandı.

Materyal ve Metot: Araştırma, Romatoid Artritli 66 kadın hasta (32 deney, 34 kontrol) ile bir üniversite hastanesinin Romatoloji kliniği ve polikliniğinde yürütüldü. Veriler; "Romatoid Artrit Yaşam Kalitesi Ölçeği", "Sağlık Değerlendirme Anketi" ve "Hastane Anksiyete Depresyon Ölçeği" kullanılarak toplandı.

Bulgular: Deney grubundaki hastaların "Romatoid Artrit Yaşam Kalitesi Ölçeği" başlangıç ve üçüncü ay puan ortalamaları arasında anlamlı fark bulundu (p <0,05). Deney grubunun Romatoid Artrit Yaşam Kalitesi Ölçeği puanları ile eğitim düzeyi ve artrit nedeniyle etkilenen deformitesi olma durumu gibi sosyodemografik ve hastalığa ilişkin özellikleri arasında anlamlı ilişkiler bulundu (p <0,05).

Sonuç: Bu çalışma, hastalık yönetimine ilişkin verilen eğitimin Romatoid Artritli kadınların yaşam kalitesi üzerindeki etkisini göstermektedir. Romatoloji hemşireleri tarafından Romatoid Artritli kadınlara hastalık yönetimine ilişkin verilecek bireysel eğitimin yaşam kalitesini arttıracağı düşünülmektedir. Romatoid Artritli kadınlara semptomlara bağlı yaşadıkları sorunlara yönelik psikososyal destek almaları önerilmektedir.

Anahtar Kelimeler: Anksiyete, depresyon, kadın, romatoid artrit, yaşam kalitesi

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic inflammatory disease that primarily affects the synovial joints. Inflammation of joints damages the cartilage and causes the joints to erode.[1,2] The prevalence of RA is three times higher in women than in men.[3] In Türkiye, the prevalence of RA has been reported to be 0.56%, and 0.89% in women.[4]

Rheumatoid arthritis, which is characterized by recurrent cycles of exacerbation and remission, causes disability and decreases the functional status of the patients.[5] Patients who are unable to perform daily activities due to pain and joint involvement caused by synovial inflammation have limited mobility.[6] Disease symptoms can lead to a reduction in quality of life due to pain, fatigue, and disability, which can cause mood changes such as anxiety and depression.[3,7] Depression is highly prevalent in patients with RA, with some studies reporting rates as high as 41.5%, surpassing the general population.[8] In a study, the prevalence of depression and anxiety in patients with RA was found to be 23.3% and 42.3%, respectively.[9]

Patient education is important for the management of RA and the reduction of symptoms as it contributes to the patient's adaptation to the treatment and the maintenance of a healthy lifestyle.[10] Previous studies have reported that patients with RA in the intervention group have a higher quality of life after training. Education on individual disease management has been shown to increase the quality of life.[7,11] When the patient is educated in disease management, the effectiveness of the treatment increases, functional competence is provided, and the quality of life can be increased. Moreover, healthcare professionals play an important role in disease management, especially rheumatology nurses, who spend more time with patients. Nurses should support individuals to improve their daily lives, adapt to illness, and improve their quality of life.[11,12]

This study aimed to examine the effect of training provided by nurses who interact with patients the most on their quality of life, anxiety and depression. There are many similar studies in the international arena, but when looked at nationally, it was the first time in our country. Therefore, our study purposed to examine the effect of education on disease management, on the quality of life, anxiety and depression of women with RA.

MATERIALS AND METHODS

Ethical Considerations: A University Research Ethics Committee confirmed the study protocol, which adhered to the Helsinki Declaration (Date: 17.09.2018 Decision no: 16/23). The patients were briefed about the study before it began, and both written and verbal consent was received.

Study Design: This prospective pretest and posttest study was carried out as a randomized controlled trial between February 2019 and October 2019 at the outpatient clinic of the Department of Rheumatology in a university hospital in Türkiye. The trial was registered in ClinicalTrials.gov (Protocol ID-NCT04850183).

Study Participants: Women with rheumatoid arthritis who met the 2010 American College of Rheumatology (ACR) criteria, had a disease duration of at least 6 months and were 18 years of age or older voluntarily agreed to participate in this study.[13]

When the literature was examined, there was no study similar to our study done in Türkiye. This study aimed to reach a medium effect, therefore performed with effect size d=0.60, 80% (1 − β error) power, and 95% (α error) confidence level. The sample size required a total of 72 patients, 36 patients for each group (G* Power 3.1.9.4). Anticipating a possible sample loss, we increased the sample size by 10%. Therefore, 40 patients were included in each group, thus the total number of patients enrolled was 80.

Randomization: A single-blind technique was used to eliminate any bias. The patients were selected using a simple random sampling method and divided into intervention and control groups using the Research Randomizer program. Consolidated Trial Standards of Reporting List (CONSORT) principles were the foundation for the study's design and conduct (Figure 1).

Study Instruments: The Patient Information Form, Rheumatoid Arthritis Quality of Life Scale, the Health Assessment Questionnaire, and the Hospital Anxiety Depression Scale were used to collect data.

Patient Information Form: The form was developed by researchers in line with a literature.[7,10,11] The form consisted of eight questions about sociodemographic characteristics (age, marital status, education, etc.), clinical diagnosis, medication of RA, concomitant chronic disease, and deformity in consequence of arthritis.

Rheumatoid Arthritis Quality of Life Questionnaire (RAQoL): The questionnaire consists of 30 questions. The scores ranged from 0 to 30, with high scores showing poor quality of life. In 2003, Kutlay et al. verified the scale's validity and reliability.[14]

Stanford Health Assessment Questionnaire (HAQ): The HAQ is a functional status questionnaire whose score has been demonstrated to correspond with disease activity indicators. The HAQ is composed of 20 questions that are divided into eight categories: waking up, moving, feeding, dressing and grooming, hygiene, grip, reach, and tasks. The score is computed as an average of eight domains with scores vary-
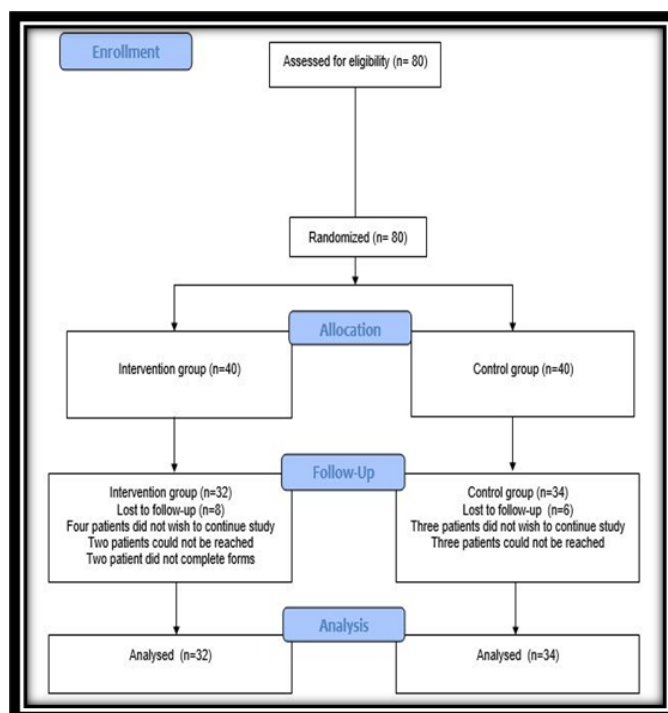
Figure 1. CONSORT 2010 Flow Diagram.

ing from 0 to 3, with a higher score displaying significant impairment. Kucukdeveci et al. verified the scale's validity and reliability in 2004.[15]

Hospital Anxiety and Depression Scale (HADS): The HADS includes both anxiety and depression sub-scales and consists of 14 items, 7 of which examine depression (Hospital Anxiety and Depression Scale-Depression, HAD-D) and 7 of which examine anxiety (Hospital Anxiety and Depression Scale-Anxiety, HAD-A). Patients with scores above these scores are regarded as a risk category. The purpose of the scale is not to diagnose but to assess the risk group by checking for anxiety and depression over a short period. Aydemir et al. verified its validity and reliability in 1997.[16]

Data Collection: Data were collected through face-to-face interviews. The researcher collected data in accordance with the randomization table.

Standard Intervention: Patients are informed about medication and its side effects by rheumatology specialists at the time of diagnosis. Regular education is not provided to patients. If patients had a question or medical problem, they could get information if they had made an appointment and came for a visit. Nurses are the health professionals who interact the most with patients. For this reason, it is an important responsibility of nurses to support and inform patients with such a complicated disease. It is crucial for them to not only oversee the treatment but also to manage the physical, mental, cognitive, and spiritual complications of the disease. In this context, an educational booklet was created that nurses can use in informing patients with RA in addition to standard care.

This study was conducted in three stages.

First Stage: Rheumatoid Arthritis Patient Education Booklet: Researchers prepared the booklet's content in accordance with the literature.[7,9,17] The education topics included description, symptoms, and signs of RA, diagnostic methods, treatment choices, information on medications, RA in pregnancy, disease management, nutritional recommendations, emotional health, and support in daily living. After taking expert opinions, the booklet was revised according to the recommendations.

Second Stage: Before the study, patients in all groups were informed about the study. Baseline data were obtained from both intervention and control groups using the study instruments. All the data collection tools were completed by the patient's self-reports. While the patients in the control group received standard care, patients in the intervention group were informed by the researcher via an education booklet. The education took an average of 30 minutes. The training was done individually. It was done when they came to the outpatient clinic for routine controls. After the training was over, the questions of the patients in the intervention group were answered.

Third Stage: Third months after the baseline, the patients in all groups underwent a routine examination, whereby the study instruments were applied to the patients a second time.

Data Analysis: Data were analyzed using the IBM SPSS 20.0 program. Socio-demographic data were analyzed using the mean, standard deviation, and frequency. Mann-Whitney U tests were used to compare variables in two groups. Pearson Chi-Square Test, Continuity Correction test and Fisher's Exact test were used to compare qualitative data. The Wilcoxon signed-rank test was used for the paired comparisons in the comparison of qualitative data. The significance level was set at $p \leq 0.05$.

RESULTS

Table 1 shows the sociodemographic and disease-related characteristics of the women. When the personal and disease-related characteristics in the intervention and control groups were examined, they were found to be similar in terms of age, educational and marital status, period of clinical diagnosis, treatment of RA, chronic diseases, and deformities affected by arthritis. The patients' characteristics showed a homogeneous distribution between the groups.

The mean RAQoL score of the women in the intervention group was lower in the 3rd month (p=0.004) compared to the baseline. There was no significant difference between the HAQ and HADS mean scores of the women after training (p >0.05). There was no significant difference found between the RAQoL, HAQ, and HADS mean scores of women in the control group in the 3rd month (p >0.05). However, the intervention group had a higher mean HAD-D score at baseline. Additionally, in the 3rd month, the mean HAD-D score was higher in the intervention group compared to the control group (p=0.038) (Table 2).

Table 1. The sociodemographic and disease-related characteristics of the patients.

Characteristics		Intervention group (n=32)	Control group (n=34)	Test and p values
Age	Min-Max	30-73	39-82	Z: 489.0
	Mean±SD	56.46±11.88	59.50±9.97	p*: 0.480
Time of clinical diagnosis (year)	Min-Max	1-55	1-56	Z: 410.0
	Mean±SD	18.59±12.68	13.55±10.66	p*: 0.085
Education Status; n (%)	Primary and below (≤5 years)	21 (65.6)	20 (58.8)	χ^2:0.324
	Secondary and above (≥6 years)	11 (34.4)	14 (41.2)	p†: 0.569
Marital Status; n (%)	Married	28 (87.5)	31 (91.2)	χ^2:0.007
	Single	4 (12.5)	3 (8.8)	p‡: 0.932
Treatment of Rheumatoid Arthritis; n (%)	cDMARDs	9 (28.1)	9 (26.5)	χ^2:0.190
	bDMARDs	7 (21.9)	9 (26.5)	p†: 0.910
	cDMARD+bDMARD	16 (50.0)	16 (47.1)	
Chronic disease; n (%)	No	15 (46.9)	13 (38.2)	χ^2:0.504
	Yes	17 (53.1)	21 (61.8)	p†: 0.478
Deformity-inconsequence by arthritis; n (%)	No	11 (34.4)	7 (20.6)	χ^2:1.580
	Yes	21 (65.6)	27 (79.4)	p†: 0.209

*: Mann Whitney U Test; †: Pearson Ki-kare Test; ‡: Continuity Correction Test; §: Fisher's Exact Test, Min: Minimum, Max: Maximum, Mean±SD: Mean ±Standart deviation; bDMARD: biologic disease-modifying antirheumatic drugs cDMARD: conventional disease-modifying antirheumatic drugs.

Table 2. The distribution of RAQoL, HAQ, and HADS mean scores of the groups according to the months which baseline and third month.

Scales		Intervention group (n=32) Mean±SD	Control group (n=34) Mean±SD	Test value	p*
RAQoL	Baseline	19.50±7.29	14.97±8.80	377.00	**0.032**
	3rd month	17.31±6.49	15.38±8.36	455.00	0.253
Test value		-2.876	-0.918		
p†		**0.004**	0.358		
HAQ	Baseline	0.46±0.42	0.40±0.37	495.50	0.532
	3rd month	0.45±0.43	0.40±0.35	505.00	0.616
Test value		-0.086	-0.178		
p†		0.932	0.858		
HAD-A	Baseline	10.06±5.41	8.79±5.04	482.50	0.429
	3rd month	10.46±5.19	8.73±5.01	438.50	0.175

RAQoL: Rheumatoid Arthritis Quality of Life Questionnaire; **HAQ:** Stanford Health Assessment Questionnaire; **HAD-A:** Hospital Anxiety and Depression Scale-Anxiety; **HAD-D:** Hospital Anxiety and Depression Scale-Depression; *: Mann Whitney U test; †: Wilcoxon Signed Ranks test; Mean±SD: Mean±Standart deviation.

Table 2. Continue.

Test value		-0.669	-0.213		
p[†]		0.504	0.832		
HAD-D	Baseline	8.21±4.74	6.52±3.74	422.00	0.116
	3rd month	8.71±4.61	6.67±3.68	383.00	**0.038**
Test value		-1.463	-0.544		
p[†]		0.144	0.586		

RAQoL: Rheumatoid Arthritis Quality of Life Questionnaire; **HAQ:** Stanford Health Assessment Questionnaire; **HAD-A:** Hospital Anxiety and Depression Scale-Anxiety; **HAD-D:** Hospital Anxiety and Depression Scale-Depression; *: Mann Whitney U test; †: Wilcoxon Signed Ranks test; Mean±SD: Mean±Standart deviation.

The mean RAQoL scores of the patients in the intervention group declined significantly in the 3rd month, regardless of their education level (p=0.050 for primary school and below; p=0.029 for secondary school and above). The quality of life of women, regardless of their education levels, in the intervention group improved after training than the control group. There was no significant difference in the HAQ mean scores of women with RA after training (p >0.05) (Table 3).

In the intervention group, RAQoL mean scores of women with deformities affected by arthritis were significantly lower than those control group after training (p =0.008). After training, women with deformities affected by arthritis in the intervention group had a higher quality of life than the control group in 3rd month. There was no significant difference between the mean HAQ and HADS scores in the intervention group after training (p > 0.05) (Table 4).

Table 3. Comparison of the scales (RAQoL, HAQ, HAD-A, HAD-D) mean scores of the groups according to educational status.

Scales		Educational Status					
		Primary and below			Secondary and above		
		Intervention group (n=21) Mean±SD	Control group (n=20) Mean±SD	p*	Intervention group (n=11) Mean±SD	Control group (n=14) Mean±SD	p*
RAQoL	Baseline	21.33±6.94	15.80±8.72	**0.045**	16.00±6.91	13.78±9.10	0.443
	3rd month	19.42±5.58	16.75±7.63	0.205	13.27±6.42	13.42±9.23	0.742
p[†]		**0.050**	0.183		**0.029**	0.888	
HAQ	Baseline	0.53±0.41	0.49±0.36	0.804	0.32±0.42	0.28±0.35	0.486
	3rd month	0.54±0.42	0.49±0.34	0.875	0.30±0.42	0.26±0.34	0.435
p[†]		0.598	0.532		0.180	0.340	
HAD-A	Baseline	10.76±5.29	9.00±5.56	0.289	8.72±5.64	8.50±4.40	0.912
	3rd month	11.23±4.80	9.10±5.47	0.174	9.00±5.83	8.21±4.42	0.762
p[†]		0.668	0.715		0.257	0.414	
HAD-D	Baseline	9.19±4.43	7.05±4.14	0.094	6.36±4.96	5.78±3.06	0.978
	3rd month	9.90±4.03	7.40±3.95	**0.031**	6.45±4.98	5.64±3.10	0.912
p[†]		0.177	0.277		0.655	0.458	

RAQoL: Rheumatoid Arthritis Quality of Life Questionnaire; **HAQ:** Stanford Health Assessment Questionnaire; **HAD-A:** Hospital Anxiety and Depression Scale-Anxiety; **HAD-D:** Hospital Anxiety and Depression Scale-Depression; *: Mann Whitney U Testi; †: Wilcoxon Signed Ranks Test; Mean±SD: Mean±Standart deviation.

Table 4. Comparison of the mean scores for the scales (RAQoL, HAQ, HAD-A, HAD-D) among the groups based on arthritis-related deformities.

Scales		Deformities resulting from arthritis					
		Yes			No		
		Intervention group (n=21) Mean±SD	Control group (n=27) Mean±SD	p*	Intervention group (n=11) Mean±SD	Control group (n=7) Mean±SD	p*
RAQoL	Baseline	19.80±7.83	15.59±8.73	0.098	18.90±6.42	12.57±9.34	0.134
	3rd month	17.04±6.82	15.77±8.19	0.539	17.81±6.11	13.85±9.49	0.296
p[†]		**0.008**	0.690		0.229	0.109	
HAQ	Baseline	0.47±0.42	0.41±0.36	0.603	0.44±0.42	0.36±0.40	0.553
	3rd month	0.47±0.46	0.40±0.35	0.602	0.42±0.37	0.38±0.38	0.785

RAQoL: Rheumatoid Arthritis Quality of Life Questionnaire; **HAQ:** Stanford Health Assessment Questionnaire; **HAD-A:** Hospital Anxiety and Depression Scale-Anxiety; **HAD-D:** Hospital Anxiety and Depression Scale-Depression; *: Mann Whitney U Testi; †: Wilcoxon Signed Ranks Test; Mean±SD: Mean±Standart deviation

Table 4. Continue.

p[†]		0.892	0.636		0.918	0.109	
HAD-A	Baseline	9.14±5.86	9.18±4.97	0.661	11.81±4.09	7.28±5.43	0.050
	3rd month	9.66±5.73	9.22±4.80	1.000	12.00±3.76	6.85±5.75	0.050
p[†]		0.501	0.811		0.865	0.317	
HAD-D	Baseline	7.76±4.99	6.88±3.88	0.545	9.09±4.30	5.14±2.96	0.056
	3rd month	8.23±5.15	7.11±3.75	0.364	9.63±3.38	5.00±3.05	**0.018**
p[†]		0.275	0.499		0.348	0.317	

RAQoL: Rheumatoid Arthritis Quality of Life Questionnaire; **HAQ:** Stanford Health Assessment Questionnaire; **HAD-A:** Hospital Anxiety and Depression Scale-Anxiety; **HAD-D:** Hospital Anxiety and Depression Scale-Depression; *: Mann Whitney U Testi; [†]: Wilcoxon Signed Ranks Test; Mean±SD: Mean±Standart deviation

DISCUSSION AND CONCLUSION

The present study determined that the life quality of women with RA improved after training. It can be said that the education given to patients with RA positively affects their quality of life.

In this study, we found that women with RA, regardless of their education level, improved their quality of life after training. Initially, the depression levels of women in the intervention group were higher than those in the control group. Therefore, after the training, the depression levels of the patients in the intervention group were found to be slightly higher than those in the control group. Al-Jabi et al. found that a higher level of education was associated with an improved quality of life in RA patients.[18] In patients with RA, Zhang et al. found that low quality of life and low level of education were risk factors for depression and anxiety.[19] The current study results suggest that women's willingness to learn and educate themselves had a positive impact on their quality of life.

In our study, the quality of life of women with deformities that occurred as a consequence of arthritis was higher after training. In a previous study conducted in patients with RA, the number of swollen joints was found to be associated with depression, with a high number of sensitive joints indicating poor quality of life.[9] In a recent study, it is stated that the quality of life of patients with RA is significantly affected negatively by having a joint deformity.[20] We think that the majority of women with RA who had arthritis-related deformities and taking conventional and biologic DMARDs together are willing to education, and women with RA in this group attribute more importance to education for symptom management, and this improves their quality of life.

In our study, no change was observed in the functional status of women with RA in the intervention and control groups in daily life at the baseline and 3rd month. Gronning et al. stated that there was no change in the functional status of the patients in the intervention group before and after the training.[21] In a study by Abourazzak et al. evaluating the long-term effects of training, no change was found in the patients' functional status in daily life at the beginning and 3 years later.[22] There is a need for more evidence-based research evaluating the functional status in the daily life of individuals with rheumatoid arthritis.

In conclusion, our study determined that the quality of life of women with RA improved after training. We suggest that women with RA should be trained in disease management by rheumatology nurses at regular intervals using educational material. Considering sociodemographic (marital status, education, etc.) and disease-related characteristics (treatment of RA, deformity, chronic disease, etc.) are essential in training programs planned for women with RA. The study has some limitations. A small sample is one of them. Additionally, the study was conducted in a single center in Türkiye, and the effectiveness of the training was only evaluated three months later. Future studies should investigate the long-term effects of patient training. The prevalence of RA is three times higher in women than in men.[3] In Türkiye, the prevalence of RA in women was reported to be 0.89%.[4] The significance of the study, therefore, lies in the fact that it was a randomized, controlled study conducted on women.

their contributions.

Other Information: This study was presented as an oral presentation at the 2nd International Internal Medicine Nursing Congress (17-19 December 2020).

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