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Development of a nursing practice scale for rheumatoid arthritis treatment with biological disease-modifying anti-rheumatic drugs

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ABSTRACT

Objective: The objective of the study was to develop a nursing practice scale for rheumatoid arthritis treatment with biological disease-modifying anti-rheumatic drugs.

Methods: An anonymous self-administered questionnaire survey was administered to 1826 nurses, 960 of whom were Certified Nurses by Japan Rheumatism Foundation (CNJRFs) and 866 were registered nurses (RNs). Using exploratory factor analysis, criterion validity, and known-groups technique, we assessed the reliability and validity of the self-created 19-item nursing practice scale to evaluate the care provided to patients with rheumatoid arthritis receiving biological disease-modifying anti-rheumatic drugs based on the nurse's role as clarified from a literature review of relevant studies.

Results: A total of 698 (38.4%) responses were collected from 407 CNJRFs and 291 RNs. Exploratory factor analysis was conducted on 18 items to examine three factors: 'nursing to enhance patients' capacity for self-care', 'nursing in which patients participate in decision-making', and 'nursing in which team medical care is promoted'. Cronbach's α was .95. The Spearman's coefficient was $\rho = .738$ for criterion validity. Using the known-groups technique, CNJRFs had higher total scale scores than RNs ($P < .05$).

Conclusions: The results confirmed the reliability, criterion validity, and construct validity of the scale.

KEYWORDS: Biological disease-modifying anti-rheumatic drugs; Certified Nurses by Japan Rheumatism Foundation; nursing practice scale; rheumatoid arthritis; registered nurses

1. Introduction

Rheumatoid arthritis (RA) is a debilitating chronic autoimmune condition. It results in comorbidities that affect the cardiovascular, pulmonary, and ophthalmic systems, as well as joint deformities, function limitations, and joint pain [1, 2]. RA is commonly diagnosed in the sixth decade of life [3]. The causes of several rheumatic conditions remain unknown, and delayed treatment results in significant functional limitation, irreversible impairment [4], and significantly lower quality of life and activities of daily living [5, 6]. RA is an incurable disease that persists for life. In developed countries, 0.4%–1.3% of the population develops RA [3]. In Japan, RA occurs in 0.65% of the population [7].

RA treatment has four pillars: basic therapy, rehabilitation, drug therapy, and surgical therapy. The aetiology of RA remains unknown, and the condition is not preventable. Conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), such as anchor drug and methotrexate [3], significantly improve clinical symptoms and slow the progression of joint damage in patients with RA. However, despite the effectiveness of csDMARDs, many patients continue to experience clinical manifestations of inflammation and progressive joint destruction. As our understanding of the pathogenesis of RA evolves, novel cell and molecular targeted biological DMARDs (bDMARDs) [8] have revolutionised the treatment paradigm of RA given their better efficacy compared with csDMARDs [9]. bDMARDs are highly effective, and many studies in and outside Japan have shown that they significantly suppress not only the disease activity but also the progression of joint destruction and physical dysfunction [10–13]. Clinical remission is the main therapeutic target for patients with RA with low disease activity as the best possible alternative, and a treat-to-target strategy should be applied when treating patients with RA [14].

However, among patients with RA who have been treated with bDMARDs and achieved sustained remission, many will require lifelong treatment [15]. Thus, patients continue self-injection of bDMARDs in daily life. Owing to anxiety and the large burden in terms of personal, social, and medical costs, patients may experience difficulties before remission [16, 17].

Moreover, the use of bDMARDs increases the risk of infection and complications [18]. However, the mortality rate can be reduced by raising awareness of infection risk management [19]. In addition to disease treatment, patients with RA must pay attention to various aspects, such as recognising addiction and complications, coping with life events due to the deterioration of physical function and health literacy for infection prevention measures. Medical care for RA is based on the collaborative decision-making of patients and rheumatologists [20]. In the medical field, important medical data related to the patient's health condition should be obtained; however, not all data were revealed to doctors [21]. As an 'advocate' [22], the nurse, who is the closest medical staff to the patient, should be aware of the patient's condition, understand the patient's will, and alleviate their anxiety and difficulties. To date, most studies have focused on patients with RA, but few have focused on nurses.

The Japan Rheumatism Foundation aims to contribute to the health and welfare of the people through systematic treatment and care by advancing medical technology and improving medical standards. The Registered Physician to Japan Rheumatism Foundation (RPJRF) was established in 1986 [23], Certified Nurses by Japan Rheumatism Foundation (CNJRFs) in 2010 [24], Certified Pharmacist by Japan Rheumatism Foundation in 2014 [25], and Certified Physical and Occupational Therapist by Japan Rheumatism Foundation in 2019 [26], and specialist medical professionals with experience and knowledge in RA nursing were born. Recently, medical institutions have promoted team medical care, such as cooperation and coordination among highly skilled professionals [27]. We believe that efficient medical care for RA can be provided with the cooperation of specialist medical professionals, and improving the quality of patient care will lead to improved patient satisfaction.

In team medical care, nurses as advocates should deepen their understanding of RA, understand the detailed background of patients, and work with doctors and medical staff to meet the needs of the patients.

The location and frequency of workshops differ among regions. Even if a rheumatology nurse is qualified, each nurse is in a different situation, depending on the geographical and temporal backgrounds involved in maintaining the qualification [28]. Furthermore, many patients with RA are not being cared for by CNJRFs. Thus, this study aimed to examine nursing practice for RA treatment with bDMARDs. The results of this study can be used to improve the quality of nursing care by raising awareness and knowledge of RA among nurses in hospitals without CNJRFs so that more patients with RA can receive appropriate nursing care with effective bDMARDs. Based on regional characteristics, we consider education proposals that can strengthen cooperation among RA medical professionals through cross-sectional surveys targeting the whole country.

2. Materials and methods

2.1 Process of creating a draft nursing practice scale for RA treatment with bDMARDs

First, a literature review was conducted to clarify nursing practice based on the role of nursing in bDMARD treatment [29]. We were supervised by three rheumatology nursing managers to enhance the validity of the qualitative data analysis. As such, nursing practice based on the role of nursing for RA patients after the introduction of bDMARDs was divided into three categories and 27 items: 'Support to increase self-initiative towards treatment', 'Self-care management and preventive support for symptoms', and 'Support for life recuperation using team medical care'.

Next, we asked six specialist nurses with >10 years of clinical experience to investigate the survey items that represent nursing practice and examine overlapping items in terms of meaning and face validity. Finally, a nursing practice scale (draft) containing 19 items was established for patients with receiving bDMARD treatment.

2.2 Design

A self-administered anonymous questionnaire was used for this cross-sectional survey.

2.3 Sample

CNJRFs and registered nurses (RNs) were recruited according to the following procedure.

2.3.1 CNJRF group

On the Japan Rheumatism Foundation website, which lists registered physicians, certified nurses, certified pharmacists, and certified physical and occupational therapists of medical institutions that belong to the Japan Rheumatism Foundation [30], considering the population distribution by prefecture, 960 of 1268 nurses were selected by stratified random sampling.

2.3.2 RN group

(1) On the Japanese College of Rheumatology (JCR) website, which lists JCR-board certified rheumatologists, JCR-board certified rheumatologist instructors, and medical institutions [31], the medical institutions were searched by prefecture using the keywords 'rheumatism' and 'collagen disease'.

(2) On the Japan Rheumatism Foundation website, which lists registered physicians, certified nurses, certified pharmacists, and certified physical and occupational therapists of medical institutions affiliated with the Japan Rheumatism Foundation [30], medical institutions were searched for RPJRF nationwide.

(3) After excluding the overlapping data in (1) and (2) lists and the list of 2669 medical institutions, except for institutions that do not provide rheumatism treatment (research institutions, etc.) and medical institutions that specialise in paediatrics, we extracted 138 medical institutions that reliably provide bDMARDs with advice from specialists. A total of 120 medical institutions were identified by stratified random sampling.

For the scale analysis, it was necessary to collect 200–400 samples, which was 10–20 times the number of questions set for the exploratory factor analysis. Aiming for a 40–50% effective response rate, questionnaires were distributed to 800 nurses to ensure the collection of responses from 400 nurses.

2.4 Methods

In the CNJRF group, a research cooperation request, a questionnaire survey, and a return envelope were mailed and distributed to the participants. For collection, each nurse filled

out the questionnaire, put it in a self-addressed envelope, and returned it to the researcher. We conducted a mail questionnaire survey and a web-based survey using self-administered questionnaires and asked them to answer either one. The questionnaires of six nurses with unknown addresses were returned, and the questionnaires were distributed to 954 nurses. The survey was conducted from October to December 2020.

In the RN group, we mailed inquiries about participation in the research to the nursing director of the medical institutions and sent a research cooperation request form and a questionnaire survey form to the nurses of the medical institutions that cooperated with the research. Questionnaires were collected by postal mail, in which nurses voluntarily filled in the questionnaires and returned them directly to the researchers. Of the 120 medical institutions, questionnaires were distributed to 866 nurses from 37 medical institutions who agreed to participate in the study. The survey was conducted from December 2021 to March 2022.

2.5 Measures

2.5.1 Personal attributes

The questionnaire included items about personal attributes (such as age, years of experience as a nurse, position, number of beds in their hospital, experience in nursing patients with RA, and presence of CNJRF qualification), whether there are any specialist medical professionals of Japan Rheumatism Foundation working at the medical institutions, and medical knowledge about bDMARDs.

2.5.2 Nursing practice scale for RA treatment with bDMARDs (draft)

The 19 items of the nursing practice scale (draft) for RA treatment with bDMARDs were classified into five categories. Higher scores showed higher self-evaluation of the practice ability of nursing (1, never; 2, sometimes; 3, neutral; 4, often; and 5, always).

2.5.3 Scale for the Core Competencies of Rheumatology Nurse Practice

Criterion validity was confirmed using the scale for the Core Competencies of Rheumatology Nurse Practice [32], whose reliability and validity have been verified as a scale for nursing patients with RA who are not taking bDMARDs. Permission was obtained from the developer to use the scale. The scale included 23 items about 'knowledge and skills specialised in rheumatology', 'listening attitude', 'coordination for smooth rheumatology care provision', 'practical techniques to support self-care', and 'support for patients under treatment'. The grade was classified into five categories: 1, never; 2, sometimes; 3, neutral; 4, often; and 5, always. The score ranges from 23 to 115, with higher scores indicating higher nursing practice ability according to self-evaluation. Cronbach's α was .931.

2.6 Analytical strategy

Data analysis combined the CNJRF and RN questionnaires and included those with no missing values for the nursing scale questions. IBM SPSS Statistics for Windows, version 27 (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

2.6.1 Item analysis

Ceiling effects [mean + standard deviation (SD) > 5] and floor effects (mean + SD < 1) were confirmed by means and SDs of each item of the nursing practice scale. Furthermore, the correlation coefficient between each item and the scale as a whole (I-T correlation) was calculated. In the I-T correlation, items with a correlation coefficient of ≤.30 between each item score and the total score were subject to deletion [33].

2.6.2 Exploratory factor analysis

To ensure sampling sufficiency and compatibility for the factor analysis, we performed the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity. With a KMO value of >.5 and significant Bartlett's test ($P < .001$), the sample was sufficient and suitable for factor analysis [34]. Exploratory factor analysis (the principal factor method, promax rotation, and factor loading of <.4 were removed [35]) was performed on the items sorted in the item analysis. The subscale factors were reviewed and interpreted to name the factors.

2.6.3 Examination of reliability and validity

To examine the reliability of the scale, Cronbach's α was calculated for the overall scale and subscale factors. In addition, to confirm the reliability of the existing scale in this study, Cronbach's α was calculated for the overall nursing practice scale and subscale factors.

Criterion validity, construct validity, and content validity were used to examine the validity of scales. In examining criterion validity, we used an external criterion, the scale for the Core Competencies of Rheumatology Nurse Practice [32]. This scale, which measures the nursing practice ability of rheumatism nurses, was selected because it can confirm a reasonable relevance to the nursing practice ability of patients with RA treated with bDMARDs. Spearman's correlation coefficient was calculated for the total score of both scales and for each subscale factor using the self-made scale and the nursing practice scale for rheumatism nurses. A correlation coefficient of as low as .3 or .4 is sufficient for criterion validity [36].

Construct validity was examined by the Mann–Whitney U test using the known-groups technique after the exploratory factor analysis (main factor method and promax rotation). The known-groups technique estimates the construct validity of an instrument by analysing the degree to which the instrument separates groups predicted to differ based on known characteristics or theory [37].

Currently, patients with RA treated with bDMARDs receive nursing care from CNJRFs who have professional qualifications related to RA treatment and RNs who do not have professional qualifications. As it is possible to extract variables that may be related to differences in nursing practice, the presence and absence of professional qualifications were set as attributes assuming differences in scale scores.

2.7 Ethical statement

We explained in writing that participation in the study was voluntary, that an anonymous self-administered questionnaire would be used, and that patients would not be disadvantaged even if they did not participate. The Ethical Committee for

Epidemiology of Hiroshima University approved this investigation (permit nos. E-2211, E-2655).

3. Results

Responses from 466 (48.8%) CNJRFs were received, including 384 CNJRFs by mail and 82 CNJRFs via the Internet, and 59 CNJRFs with missing answers were excluded from the analysis. Consequently, 407 (42.7%) CNJRFs were included in the analysis.

Responses from 402 (46.4%) RNs were received. Moreover, 78 CNJRFs and 5 RNs who did not answer whether they had professional qualifications were excluded from the analysis to eliminate overlapping with the CNJRF survey. Ten RNs with no RA nursing experience and 18 RNs with missing answers were excluded from the analysis; thus, 291 (33.6%) RNs were included. Based on the above results, a total of 698 nurses were analysed.

3.1 Personal attributes (Table 1)

The age of the nurses varied from 21 to 65 (average, 44.0 ± 10.1) years. The duration of nursing experience varied from 1 to 45 (average, 20.3 ± 9.8) years. More than 80% of CNJRFs were >40 years old, and <50% were RNs. As regards position, most CNJRFs and RNs were staff nurses, but CNJRFs were more likely managers.

3.2 Nursing practice scale for RA treatment with bDMARDs

3.2.1 Item analysis

The score distribution and I-T correlation were confirmed for all 19 items using the mean and SD (Table 2). The I-T correlation of items and scale showed a significant correlation over .539 ($P < .01$). The item with the highest average value of 4.38 ± 0.88 points was '6 Check the patients for symptoms of side effects of the injection'. A total of nine items (Items 4 and 6–13) showed a biased ceiling effect, but many items were related to the self-injection of bDMARDs. We considered that the question items were also essential for evaluating the nursing role; thus, we analysed all items.

3.2.2 Exploratory factor analysis

The exploratory factor analysis of the 19 items (main factor method and promax rotation) showed that they had factor loadings of <.4, except for one item (Item 15). After removing this item, the factor analysis was conducted again. Subsequently, 18 items were extracted, which were included in the three factors identified (Table 3). The KMO value, which indicates the sample validity of the factor analysis, was .944, and the result of Bartlett's test was significant ($P < .001$).

The first factor contained seven items that captured the construct about improving self-care skills such as 'self-injection technique', 'difficulties in life', and 'abnormalities at the injection site'. Therefore, the first factor was termed 'nursing to enhance patients' capacity for self-care'. The second factor contained eight items that captured the construct about the attitude to treatment, such as 'treatment effect', 'decision-making treatment', 'differences in treatment policy', and 'distrust of treatment'. Therefore, the second factor was termed 'nursing in which patients participate in decision-making'. The third factor contained three items that captured the construct about the promotion of team medical care, such as 'lifestyle suggestions', 'treatment goal sharing', and 'patient association settings'. Therefore, the third factor was termed 'nursing in which team medical care is promoted'.

When examining the correlation between factors, the first (nursing to enhance patients' capacity for self-care) and second (nursing in which patients participate in decision-making) factors were found to have a strong correlation. The second (nursing in which patients participate in decision-making) and third (nursing in which team medical care is promoted) factors were found to have a moderate correlation. The first (nursing to enhance patients' capacity for self-care) and third (nursing in which team medical care is promoted) factors were found to have a weak correlation.

3.2.3 Reliability

The internal consistency of this scale was calculated (Table 3). Cronbach's α coefficient of the 18 items was .95, with .96, .91, and .84 for the first, second, and third factors, respectively.

Subscale correlations of the nursing practice for RA treatment with bDMARDs are shown in Table 4. The three subscales were significantly correlated with each other.

Table 1. Personal attributes of participants [$N = 698$ (%)].

Personal attributes		CNJRFs ($n = 407$)	RNs ($n = 291$)	Total ($N = 698$)
Age (years)	Average	47.3 ± 8.0	39.3 ± 10.8	44.0 ± 10.1
	Range	24–65	21–62	21–65
	21–29	9 (2.2)	75 (25.8)	84 (12.0)
	30–39	57 (14.0)	68 (23.4)	125 (17.9)
	40–49	185 (45.5)	92 (31.6)	277 (39.7)
	>50	156 (38.3)	56 (19.2)	212 (30.4)
Years of experience as a nurse	Average	23.4 ± 8.3	16.0 ± 10.0	20.3 ± 9.8
	range	4–45	1–41	1–45
	<10 years	20 (4.9)	96 (33.0)	116 (16.6)
	10–20 years	96 (23.6)	79 (27.1)	175 (25.1)
	>20 years	291 (71.5)	116 (39.9)	407 (58.3)
Position	Staff nurse	283 (69.5)	260 (89.3)	543 (77.8)
	Manager	120 (29.5)	30 (10.3)	150 (21.5)
	Unanswered	4 (1.0)	1 (0.4)	5 (0.7)

Table 2. Score of the mean and SD with 19 items [$N = 698$ participants (%)].

Items		M	SD	I-T
Support to increase self-initiative towards treatment				
1	Set treatment goals with the patients	3.23	1.14	.702**
2	Check if the patients have any differences in treatment policy with the medical staff	3.59	1.05	.701**
3	Make sure the patients have decided on the treatment	3.72	1.03	.690**
4	See if the patients are feeling the effects of the treatment	4.16	0.88	.590**
5	Check the patients for distrust of treatment	3.91	0.92	.651**
Self-care management and preventive support for symptoms				
6	Check the patients for symptoms of side effects of the injection	4.38	0.88	.672**
7	Check if the patients have any difficulties with self-injection	4.09	1.01	.715**
8	Check if the patients are afraid of self-injection	4.17	1.01	.704**
9	Check if the patients' self-injection craft is accurate	4.26	1.06	.674**
10	Check the patients for abnormalities at the injection site	4.29	0.99	.670**
11	Check the degree of pain from self-injection	4.08	1.05	.697**
12	Check the patients how to deal with self-injection problems	4.00	1.08	.734**
Support for recuperation life using team medical care				
13	Check if the patients have physical difficulties caused by joint deformities	4.16	0.89	.662**
14	Make sure the patients' family understands the pain of the illness	3.47	.99	.653**
15	Explain to patients the public support system that can be used for RA	3.12	1.16	.644**
16	Provide a place where patients can freely ask questions to nurses	3.61	1.01	.604**
17	Provide a place where patients can communicate to each other	2.50	1.15	.539**
18	Propose a lifestyle that suits the patients' disability through team medical care	2.79	1.15	.609**
19	Share patient-set goals with team medical staffs	3.03	1.18	.619**
Total		70.59	19.62	

The number before the item indicates the question item number.
Choices: 1 = never, 2 = sometimes, 3 = neutral, 4 = often, 5 = always.
**$P < .01$.

Table 3. Exploratory factor analysis of the nursing practice scale for RA treatment with bDMARDs.

Item $\alpha = .95$	R1	R2	R3
R1. Nursing to enhance patients' capacity for self-care ($\alpha = .96$)			
9 Check if the patients' self-injection craft is accurate	**.99**	−.16	.05
11 Check the degree of pain from self-injection	**.95**	−.13	.11
10 Check the patients for abnormalities at the injection site	**.87**	.04	−.02
12 Check the patients how to deal with self-injection problems	**.87**	−.02	.08
8 Check if the patients are afraid of self-injection	**.79**	.19	−.10
7 Check if the patients have any difficulties with self-injection	**.77**	.16	−.03
6 Check the patients for symptoms of side effects of the injection	**.57**	.41	−.12
R2. Nursing in which patients participate in decision-making ($\alpha = .91$)			
3 Make sure the patients have decided on the treatment	−.05	**.85**	.02
5 Check the patients for distrust of treatment	.06	**.80**	−.07
2 Check if the patients have any differences in treatment policy with the medical staff	−.08	**.78**	.14
4 See if the patients are feeling the effects of the treatment	.17	**.75**	−.17
1 Set treatment goals with the patients	−.05	**.58**	.28
13 Check if the patients have physical difficulties caused by joint deformities	.27	**.52**	.07
14 Make sure the patients' family understands the pain of the illness	.13	**.41**	.29
16 Provide a place where patients can freely ask questions to nurses	.09	**.40**	.26
R3. Nursing in which team medical care is promoted ($\alpha = .84$)			
18 Propose a lifestyle that suits the patients' disability through team medical care	.02	−.05	**.91**
19 Share patient-set goals with team medical staffs	−.06	.13	**.79**
17 Provide a place where patients can communicate to each other	.07	−.06	**.67**
Interactor correlation	**R1**	**R2**	**R3**
R1		.71	.36
R2			.58
R3			

Factor extraction method: principal factor method.
Rotation method: promax method with Kaiser normalisation.
α: Cronbach's α coefficient. bold values: factor loading.

In this study, Cronbach's α coefficient of the scale for the Core Competencies of Rheumatology Nurse Practice was .950, with .819–.963 for the subscale, maintaining internal consistency.

3.2.4 Validity

3.2.4.1 Consideration of criterion validity The criterion validity was examined using the scale for the Core Competencies of Rheumatology Nurse Practice. The

Table 4. Subscale correlations of the nursing practice scale for RA treatment with bDMARDs.

	Nursing to enhance patients' capacity for self-care	Nursing in which patients participate in decision-making	Nursing in which team medical care is promoted
Nursing to enhance patients' capacity for self-care	–	.63**	.29**
Nursing in which patients participate in decision-making	–	–	.58**
Nursing in which team medical care is promoted	–	–	–

**P < .01.

Table 5. Correlation between the nursing practice scale for RA treatment with bDMARDs and the scale for the Core Competencies of Rheumatology Nurse Practice.

	Scale for the Core Competencies of Rheumatology Nurse Practice					
	Total scores	Knowledge and skills specialised in rheumatology	Listening attitude	Coordination for smooth rheumatology care provision	Practical techniques to support self-care	Support for patients under treatment
Total scores of the nursing practice scale for patients with RA treated with bDMARDs	.736**	.718**	.399**	.591**	.461**	.650**
Nursing to enhance patients' capacity for self-care	.518**	.541**	.397**	.415**	.244**	.438**
Nursing in which patients participate in decision-making	.710**	.698**	.411**	.589**	.425**	.602**
Nursing in which team medical care is promoted	.577**	.501**	.170**	.477**	.533**	.534**

Spearman's correlation explained;
**P < .01.

correlation between the total scores of the nursing practice scale for RA treatment with bDMARDs and the total scores of the scale for the Core Competencies of Rheumatology Nurse Practice was $r = .736$ ($P < .01$) (Table 5). The correlation between the total scores of the nursing practice scale for RA treatment with bDMARDs and the five subscales of the scale of the Core Competencies of Rheumatology Nurse Practice ranged from $r = .399$ to $r = .718$ ($P < .01$). In addition, the correlation between the three subscales of the nursing practice scale for RA treatment with bDMARDs and the five subscales of the scale of the Core Competencies of Rheumatology Nurse Practice ranged from $r = .170$ to $r = .698$ ($P < .01$). A significant correlation was observed at the $P < .01$ level with the scale to evaluate the Core Competencies of Rheumatology Nurse Practice as the external standard.

3.2.4.2 Consideration of construct validity We compared the total scale and subscale scores of the nursing practice scale between the CNJRF group and the RN group based on the presence or absence of professional qualifications related to RA treatment. The total scale scores ($P < .01$), as well as those for 'nursing to enhance patients' capacity for self-care' ($P < .001$) and 'nursing in which patients participate in decision-making' ($P < .05$) were significantly higher in the CNJRF group than in the RN group. The RN group had a

significantly higher score for 'nursing in which team medical care is promoted' ($P < .001$) (Table 6).

4. Discussion
4.1 Statistical reliability and validity
In this study, we created an original draft scale from previous studies, and using stratified random sampling, we recruited CNJRFs and RNs working at medical institutions nationwide providing treatment with bDMARDs and examined their responses. After confirming the 18-item three-factor structure by item analysis and exploratory factor analysis, we verified the reliability and validity of the scale by internal consistency, criterion validity, and construct validity. The developed nursing practice scale for RA treatment with bDMARDs consists of 18 items. The total score ranges from 18 to 90 points, and it is interpreted that the higher the score, the higher the degree of nursing practice ability.

Cronbach's α coefficients for the scale as a whole and for the first, second, and third factors were all $\geq .800$, which satisfies the criterion for admissibility as a measurement tool, and its internal consistency was confirmed [38]. In addition, the Cronbach's α coefficient for the Core Competencies

Table 6. Comparison of mean values between the known-groups.

Scores and subscales	Professional qualifications		P-value
	CNJRFs (n = 407)	RNs (n = 291)	
Total scores	72.09 ± 12.92	68.48 ± 15.47	.004
Nursing to enhance patients' capacity for self-care	30.33 ± 5.56	27.81 ± 7.06	.000
Nursing in which patients participate in decision-making	30.41 ± 5.82	29.09 ± 6.61	.018
Nursing in which team medical care is promoted	7.93 ± 3.01	8.86 ± 2.95	.000

Mann–Whitney U test.

of Rheumatology Nurse Practice was .945, confirming the reliability of existing scales in this study.

The criterion validity strongly correlated with the scale for the Core Competencies of Rheumatology Nurse Practice and the total scores of this study. Moderate correlations were also observed between the subscales of both scales, but the correlation between 'nursing in which team medical care is promoted' and 'listening attitude' was not as strong. Thus, the factor 'nursing in which team medical care is promoted' is mainly about the cooperation between health professionals, which is not covered by the 'listening ability'.

Since the I-T correlation of this scale was ≥.539 for all items, no items had low relevance, and 18 items of the total scale were content items with originality.

Using the known-groups technique, we found clear differences in scale scores depending on professional qualifications. This indicates that the scale can measure differences in the quality of nursing practice in RA treatment with bDMARDs in the presence or absence of professional qualifications. Therefore, a known difference was found between the groups, which supports the construct validity of this measure [39].

The cause of RA and its treatment method are not yet known, and no treatment method can completely cure it. Life-long health management is important. Thus, medical staff should provide appropriate content on health-care and self-care methods to patients with RA. Self-care is said to have beneficial effects, such as improved well-being and lower morbidity, mortality, and health-care costs [40]. It can suppress illness prevention or accidents and the provision of social, emotional, and psychological needs of patients with RA [41]. Nurses are expected to use their specialised knowledge and skills to provide support and enhance appropriate self-care abilities.

A patient's cultural, linguistic, cognitive, physical, and psychological needs, as well as their permission for care and related treatment, should be based on clear, accurate, sufficient, and timely information that the patients and family receive from the nurse [42]. In addition, even if the conclusion is the same, the patient's degree of satisfaction varies greatly depending on whether the patient fully participated in decision-making related to the treatment [43]. The factor 'nursing in which patients participate in decision-making' refers to the important role of nurses as advocates.

With the advancement and complexity of medical care, nurses are the largest group of health-care professionals [44], helping patients in various settings, and the clinical outcomes they achieve are similar to those of specialist rheumatologists [45]. In parallel with treatment, patients with RA are treated as outpatients [46], and the home is the primary place of care; thus, we believe that nurses should understand the

recuperation life of patients and their families and feedback obtained from the patients and doctors and play a supporting role in promoting communication between patients and doctors. In addition, RA treatment requires not only drug therapy but also care, including rehabilitation, surgical therapy, and nursing care. Medical professionals, such as doctors, pharmacists, physiotherapists, occupational therapists, and medical social workers, can address concerns related to the side effects of medications, questions about abnormal laboratory results, psychological support, and self-management of arthritic flares [47]. By promoting medical care in collaboration with other professions, we can provide higher quality nursing and medical care. 'Nursing in which team medical care is promoted' is considered an important aspect of nursing as nurses are key persons in team medical care. Based on the above, we can generally confirm the reliability and validity of this scale.

4.2 Suggestions for nursing practice by the developed scale

Previous research has focused on general rheumatology nursing, and a survey targeting CNJRFs has developed a scale for Core Competencies of Rheumatology Nurse Practice [32]. However, the introduction of bDMARDs throughout Japan in 2013 [48] has created the need for individualised medical care, such as self-injection guidance, infection prevention, and guidance on daily life to continue bDMARD treatment. The nursing practice scale created in the current study focuses on bDMARDs, and our survey involved not only CNJRFs but also RNs. Our results showed that CNJRFs promoted improved self-care ability and decision-making support than did RNs, whereas RNs promoted better team medical care than did CNJRFs. This finding recognises that nurses should have access to and undertake continuous medical education in the specialty of rheumatology to improve and maintain their knowledge and skills [49]. In addition, given that the RN group had lower expertise than the CNJRF group, we emphasised the need for team medical care by consulting with more professionals. The scale developed in this study allows for the calculation of the scores for the entire scale and for each subscale. Nurses caring for patients with RA can objectively grasp the need for improvement or adjustment by self-evaluating nursing practice and assessing the current situation using the scale. Consequently, nurses should use this scale to self-evaluate, clarify, and improve their behaviours in nursing practice.

4.3 Limitations and future issues

In this study, a nationwide survey was conducted on CNJRFs in the Japan Rheumatism Foundation and RNs of general

hospitals. The recovery rate of RNs was low. RNs were less frequently associated with the interest of patients with RA than CNJRFs. The subjects of this study were limited to nurses who had experience with patients with RA. There was a high possibility that these nurses were interested in caring for patients with RA and worked actively. We believe that the validity of this scale may have been overestimated regardless of whether the responders were CNJRFs or RNs. In addition, although this study was an analysis of a national survey, the type of medical facility or region was not examined, which, we believe, needs to be investigated. Furthermore, we will use the nursing practice scale for RA treatment with bDMARDs to examine the difference in the practice skills of nurses with experience in nursing patients with RA and clarify whether they are related to any factors. Furthermore, we will develop an educational intervention programme to improve nursing practice and contribute to improving the quality of care provided by RNs and the uniformity of nursing care received by patients with RA.

5. Conclusions

This study developed a nursing practice scale for RA treatment with bDMARDs that included 18 items, with the following three factors: 'nursing to enhance patients' capacity for self-care', 'nursing in which patients participate in decision-making', and 'nursing in which team medical care is promoted'. The reliability, criterion validity, and construct validity of the scale were all confirmed statistically. Nurses are expected to use this scale to self-evaluate, clarify, and improve their behaviours in nursing practice intentionally.

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Conflict of interest

None declared.

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Author contributions

F.S. and H.N. conceived the idea of the study. F.S., H.N., E.S., and S.H. designed the analysis. F.S. and H.N. collected the data, and F.S. analysed contributed data with SPSS software and drafted the original manuscript. All authors critically reviewed and revised the manuscript and approved the final version for submission.

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