

## A structured self-management protocol on awareness, disability and complications among patients with rheumatoid arthritis receiving biological therapy: A quasi-experimental study

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### Abstract

**Background:** Rheumatoid arthritis (RA) is a chronic condition that impacts many aspects of life. Biological therapy usually is used to treat moderate to severe disease conditions. Education and support could help people with RA to foster strategies to cope with the disease and its related complications.

**Aim:** To evaluate the effect of a structured self-management protocol on awareness, disability and complications among patients with rheumatoid arthritis receiving biological therapy.

**Methods:** A quasi-experimental design was utilized. A Hundred twenty patients with rheumatoid arthritis currently receiving biological therapy were enrolled from the Rheumatic Disease Unit & Outpatient clinic, divided into control and study groups (60 for each). The study group received a structured self-care protocol developed by the authors including educational sessions, printed materials, and weekly follow-up for 8 weeks. Awareness and disability levels were measured pre- and post-intervention using a validated RA awareness questionnaire, the Health Assessment Questionnaire Disability Index (HAQ-DI), and Biological therapy complications scale (BTCS).

**Results:** The study group showed statistically significant improvements in awareness scores and a significant decrease in disability scores and biological therapy complications at  $p < 0.001$  compared to the control group.

**Conclusion and Recommendations:** The structured self-management protocol significantly improved awareness and reduced disability in RA patients receiving biological therapy. Incorporating such protocols into routine care is recommended to enhance patient outcomes.

**Keywords:** Awareness; Biological therapy; Disability; Self-management; Rheumatoid arthritis

### 1. Introduction

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disease mostly affecting small synovial joints usually proportionally. Symptoms more than 6 months are established the diagnosis of RA <sup>[1]</sup>. A setup of cytokines and cells provoke synovial cell creation and cause impairment to both cartilage and bone <sup>[2]</sup>. In 2019, 18 million people worldwide were living with rheumatoid arthritis <sup>[3]</sup>. In Egypt the average age at onset of patients with RA was 38 years, and the

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ratio of females to males was 5-4:1. The continuum of RA phenotype in Egypt is varying across the country. Nevertheless, genetic and environmental factors cannot be omitted [4].

Biological therapy for patients with moderate to severe rheumatoid arthritis activity and poor prognostic factors after 6 months of conventional Disease-Modifying Anti-Rheumatic therapy Egypt. To improve the clinical outcome in RA, various therapeutic tactics are required [4]. The appearance of biologics has changed the treatment of RA due to their remarkable impact on disease manifestations and their ability to lessen joint damage. With the advance of biologics and Janus kinase inhibitors, these agents are being used by an increasing number of patients including those with a mild disease [5 and 6].

Best promising care for patients with RA includes an incorporated approach that includes non-pharmacologic as well as pharmacologic therapeutic interventions. Physical activity is a significant intervention for cultivating disability in rheumatic disease. Several non-pharmacologic actions are available for this disease, including tailor-made exercise, specifically endurance exercise, diet, occupational therapy, stress reduction, physiotherapy, and surgery [7]. Also Psychotherapy helps to advance self-confidence and regaining positive assertiveness to cope with the depression and associated comorbidities in patients with RA [8 and 9].

Self-management are interventions that aim to provide patients with awareness and practices that allow them to participate and take responsibility in disease management in order to minimize or control disability and ultimately function optimally. These practices include acquiring knowledge and a mixture of independent sign / symptom monitoring, medication management, enhancing problem solving and decision-making skills for medical treatment, managing and changing physical activity, dietary habits, and smoking behavior [10].

At today, there is an extensive need for conducting studies to specify which RA patients will have resolve symptoms of the disease and which will entail adverse effects and complications of biological therapy. The major focus of authors of this study is to evaluate the effect of implementation of self-care management protocol on awareness, disability and complications of biological therapy especially as its one of the expensive therapies among RA patients which causing financial burdens.

### *Aim of the Study*

To evaluate the effect of a structured self-management protocol on awareness and complications among patients with rheumatoid arthritis receiving biological therapy.

#### **1.1. Research Hypotheses**

- [H1] Patients who receive the structured self-management protocol will demonstrate improved awareness levels compared to baseline.
- [H2] Patients who receive the structured protocol will exhibit reduced disability levels compared to the control group.
- [H2] Patients who receive the structured protocol will exhibit reduced complications of biological therapy compared to the control group.

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## **2. Subjects and Methods**

**Design and Setting:** A quasi-experimental, pre-post controlled study was conducted at The study was conducted at Rheumatic Disease Unit and Outpatient clinic, affiliated to Ain Shams University Hospitals, Cairo, Egypt.

**Sample and Participants:** A Hundred twenty patients with RA undergoing biological therapy were recruited using purposive sampling and randomly assigned into: Study group (n=60) and Control group (n=60). Inclusion criteria included age 18–60, ability to communicate, and willingness to participate. Exclusion criteria: other autoimmune diseases, Comorbidities severely affecting functional ability, Cognitive impairment, or Recent surgery. Sampling adequacy was evaluated by Kaiser–Meyer–Olkin (equals 0.7) and Bartlett's test ( $p < 0.001$ ).

### **2.1. Tools of Data Collection**

#### *2.1.1. Characteristics and Clinical Data Sheet*

To entail the characteristics and clinical data of the patients in both groups

### *2.1.2. Rheumatoid Arthritis Patient Awareness Questionnaire (RAPAQ)*

Developed by researchers after reviewing the recent literature. The questionnaire composed of 20 multiple-choice questions measuring disease understanding, categorized into 2 sections [I: RA General information] [II: Self-management practices, and therapy adherence. RAPAQ scored for correct answer equal 1 point. Incorrect/unanswered answer = 0 point. Total score of RAPAQ is categorized into: 0–6 Points is Low awareness, 7–13 is Moderate awareness and 14–20 is High awareness <sup>[11 and 12]</sup>.

### *2.1.3. The Stanford Health Assessment Questionnaire–Disability Index (HAQ-DI)*

Measures functional disability among patients with RA. HAQ-DI is calculated by averaging the scores of eight functional categories: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and usual activities. Each category includes patient response on a scale of 0-3.

### *2.1.4. Biological Therapy Complications Scale (BTCS)*

Designed by the researchers and referenced from <sup>[15 and 16]</sup>. The scale filled twice after the biology therapy session, the first one in the first week of pre-intervention phase of self-management protocol, while the second time at the last week of post- intervention phase of self-management protocol to observe the patient during and record the problems that occurred and estimate the reappearance of complications before and after implementation of self-care management protocol. The scale composed of 10 complications as follow; respiratory infections, urinary tract infections, injection site reactions, hypersensitivity reactions, elevated liver enzymes, hematologic abnormalities, cardiovascular events, skin infections, neurological complaints, and autoimmune flare-ups. The patient responses are categorized on a 4-point Likert scale shifting from (1) for None, (2) for Moderate, (3) Mild, and (4) for Sever. The higher scores refer to the worst complications.

## **2.2. Tools Validity and Reliability**

Evaluating face and content validity of the recommended tools throughout a jury of Five expert's professors of Nursing and Medicine, Ain Shams University, who revised the tools, for clearness, significance, inclusiveness, comprehension, and easiness for application, no changes were requisite. Tools Reliability: Cronbach's Alpha test was applied to determine the internal consistency of the study tools, with reliability rate equals 0.87 and 0.89.

## **2.3. Self-Management Protocol**

It was designed and revised by the researchers, and validated by a pilot testing for content and face validity. The Protocol materials were including Handout, Images, Posters and Videos which printed and shared with patients via a group of WhatsApp. The Protocol materials were based on reviewing relevant literature <sup>[17 and 18]</sup>.

## **2.4. Procedure**

Field work (Time duration: 2 months): Approvals is finalized, including Ethical approval which obtained from the Faculty of Nursing IRB. Also a Written Informed consent was taken from all participants. In addition of the development and validation of the tools.

### **2.5. Pre intervention phase (Time duration: 1 month)**

The researchers were visiting Rheumatology Medicine Unit and Outpatient clinic around 5 days/week for six months from 9.00 am to 2.00 pm "Time is occasionally modified according the schedule of Biology treatment for patients individually". The aim of the study was explained with confirming on confidentiality and anonymity to patients who consented to participate in the study preceding data collection. Baseline data is generated for both groups by the researchers to fulfill the data instruments before intervention of Self-Management Protocol by distribution of the instruments among patient prior to time of hospital visit for each patient individually.

### **2.6. Intervention Phase (Time duration: 2 months/ 4 sessions/wk.)**

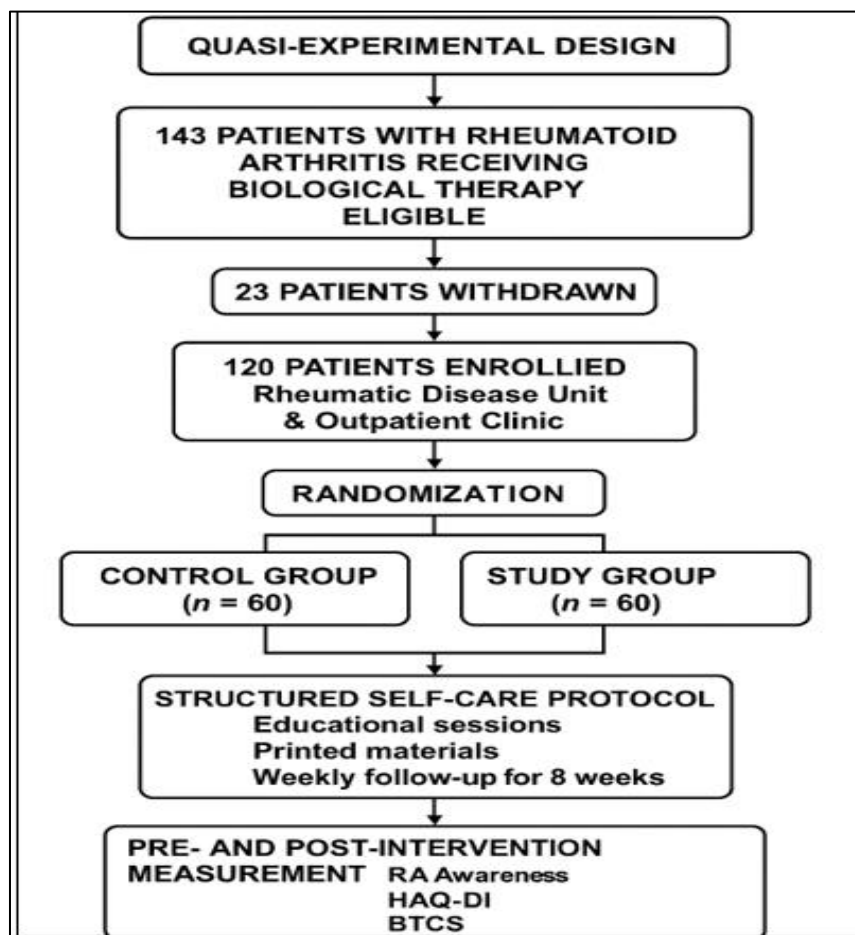
Application of Self-Management Protocol is initiated by researchers to the intervention group, by providing 4 sessions weekly face-to-face (45-60 minutes each), Illustrated materials covering, disease information, joint protection, exercise, nutrition, medication adherence, Monitoring complications and coping skills. In addition to tele-sessions via WhatsApp group. The intervention group received a structured self-management protocol over six weekly sessions (60–90 minutes each), delivered by trained nurses. Sessions included:

Regarding the control group only received standard care which including routine care and prescribed therapy. Sessions were mostly done before Biology treatment, as usually patients being exhausted and not ready for demonstrative sessions. The study subjects were categorized into small groups; of 3–4 patients per each session. The self – management protocol was covered by the researchers to the intervention group and their caregivers go along with figures and videos about technique of patient preparation, joint protection, exercise, and how to deal with emerging complications and methods of prevention. Finally, each session ended with debriefing feedback gotten by the researchers. Weekly follow-ups via phone for all patients is performed for both groups.

## 2.7. Post intervention phase (Time duration: 2 months)

The researchers evaluated the effect of self- management protocol intervention by matching the results pre and post phase to evaluate the mean differences in occurrence of complications among patients in both groups by using the same data collection tools for both groups. The participants were evaluated through assessment of their awareness and disability scores.

## 2.8. The study flow chart



**Figure 1** Flowchart of the quasi-experimental study design. The initial sample include 143 eligible patients from the Rheumatic Disease Unit and Outpatient Clinic, diagnosed with rheumatoid arthritis and receiving biological therapy, 23 withdrew, and 120 were enrolled. Patients were randomized into control (n = 60) and study (n = 60) groups. The study group received a structured self-care protocol including educational sessions, printed materials, and weekly follow-up for 8 weeks. Pre- and post-intervention assessments included RA Awareness, HAQ-DI, and BTCS

### 3. Results

**Table 1** Participants characteristics and clinical data

Data	Study Group (n=60)	Control Group (n=60)	p-value
Age (Means $\pm$ SD)	41.8 $\pm$ 5.9	42.5 $\pm$ 6.2	0.61
Females (%)	83.3%	80%	0.75
Duration of RA (years)	7.2 $\pm$ 1.8	7.4 $\pm$ 2.1	0.68

Table 1 Shows that both groups were similar in age, gender, and disease duration (no significant difference,  $p > 0.05$ ).

**Table 2** Total awareness scores pre-post intervention of self-management protocol (n=120)

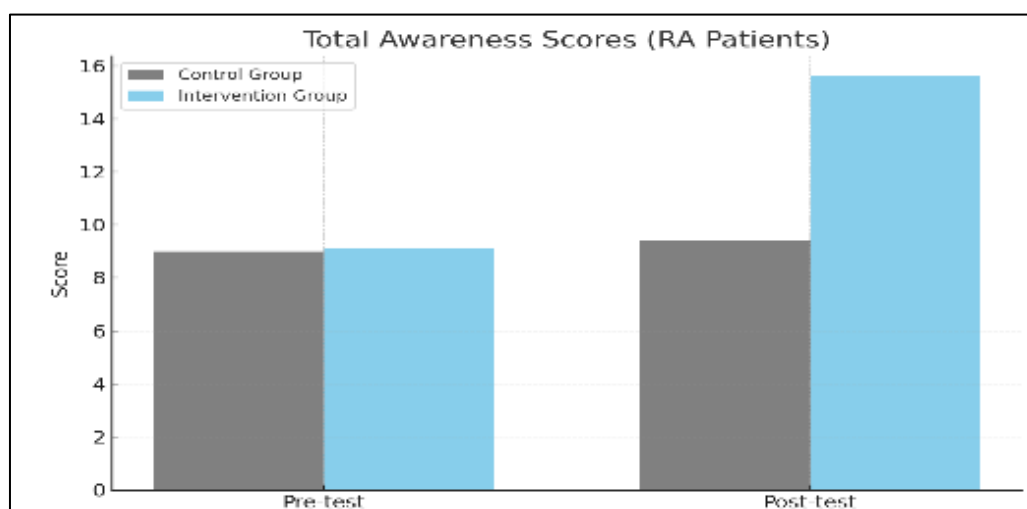
Group	Pre-Test	Post-Test	p-value
Study	9.5 $\pm$ 2.1	16.8 $\pm$ 1.3	< 0.001**
Control	9.3 $\pm$ 2.0	9.6 $\pm$ 2.1	0.27

Table 2 Indicates significant improvement in means and standard deviations of patients' awareness in post intervention of self-management protocol in the study group (16.8  $\pm$  1.3) compared to (9.6  $\pm$  2.1) in control group. Also, it shows a high significant differences at  $P < 0.001$ .

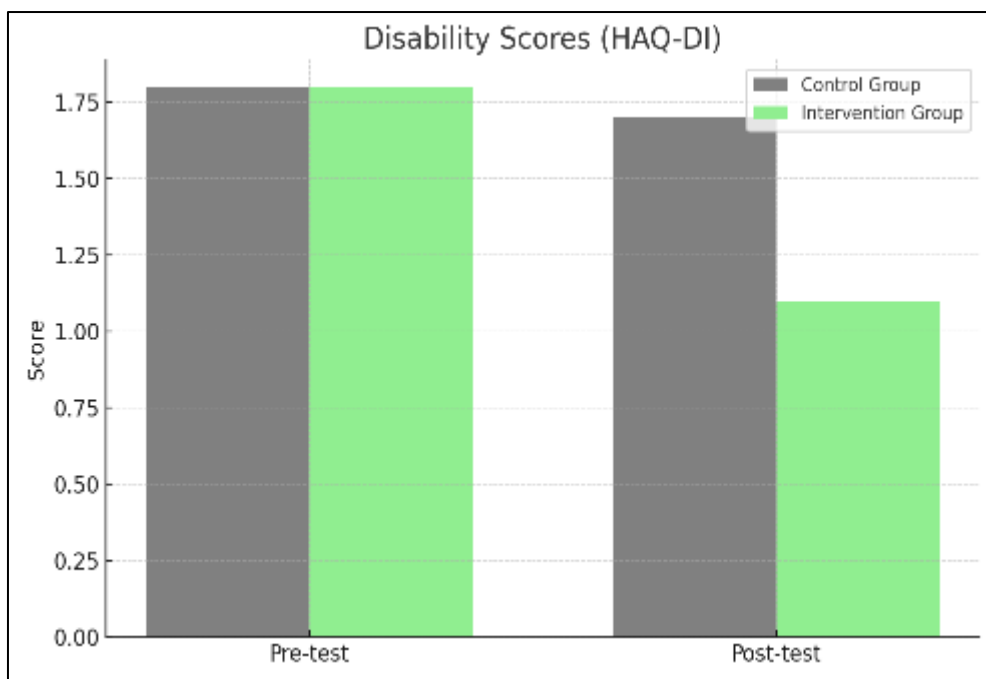
**Table 3** Total Disability Scores pre-post intervention of self-management protocol (n=120)

Group	Pre-Test	Post-Test	p-value
Study	1.6 $\pm$ 0.4	0.9 $\pm$ 0.3	< 0.01**
Control	1.5 $\pm$ 0.5	1.4 $\pm$ 0.4	0.32

Table 3 Reveals significant improvement in means and standard deviations of patients' disability scores in post intervention of self-management protocol in the study group (0.9  $\pm$  0.3) compared to (1.4  $\pm$  0.4) in control group. Also, it shows a high significant differences at  $P < 0.001$ .



**Figure 2** Awareness and Disability Scores in Control and Intervention Groups post intervention of self-management protocol (n=120)



**Figure 3** Disability Scores in Control and Intervention Groups post intervention of self-management protocol (n=120)

**Table 4** Comparison of both groups Mean  $\pm$  SD regarding items of HAQ-DI Post Intervention of Self-management protocol (n=120).

Disability Item	Study Group (n=60)		Control Group (n=60)		T-test	p-value
	Pre	Post	Pre	Post		
Dressing	3.9 $\pm$ 2.3	1.5 $\pm$ 1.3	3.1 $\pm$ 3.1	2.6 $\pm$ 5.2	7.442	<0.001**
Arising	3.2 $\pm$ 5.2	1.7 $\pm$ 2.3	2.9 $\pm$ 2.5	3.6 $\pm$ 6.1	6.453	<0.001**
Eating	2.6 $\pm$ 4.2	1.3 $\pm$ 2.2	2.8 $\pm$ 3.2	2.7 $\pm$ 6.9	4.365	<0.001**
Walking	3.1 $\pm$ 4.5	1.6 $\pm$ 2.4	3.1 $\pm$ 2.5	2.9 $\pm$ 4.3	5.321	<0.001**
Hygiene	3.0 $\pm$ 3.7	1.4 $\pm$ 1.6	3.3 $\pm$ 3.3	3.2 $\pm$ 4.0	4.311	<0.001**
Reach	3.3 $\pm$ 3.8	1.8 $\pm$ 1.2	3.2 $\pm$ 4.4	3.0 $\pm$ 6.4	5.232	<0.001**
Grip	3.8 $\pm$ 4.1	1.2 $\pm$ 2.8	3.6 $\pm$ 3.7	3.5 $\pm$ 4.1	4.733	<0.001**
Activities	3.1 $\pm$ 4.9	1.2 $\pm$ 3.1	3.0 $\pm$ 5.3	2.9 $\pm$ 7.3	4.273	<0.001**

Table 4 Shows significant improvement in means and standard deviations of HAQ-DI categories post intervention of self-management protocol in the study group compared to control group. Also, it shows a high significant differences at  $P < 0.001$ .

**Table 5** Comparison of both groups Mean  $\pm$  SD according occurrence of the complications Post Implementation of Self-management protocol (n=120).

Complications of Biological Therapy	Study Group (n=60)	Control Group (n=60)	t-test	p-value
Respiratory Infections	1.6 $\pm$ 0.2	2.2 $\pm$ 0.6	5.32	<0.001*
Urinary Tract Infections	1.0 $\pm$ 0.5	1.9 $\pm$ 0.7	5.43	<0.001*
Injection Site Reactions	1.5 $\pm$ 0.8	2.4 $\pm$ 0.7	4.84	<0.001*
Hypersensitivity Reactions	1.1 $\pm$ 0.3	1.8 $\pm$ 0.5	3.74	<0.001*
Elevated Liver Enzymes	1.2 $\pm$ 0.5	2.0 $\pm$ 0.7	4.56	<0.001*
Hematologic Abnormalities	1.1 $\pm$ 0.1	1.8 $\pm$ 0.7	4.21	<0.001*
Cardiovascular Events	1.8 $\pm$ 0.2	2.1 $\pm$ 0.6	3.32	<0.001*
Skin Infections	1.2 $\pm$ 0.5	1.9 $\pm$ 0.8	4.94	<0.001*
Neurological Complaints	1.1 $\pm$ 0.3	1.8 $\pm$ 0.6	3.68	<0.001*
Autoimmune Flare-Ups	1.5 $\pm$ 0.4	2.2 $\pm$ 0.8	4.34	<0.001*

Table 5 Presents significant improvement in means and standard deviations of Biological therapy complications among patients with RA post intervention of self-management protocol in the study group compared to control group. Also, it shows a high significant differences at  $P < 0.001$ .

## 4. Discussion

### 4.1. Baseline Homogeneity of Participants

The findings of this study clearly demonstrate the effectiveness of a structured self-management protocol in enhancing awareness and reducing disability among patients with rheumatoid arthritis (RA) receiving biological therapy. Notably, there were no statistically significant differences between the study and control groups at baseline regarding demographic and clinical characteristics, including age, gender, and duration of RA, with no statistically significant differences ( $p > 0.05$ ). This baseline homogeneity strengthens the internal validity of the study by reducing potential confounding effects, and confirms that the improvements observed post-intervention can be attributed to the implemented protocol [19].

### 4.2. Effect of the protocol on Awareness of patients with RA

The significant improvement in awareness scores among the study group post-intervention (mean =  $16.8 \pm 1.3$ ) compared to their baseline score (mean =  $9.5 \pm 2.1$ ), as well as the control group's post-test score (mean =  $9.6 \pm 2.1$ ), reflects the success of the educational component of the self-management protocol. These findings are consistent with previous studies that have emphasized the critical role of patient education in chronic disease self-management, particularly in RA, where disease complexity necessitates informed patient participation in care decisions [20 and 21]. For instance, a study by [22] found that structured self-management education significantly improved knowledge, coping strategies, and adherence among patients with autoimmune disorders. Similarly, [23] reported improved health literacy and treatment compliance in RA patients after nurse-led educational interventions.

### 4.3. Effect of the protocol on Disability patients with RA

Furthermore, the reduction in disability as evidenced by the significant decrease in HAQ-DI scores among the study group (from  $1.6 \pm 0.4$  to  $0.9 \pm 0.3$ ) illustrates the protocol's effectiveness in improving functional status. This improvement was not observed in the control group, whose scores remained relatively unchanged. This supports the notion that empowering patients through self-care education and structured support enhances their ability to manage symptoms and maintain independence in daily activities [23]. Functional improvement is particularly important in RA management, as disability is a key determinant of quality of life and long-term prognosis. A study by [24] confirmed that self-management education significantly reduced disability and improved quality of life among RA patients undergoing biological therapy. Likewise, [25] found that combining medication with lifestyle education yielded better functional outcomes than medication alone.

#### **4.4. Effect of the protocol on Biology therapy complications among patients with RA**

The results of the present study showed that there was a significant improvement of the study group according occurrence of most complications post application of self-management protocol. This is may be due to improvement of patients' awareness about the side effects of biological therapy and how they can monitor and self-managed the occurrence of such complications which ranges from mild to severe. This was in the same line with <sup>[26]</sup> who stated that Biological therapy is generally safe, particularly when compared to conventional therapy. Critical adverse events appear to be rare, but are potentially associated with life-threatening conditions. Most of them can be avoided by implementation of preventive/prophylactic measures. The outcome may be considerably changed by close awareness and an early appropriate management.

While biologics have revolutionized RA treatment. Integrating biosimilar, personalized treatment approaches, and early intervention strategies has demonstrated potential for optimizing both clinical outcomes and economic efficiency. Holistic management, encircling regular monitoring, patient education, and multidisciplinary care, remains vital for addressing the diverse challenges of RA. Awareness of the possible serious side effects when using biological therapy is the first essential step for its safer use in patients with autoimmune diseases <sup>[27 and 28]</sup>.

#### **4.5. Clinical Implications**

The study's results underscore the necessity of integrating structured self-management protocols into routine RA treatment frameworks. Such protocols not only enhance patient awareness and engagement but also potentially reduce disability and dependence on healthcare resources. The findings support integrating structured nursing-led education protocols into standard RA care, especially for those on complex treatment regimens such as biologics. Patient education is widely recognized as a must. It is an important aspect of nursing care that would allow patients to manage their disease and improve their health outcomes, thus maintaining a better quality of life. Nurses play a pivotal role in empowering patients with knowledge and tools for daily disease management, ultimately improving long-term outcomes and reducing healthcare costs <sup>[29]</sup>.

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### **5. Conclusion and Recommendations**

Implementing a structured self-Management protocol is effective in increasing awareness and reducing disability and complications among patients with RA receiving biological therapy. Such interventions should be integrated into routine nursing care to support holistic RA management. Also the study should be repeated to multicenter studies for broader applicability and generalization of results.

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#### **Compliance with ethical standards**

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##### *Disclosure of conflict of interest*

None of the authors has any conflicts of interest to declare related to this study.

##### *Statement of ethical approval*

Ethical approval was obtained from the College of Nursing IRB. No surgical or invasive procedures has done.

##### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

##### *Author contributions*

All authors of the study participated in concept and design, acquisition, analysis, or interpretation of data, drafting of the manuscript, critical revision of the manuscript for important intellectual content. All the authors approved the version to be published; and agree to be accountable for all aspects of the work.



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