

## Effect of safety measures Program on Systemic lupus erythematosus patients' outcome

Dalia M. Ayad<sup>1</sup>, Manal H. Mansour<sup>2</sup> and Doaa M. Mahar<sup>2</sup>

<sup>1</sup>Nursing Specialist at Tala Technical Secondary School for Nursing, Menoufia

<sup>2</sup>Medical Surgical Nursing Department, Faculty of Nursing, Benha University  
E-Mail: [daliaayad66@gmail.com](mailto:daliaayad66@gmail.com)

### Abstract

**Background:** Systemic lupus erythematosus (SLE) is a multisystem disease associated with significant morbidity and mortality. Safety measures programs are the activities or strategies that are directed towards raising the general level of health and patients' well-being. **Aim of study:** This study aimed to evaluate the effect of safety measures program on Systemic lupus erythematosus patients' outcome. **Design:** Quasi-experimental research design was utilized to conduct the aim of this study. **Setting:** The study was conducted at Rheumatology out-patient clinic at Benha University Hospital in Qualubia Governorate. **Sample:** Purposive sample of adult patients with systemic lupus erythematosus who are attending at the previous mentioned setting. **Tools:** Five tools are used Tool I: Structure interviewing questionnaire. Tool II: Patients knowledge about safety measures, Tool III: Fatigue Severity Scale, Tool IV: patient-reported outcome (PRO) & Tool V: Safety measures activities regarding SLE. **Results:** There was a highly statistical significant differences regarding total knowledge about safety measures for SLE, fatigue level and total Lupus PRO between pre and post implementing the program (P-value < 0.001\*\*). **Conclusion:** Implementation of safety measures program had a positive and significant effect on patients' knowledge level as well as reducing fatigue severity and improving total Lupus PRO three months post safety measures program were found. **Recommendation:** Implementing educational program for patients with systemic lupus erythematosus in order to enhance their health status and prevent complications.

**Key words:** Safety measures program, Systemic lupus erythematosus, patient-reported outcome.

### Introduction

Systemic lupus erythematosus (SLE) is a chronic systemic autoimmune disorder that is characterized by a typical multi organ involvement pattern that results from immune system dysregulation which can cause multi organ damage. In auto immune diseases, a patients' immune system targets normal human tissues as if they were foreign, producing inflammation and tissue destruction throughout the body. It is distinguished by recurrent flare-ups of severe symptoms affecting any organ, which can lead to potentially fatal consequences [4].

Lupus has unknown cause and understanding of its etiology remains limited. It appears to arise from a complex interaction between genetic predisposition and environmental inputs that push an individual across the disease threshold. A patient who gets lupus most often inherits the risk from one or both parents and then develops the illness when exposed to a trigger. Being exposed to sunlight, being sick with an illness, having surgery or being pregnant can all be triggers [9].

Lupus is a disease with an unpredictable course involving flares and remissions, where cumulative damage over time significantly interferes with the quality of life and adversely affects organ function. Organ most commonly affected in lupus patients include joints, skin, mucous membranes, blood cells, brain and kidney [33]. Lupus symptoms can range from mild to life-threatening and its diversity and complexity of presentation can create challenges in diagnosis and treatment. Skin rashes, arthralgia and fatigue are common symptoms. Lupus patients have periods of low or no disease activity (remission) and times of increasing activity (flares) [5].

Although treatments for disease activity continue to advance, fatigue remains one of the most significant, unaddressed patient complaints. Fatigue is one of the most prevalent and debilitating symptoms in SLE, described by patients as an overwhelming and unpredictable experience that can dominate their lives and interfere with performing physical and mental activities for days to weeks, which is not resolved by rest [22].

Safety measures activities or strategies are directed toward raising the general level of health and well-being of an individual. These include patient education and lifestyle modification: protection from sunlight, infection control, vaccination, a diet low in salt, fat and cholesterol, exercise, rest and sleep, stress management, pregnancy, contraception, reduction of psychosocial effects and other primary prevention strategies as smoking cessation and drug use [34].

According to prior researches, patients with a high degree of self-care may have better health outcomes; thus, the patient must learn self-care knowledge and abilities, as well as identify appropriate strategies to control surrounding settings, in order to maintain optimal health. Because the major causes of mortality from SLE are its consequences, such as end-stage renal disease and cardiovascular disease, rather than the illness itself [19].

The nurse assists the patient and family by providing the required assistance, emotional support and educational activities related to safety measures of SLE and rehabilitation to enhance their quality of life. Encourage the patient to participate in self-care regimens to regulate their symptoms, reduce flares and reduce comorbidities. Avoiding over exposure to

sunlight, managing stress, exercising regularly, eating a diet low in saturated and trans fats and quitting smoking; are all significant safety measures to prevent disease activity [37], [18].

#### Significance of the study

The worldwide incidence and prevalence of SLE vary greatly according to region and ethnicity, with an incidence range of 0.3 to 23.2 per 100,000 person-years and a prevalence range of 0 to 241 per 100,000 people. Lupus is most common in women of childbearing age (15 – 45 years old) than men with a ratio 10:1, but it can occur in men and women of any age. Approximately 90% of patients with Systemic Lupus Erythematosus are women. The prevalence of SLE in the developed world is 24/100,000 population [15]. It's estimated that active SLE contributes to about a third of early deaths worldwide[7].

The overall estimated prevalence of adult SLE in Egypt was 6.1/100,000 population (1.2/100,000 males and 11.3/100,000 females). There were 316 (8.6%) juvenile-onset (Jo-SLE) and 3345 adult-onset (Ao-SLE). South had the highest age at onset and Cairo had the lowest[2].

A significant understanding of their disease will help patients to know how to be compliance with the treatment and maintain optimal self-care and follow safety measures that will be helpful on decreasing the expected complications, moreover, patients with SLE are in need for nursing education to improve their knowledge level about SLE disease and safety measures to overcome the systemic complications[19]. So, the current study was carried out to evaluate the effect of safety measures program on Systemic Lupus Erythematosus patients' outcome.

#### Aim of the study

The study aimed to evaluate the effect of safety measures program on Systemic lupus erythematosus patients' outcome.

#### Research hypotheses.

H1: Patients' knowledge will be significantly improved after implementing the safety measures program regarding systemic lupus erythematosus.

H2: Patients' reported outcome (signs and symptoms) will be improved after implementing the safety measures program regarding systemic lupus erythematosus.

#### Subjects and Methods.

##### Research design:

A quasi-experimental research design was utilized to achieve the aim of the study.

##### Setting:

This study was conducted at Rheumatology outpatient clinic at Benha University Hospital in Qualubia Governorate.

##### Subject

Purposive sample of 60 adult patients with systemic lupus erythematosus from both sexes aged from 20 - 60 years old who was attended at rheumatology outpatient clinics during six months and willing to participate in the study.

#### Exclusion criteria:

- 1- Psychiatric patients.
- 2- Patients with health complications such as renal failure, heart failure, pulmonary complication (Pulmonary embolism, pleural effusion), seizures, stroke, cognitive dysfunction, and joint deformities.
- 3- Health team worker.

#### Tools of data collection:

Data collection was gathered by using the following five tools: -

**Tool (I): Structured interviewing questionnaire:** it was designed by the researchers based on reviewing of relevant recent literatures (Constance et al., 2017; Mohamed et al., 2020 & Gulanick & Myers 2021) and scientific references and translated into Arabic language. It involved 31 multiple choice questions. It composed of two parts:

**First Part: Personal data of the studied patients:** It was constructed and included 13 multiple choice questions to assess personal data including age, gender, residence, marital status, level of education, presence of job, type of job, income and smoking habits.

**Second Part: Patients health history:** it consisted of three sections:

**First section:** Past medical and surgical history which involved 10 multiple choice questions including past illness, past hospitalization, and past surgical operation.

**Second section:** Family history: involved 2 multiple choice questions about family history of systemic lupus and degree of relation.

**Third section:** Present medical history involved 6 multiple choice questions included signs & symptoms of lupus, presence of any complications and treatment.

**Tool (II) Patients' knowledge about safety measures:**

This part included 48 multiple choice questions and divided into two parts:

**First part: Patients' knowledge about Systemic lupus erythematosus:** it was designed by the researchers after reviewing of recent relevant literatures (Sullivan, 2016; El said et al., 2019; El Saman et al., 2020 & Sayadi et al., 2021). It involved 25 multiple questions and divided into three sections as the following:

**Section 1:** Patients' knowledge about SLE disease (9 questions) including definition, risk factors, incidence, causes, types, signs & symptoms and diagnosis.

**Section 2:** The effect of SLE disease on the body's systems (11 questions) including skin and mucous membrane, hair, kidney, respiratory system, heart, digestive system, nervous system, eye, blood, reproductive system and musculoskeletal system.

**Section 3:** Treatment methods of systemic lupus erythematosus(5 questions).

**Second part: Patients' knowledge about safety measures:** It was designed by the researcher

after reviewing of recent relevant from (Wattiaux et al., 2020; Sumpter et al., 2022 & García et al., 2023). It contained 23 multiple questions and divided into three sections as the following:

**Section 1:** Patients' knowledge about safety measures (8 questions). It included definition, importance, measures to reduce disease activity such as: sun exposure, prevention of infection, nutrition (allowed and not allowed), reduce hair loss and mouth ulcer.

**Section 2:** Safety measures to avoid smoking effect. It included 4 questions about active and passive smoking.

**Section 3:** Safety measures regarding SLE treatments. It included 11 questions about treatment and its side effects and how to prevent them.

#### Scoring system for patients' knowledge:

Each correct answer was given one score and zero score for incorrect answer or unknown. According to patients' response, their total level of knowledge was ranged from 0 to 48. The knowledge scores were converted into a percent and categorized as the following:

\* **Good knowledge** if score was  $>70\%$  ( $>34$  points).

\* **Average knowledge** if score from 60-70% (29 – 34 points).

\* **Poor knowledge** if score  $<60\%$  ( $<29$  points).

**Tool (III) Fatigue Severity Scale; (FSS):** A scale with nine questions related to how fatigue interferes with physical and mental health and rating its severity. The scale was adapted from Cella & Chalder et al., (2010). The original scale composed of 11 questions about physical and mental fatigue and the researchers removed three questions (Do you make slips of the tongue?, do you find it more difficult to find the correct word? And how is your memory) and modified another two questions about do you lack energy? and do you feel weak?, exchanged by does fatigue interfere with your work, family or social life? and do you start things without difficulty but get weak as you go on? Loretzen et al., (2014).

#### Scoring system:

The patients' response for each question was scored as the following:

\* **Less than usual** = 0

\* **No more than usual** = 1

\* **More than usual** = 2

\* **Much more than usual** = 3

The total score is calculated by multiplying the highest score (3) by the number of questions (9) and then graded as the following: equaled 27 points considered as severe fatigue, less than 27 to 18 points considered moderate fatigue and less than 18 points considered as mild fatigue.

**Tool (IV) Self-reported outcome:** It was designed by the researchers after reviewing of relevant recent literature from Metry et al., (2019) & Connelly & Morand (2021). It composed of 16 items for signs and symptoms that was reported by the patient including hair loss, Having a new skin rash or irritation of a previous rash resulting from lupus, loss of appetite, mouth ulcers, poor memory, inability to concentrate, Pain and swelling in the joints and muscles, having annoyed side effects as a result of taking lupus medications, Kidney dysfunction, shortness of breathing, chronic cough, high blood pressure, chronic headache, vertigo and dizziness, Dryness and eye inflammation, anemia and high temperature

#### Scoring system:

The scoring system for patients' reported outcome was calculated as the following: two score for always, one score for sometimes and zero score for never. The total score 32.

**High incidence outcomes equaled  $\geq 70\%$  ( $\geq 22$  score).**

**Low incidence outcomes equaled  $< 70\%$  ( $< 22$  score).**

**Tool (V) Safety measures activities:** It composed of 76 questions and was adapted from (Dief et al., 2020). The original tool was composed of 25 questions divided into: Physical activity involved (5). Follow up and medications: involved (5) items. Nutrition involved (5). Reducing joint pain involved (5) items. Prevention of lupus flares included (5) items. The researchers add 51 questions related to activities of safety measures for SLE patients as sun exposure (4 questions), stress reduction (2 questions), exercise training (2 questions), rest and avoid fatigue (5 questions), nutrition (12 questions), Avoid infection (8 questions), Prevent disease activity (2 questions), reduce hair loss (7 questions), reduce mouth ulcers (6 questions) and avoid smoking (3 questions). It is a likert like scale with three responses always, sometimes and never.

#### Scoring system:

The scoring system for patients activities were calculated as the following: two score for always, one score for sometimes and zero score for never. The total patients score (152) was ranged from 0 to 152 and categorized as the following:

**Satisfactory equaled  $\geq 70\%$  ( $\geq 106$  score).**

**Unsatisfactory equaled  $< 70\%$  ( $< 106$  score).**

#### Content validity:

The content validity of the tools reviewed by a panel of five experts from the field of medical surgical nursing at Faculty of Nursing, Benha University. Jury involved 2 professors and 3 assistant professors of medical surgical nursing to check the relevancy, clarity of tools' content, comprehensiveness, understanding and applicability of the tools' content.

#### Reliability of tools:

The researcher used test-retest-methods to test the internal consistency of the tools, by administration of the same tools to the same subjects under similar condition on two different occasions. Reliability of knowledge questionnaire was determined using Cronbach's alpha coefficient which was 0.720. For the safety measures activity tool, reliability was 0.869. Fatigue severity scale was 0.948. This only proves that this tool is an instrument with good reliability.

#### Ethical consideration:

- Official permission to carry out the study was obtained from scientific research ethical committee in the Faculty of Nursing, Benha University and Medical director of Benha University Hospital after explanation of the purpose of the study.
- Interviewing with patients was conducted before starting data collection to establish a good relationship with them, explain the aim and nature of the study.
- Patients' written consent to participate in the study was obtained from patients and they informed about the nature of the study, the confidentiality of the health related data was assured and they have the right to withdraw from the study.

#### Pilot study:

A pilot study was conducted on 10% of all patients that were included in the study (6 patients) from the total number of patients (60) in order to ascertain the feasibility and applicability of the designed tools and the content of the safety measures regarding SLE booklet, to estimate time needed for each tool to be filled in as well as to identify any possible obstacles that may hinder data collection. The pilot study was conducted one month before data collection. Little modifications done for the study tools, so sample of pilot study was excluded from the study sample and replaced by another.

#### Field work:

Data collection of the current study was carried out over a period of six months from the beginning of July, 2023 to end of December, 2023.

#### Statistical Analysis:

The collected data were tabulated and statistically analyzed using an IBM computer and the statistical package for social science (SPSS) advanced statistics, version 25 (SPSS Inc., Chicago, IL). Numerical data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the difference between qualitative variables. The paired t-test was used for comparing the mean scores in two different periods within the same group.

Pearson method was used to test correlation between numerical variables. Linear regression was used for multivariate analyses on reported outcomes as dependent factor. A p-value < 0.05 was considered significant and p-value < 0.001 was considered highly significant.

#### Results

**Table (1):** shows that the age of 46.7% was within the age group of 30- <40 years with a mean age of  $39.11 \pm 0.88$  years. Concerning sex, 83.3% of the studied patients were females, 61.7 % were residing in rural area and 66.7 % were married. As for educational level, 56.7% of the studied patients had secondary education, 33.3% of them were working and 55.0% of them required physical effort in their work, moreover, 66.7% of studied patients had low monthly income.

**Figure (1):** illustrates that 50 % of studied patients had good level of total knowledge about safety measures for lupus erythematosus pre program implementation which improved to involve 81.6 % immediately post program implementation with p value  $\leq 0.001^{**}$

**Table (2):** reveals that there was a highly statistical significant differences regarding fatigue severity among the studied patients with lupus erythematosus between pre and post 3 months of implementing the program, in term of improvement in fatigue score. Where, the mean score of suffering from fatigue was 2.93 pre program implementation to be 0.48 post 3 months of program implementation with (p value = < 0.001<sup>\*\*</sup>).

**Figure (2):** illustrates that 90.0 % of studied patients had reported high incidence level of signs and symptoms for lupus erythematosus preprogram implementation while 83.3 % of them had low incidence level post 3 months of program implementation with p value = < 0.001<sup>\*\*</sup>

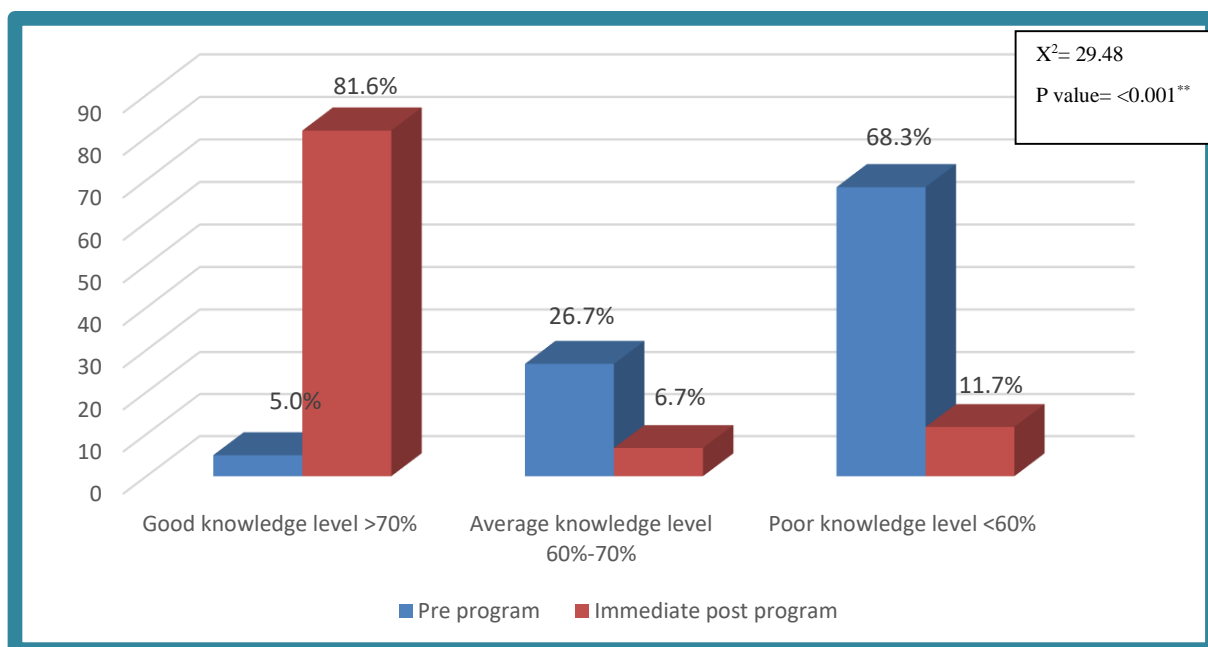
**Table (3):** shows that there was a highly statistical significant difference regarding activities related to safety measures among the studied patients with lupus erythematosus between pre and post 3 months of implementing the program, in term of improvement in total mean activity score. Where, the mean score was  $30.38 \pm 3.73$  pre program implementation to be  $123.80 \pm 5.12$  post 3 months of program implementation with p value  $\leq 0.001$ , where the highest % of score was regarding exercise as well as rest and stress avoidance with 90.8% & 90.7%, respectively.

**Table (4):** shows that there was a positive and significant correlation between total patients' knowledge with their total safety measures activity for lupus erythematosus pre and post program implementation with p-value of 0.004 & 0.012, respectively and 0.369 & 0.323, respectively.

**Table (1)** Distribution of studied patients according to their personal data (n = 60)

Patients' personal data	No.	%
-------------------------	-----	---

<b>Age / years</b>		
20-<30	15	25.0
30- < 40	28	46.7
40-<50	12	20.0
50- 60	5	8.3
<b>Mean ± SD</b>	<b>39.11 ± 0.88</b>	
<b>Sex</b>		
Male	10	16.7
Female	50	83.3
<b>Residence</b>		
Urban	23	38.3
Rural	37	61.7
<b>Marital status</b>		
Single	15	25.0
Married	40	66.7
Divorced	1	1.6
Widowed	4	6.7
<b>Educational level</b>		
Illiterate	3	5.0
Read and write	15	25.0
Secondary education	34	56.7
University education	8	13.3
<b>Occupation</b>		
Working	20	33.3
Not working/ household	40	66.7
<b>Nature of work (n=20)</b>		
Requires cognitive effort	9	45.0
Requires physical effort	11	55.0
<b>Monthly income (reported by patient)</b>		
Moderate	20	33.3
Low	40	66.7



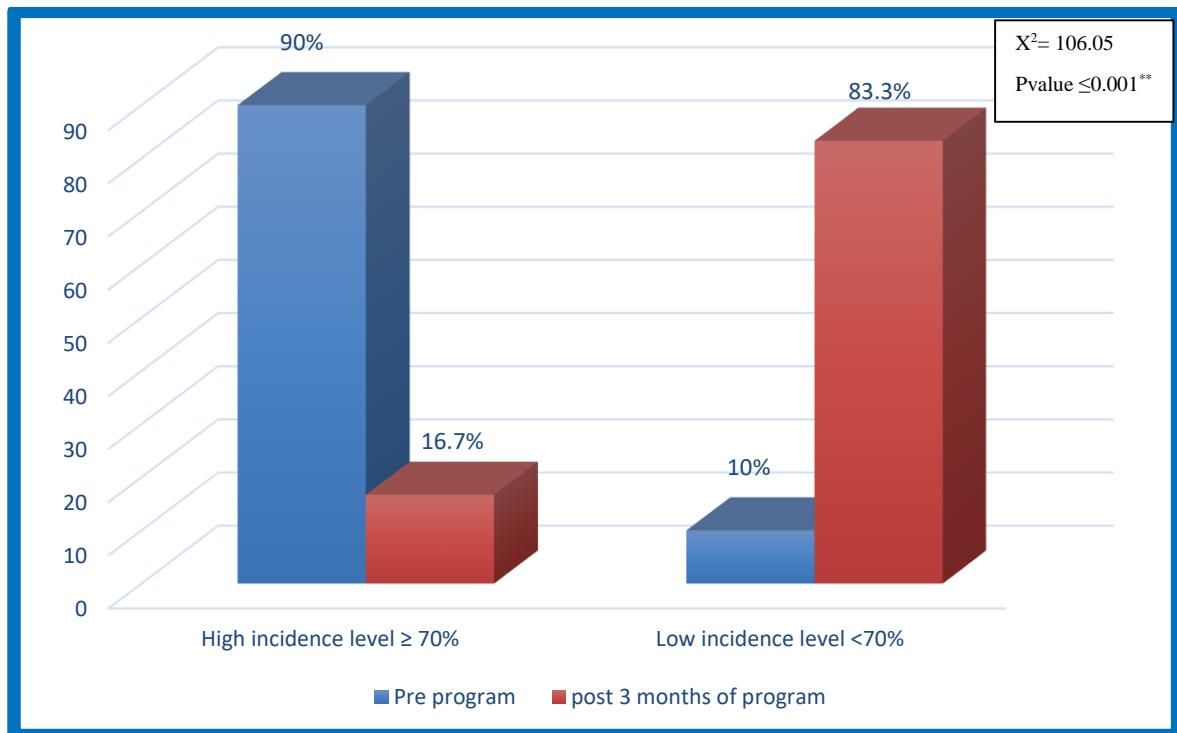
(\*\*) Highly statistically significant at  $\leq 0.001$

**Fig. (1)** Difference between studied patients’ total knowledge level about safety measures for lupus erythematosus pre and immediately post implementing the program (n=60)

**Table (2)** Difference between the studied patients according to fatigue severity pre and post 3 months of implementing the safety measures program (n=60)

Patients' fatigue severity	(pre safety measures program) n= 60	( post 3 months of safety measures program ) n= 60	t- test P value
	Mean ± SD	Mean ± SD	
Suffer from fatigue	2.93± 0.25	0.48 ± 0.50	33.575 <0.001**
Fatigue affect your role in work, family or social life	2.88 ± 0.32	0.40 ± 0.49	32.255 <0.001**
Need more rest	2.68± 0.46	0.45 ± 0.50	27.869 <0.001**
Have weakness in muscle strength	2.83 ± 0.37	0.52 ± 0.50	27.577 <0.001**
Have problems starting things	2.68 ± 0.46	0.38 ± 0.49	27.591 <0.001**
Start things off without difficulty but feel weak as progress	2.85 ± 0.36	0.50 ± 0.50	30.050 <0.001**
Still interested in the things used to do	2.72 ± 0.45	0.45 ± 0.50	23.940 <0.001**
Feel sleepy or drowsy	2.77 ± 0.42	0.43 ± 0.50	31.574 <0.001**
Feel difficulty concentrating	2.69 ± 0.47	0.40 ± 0.49	18.991 <0.001**
<b>Total</b>	12.20 ± 12.74	4.01 ± 3.76	5.052 <0.001**

t: paired t test (\*\*) Highly statistically significant p ≤ 0.001



(\*\*) Highly statistically significant at ≤0.001

**Fig. (2)** Difference between patients' total reported outcomes (signs & symptoms) pre and immediately post 3 months of program implementation (n=60)

**Table (3)** Difference between patients' total mean activities score related to safety measures pre and post 3 months of implementing the safety measures program (n=60)

Total activity related to safety measures for lupus erythematosus	Total score	(pre safety measures program) n= 60 Mean ± SD	(post 3 months of safety measures program) n= 60 Mean ± SD	t- test P value	% of score ( post 3 months of safety measures program )
Sun exposure	10	1.48± 1.54	8.73 ± 0.97	-25.190 <0.001**	87.3%
Reducing Psychological stress	16	3.01 ± 1.64	13.40 ± 1.63	-32.284 <0.001**	83.7%
Exercise	10	1.46± 1.09	9.08 ± 1.04	-34.738 <0.001**	90.8%
Rest and stress avoidance	20	3.86 ± 1.15	18.14 ± 1.15	-61.084 <0.001**	90.7%
Nutrition	34	5.76 ± 2.01	26.88 ± 2.11	-52.616 <0.001**	79.1%
Avoid infection	16	4.83 ± 1.82	13.38 ± 1.34	-23.905 <0.001**	83.6%
Preventing disease activity	14	2.81 ± 1.35	10.78 ± 1.40	-26.752 <0.001**	77.0%
Reducing hair loss	14	3.05 ± 1.44	11.35 ± 1.31	-34.524 <0.001**	81.1%
Reducing the incidence of mouth ulcer	12	2.50 ± 1.47	7.93 ± 1.17	-21.190 <0.001**	66.1%
Avoid smoking	6	1.58 ± 1.19	3.83 ± 0.37	-12.157 <0.001**	63.8%
<b>Total</b>	<b>152</b>	<b>30.38 ± 3.73</b>	<b>123.80 ± 5.12</b>	<b>-94.049 &lt;0.001**</b>	-

t: paired t test (\*\*) Highly statistically significant  $p \leq 0.001$

**Table (4)** Correlation between total knowledge and safety measures activity among the studied patients during pre and post program implementation (n=60)

variable	r-\ p values	Periods	Total knowledge	
			R	P
Total safety measures activity		Pre program	0.369	0.004*
		Post program	0.323	0.012*

(\*) Statistically Significant at  $\leq 0.05$

## Discussion

Systemic lupus erythematosus is an episodic, multi system, autoimmune disease characterized by wide spread inflammation of blood vessels and connective tissue. There is no cure for lupus, but medical interventions and following safety measures activities can help control the disease and reduce the damaging effects of SLE. The seriousness of SLE can range from mild to life-threatening. Patients with lupus who get proper medical care, preventive care and education can significantly improve function and quality of life [17] So, the researchers conducted this study to evaluate the effect of safety measures program on systemic lupus erythematosus patients' outcome.

Concerning the age, the current study findings showed that near half of the studied patients were in age 30-<40 years old with mean age of  $39.11 \pm 0.88$ . This result agreed with [29] in a study entitled "Effect of continuous care model on self-care practices and Quality of Life of Patients with systemic lupus erythematosus, in Egypt" and reported that more than two fifths of the control and study group were aged 30<40 with mean age  $35.53 \pm 6.66$  and  $34.88 \pm 6.69$  years of the control and study group, respectively.

While, This result was in consistent with [23], whose study entitled "Effect of tele nursing instructions on improvement of awareness among systemic lupus erythematosus Patients, in Egypt" and reported that more than half of the studied patients were in the age group of 20-<35 years with a mean age of  $36.4 \pm 8.7$ .

Owing to gender; the result of the present study revealed that about the majority of studied patients were females. This result may be due to the fact that systemic lupus erythematosus is most prevalent in females of child bearing age based on scientific literature. In addition,[23], confirmed that SLE affects nine times in women than in men due to differences in the metabolism of sex hormones (effects of estrogen and decreased androgen levels, hyperprolactinemia and differences in gonadotropin-releasing hormone. This result was supported by[28], whose study entitled "Effect of nurse-led lifestyle intervention protocol on associated symptoms and self-efficacy among patients with systematic lupus erythematosus, in Egypt ", and found that all the patients were females,

Moreover, [24]conducted a study entitled "Medication adherence is influenced by resilience in patients with systemic lupus erythematosus", and

reported that more than three quarters of the studied subjects were females.

Regarding the marital status, results of the present study revealed that two thirds of studied patients were married. This result agreed with [39], in a study entitled "Effect of health promotion program on quality of life for patients with systemic lupus erythematosus, in Egypt", who found that more than two thirds of studied patients were married.

Pertaining residence, results of the present study illustrated that nearly two thirds of the studied patients resided in rural areas. This result was consistent with [26], whose study entitled "Effect of nursing education on knowledge and self-care for patients' with systemic lupus erythematosus" and mentioned that more than half of them were from rural areas.

While this result disagreed with [3], in a study entitled "Effect of self-care guidelines on health outcomes and self-efficacy among patients with systemic lupus erythematosus" who reported that nearly three-quarters of studied patients were from urban areas.

Concerning the educational level, result of the present study documented that more than half of studied patients had secondary education. This result was in agreement with [16], in a study entitled "Effect of health education based intervention on self-care among systemic lupus erythematosus clients, in Egypt", and showed that more than half of the studied patients had secondary education.

While this result was inconsistent with the findings of [39], in a study entitled "Lack of patient education is a risk factor for disease flare in patients with systemic lupus erythematosus, in China", and indicated that half of the studied patients had a high level of education.

Owing to the occupation, the current study findings showed that two thirds of the studied patients were not working, this might be due to nature of disease that may cause physical disability. This result was in agreement [14], in a study entitled "The effect of implementing a protocol of nursing care on SLE patients' knowledge and health related quality of life, in Egypt", who clarified that half of the studied samples were unemployed. Moreover, this result is similar to [13], in a study entitled "Influence of self-management instruction on outcomes of health for systemic lupus erythematosus patients, in Egypt", who revealed that the majority of studied patients were unemployed.

Concerning monthly income, the current study findings showed that two thirds of the studied patients had low monthly income. This result agreed with [31], in a study entitled "Biopsychosocial needs among patients with systemic lupus erythematosus, in Egypt", who revealed that the majority of studied patients had insufficient income.

Owing to the total knowledge of the studied patients regarding systemic lupus erythematosus and safety measures, the present study clarified that there was a highly statistically significant differences regarding total knowledge about safety measures for

lupus erythematosus between pre and immediately post implementing the program. This result supports the first hypothesis of the study. This improvement could be related to safety measures program which supply the studied patients with the need knowledge about SLE and its consequences and introduced by simple manner by using clear materials. This result supported by [39], who revealed that there was a highly statistically significance improvement regarding these items post implementation of systemic lupus health promotion program.

Similarly, [27], who conducted a study entitled "Effect of self-care management on health outcomes and symptoms for females with systemic lupus erythematosus, in Egypt", and showed that there was a highly statistically significant difference between pre and one month after self-care management in all items of knowledge regarding SLE (p-value < 0.001).

Regarding to fatigue severity, the current study revealed that there was a highly statistical significant differences regarding fatigue severity among the studied patients between pre and three months post implementing the program, in term of reduction of fatigue score with (p value = < 0.001\*\*). This result in the same line with [21], whose study entitled "Effects of web-based education and counseling for patients with systemic lupus erythematosus: self-efficacy, fatigue and assessment of care" and reported a significant reduction in the level of fatigue in the experimental group that had been observed in measurements after the intervention.

Also, [27], found that there was a significant improvement with a reduction in total fatigue severity after one month of self-care management.

While, this result was contradicted with [32], in a study entitled "Fatigue and activity management education for individuals with systemic lupus erythematosus", and showed that there were no statistically significant differences in Fatigue severity scores from the beginning to the end of the study.

As regard patient' reported outcome (symptoms), the present study showed that there was statistically significant difference in patients reported out comes between pre and post three months of implementing the safety measures program, in term of decreased symptoms severity, which support the second hypothesis of the study. This could indicate the significance of safety measures program in improving health outcome for patients with SLE. This result was in accordance with, [16], who illustrated that there was highly statistical significant improvement regarding Lupus patient reported out comes post intervention.

Also, [27], demonstrated that there was a highly statistically significant difference between pre and one month after self-care management for all Lupus patient reported out comes items.

According to Safety measures activities among patients with systemic lupus erythematosus, the current study revealed that there was highly statistical significant differences regarding total safety measures



activities among lupus erythematosus patients between pre and post 3 months of implementing the program, showing improvement in activity level. This finding was in agreement with [16], reported that all self-care reported practices items of studied subjects were improved significantly at post intervention phase with highly statistical significant differences between pre and post intervention.

As well, [29], who found that there were highly statistically significant improvements in reported practices of the studied patients between pre/post telenursing instructions at all items of reported practices. As well, the study finding showed a statistically significant improvement detected among the studied patients pre/post telenursing instructions in total reported practice scores.

Concerning correlation between total knowledge and safety measures activity, the current study showed that there was a positive and significant correlation between total patients' knowledge with their total safety measures activity for lupus erythematosus pre and post program implementation. This result was consistent with [29], who showed that there was a positive statistically significant correlation between total knowledge scores and total reported practice scores.

### Conclusion

Implementation of safety measures program had a positive and significant effect on patients' knowledge level as well as reducing fatigue severity, additionally a significant improvement in total Lupus PRO three months post safety measures program were found which confirmed the study hypotheses.

### Recommendations

- Replication of the study using a larger probability sample from different geographical regions for generalization of results.
- Implementing educational safety measures program for patients with SLE in order to enhance their health status and prevent complications.
- An educational booklet should be provided to all Rheumatology outpatient clinics in Benha City to be available for all newly admitted patients with SLE.
- Periodical follow-up should be carried out to assess health status of patients with systemic lupus erythematosus.

### References

- [1] Abdelrahman, B. M., Fathy, A. T., & Sabry, S. S. (2023): Effect of Continuous Care Model on Self-Care Practices and Quality of Life of Patients with Systemic Lupus Erythematosus. *Egyptian Journal of Nursing and Health Sciences*, 4(3), 76-103.
- [2] Abousehly, O. S., El-Gazzar, I. I., El Shereef, R. R & Raafat, H. A. (2021): Adult systemic lupus erythematosus in Egypt: the nation-wide spectrum of 3661 patients and world-wide standpoint. *Lupus*, 30(9), 1526-1535
- [3] Ahmed, R. A., Saleh Ali, W. A., & Mohamed Elderiny, S. N. (2023): Effect of Self-Care Guidelines on Health Outcomes and Self-Efficacy among Patients with Systemic Lupus Erythematosus. *Egyptian Journal of Nursing and Health Sciences*, 4(3), 286-327.
- [4] Albano, S., & Gallicchio, V. S. (2023): Systemic Lupus Erythematosus & Stem Cell Therapy. *Stem Cells Regen Med*, 7(1), 1-9.
- [5] Ameer, M. A., Chaudhry, H., Mushtaq, J., Khan, O. S., Babar, M., Hashim, T & Khan, O. S. (2022): An overview of systemic lupus erythematosus (SLE) pathogenesis, classification, and management. *Cureus*, 14 (10).
- [6] Azwinda, F., Djuari, L., & Soegiarto, G. (2022): an Overview of Knowledge Level Regarding the Systemic Lupus Erythematosus (Sle) in People With Lupus (Odapus).
- [7] Barber, M. R., Drenkard, C., Falasinnu, T., Hoi, A., Mak, A., Kow, N. Y., ... & Ramsey-Goldman, R. (2021): Global epidemiology of systemic lupus erythematosus. *Nature Reviews Rheumatology*, 17(9), 515-532.
- [8] Chalder, T., Berelowitz, G., Pawlikowska, T., Watts, I., Wessely, s., Wright, D., & Wallace, E. P. (1993): Development of a fatigue scale. *Journal of psychosomatic research*, 37(2), 147-153.
- [9] Choi, M. Y., & Costenbader, K. H. (2022): Understanding the concept of pre-clinical autoimmunity: prediction and prevention of systemic lupus erythematosus: identifying risk factors and developing strategies against disease development. *Frontiers in immunology*, 13, 890522.
- [10] Connelly, K., & Morand, E. F. (2021): Systemic lupus erythematosus: a clinical update. *Internal medicine journal*, 51(8), 1219-1228.
- [11] Constance, J., Ulf, Jacob. S., Kirsten, O., Søren, J., & Morten, F. (2017): Family history of systemic lupus erythematosus and risk of autoimmune disease: Nationwide Cohort Study in Denmark 1977–2013, *Rheumatology*, Volume 56, Issue 6, Pages 957–964. Available at: <https://doi.10.1093/rheumatology/kex005>.
- [12] Dief, H., Abd El Aal, E. and Elsayed, D. (2020): Effect of joint pain on quality of life among women with systemic lupus at Benha City, master thesis, Faculty of Nursing Benha University
- [13] Elghareeb, S. M., & Mahmoud, H. M. (2022): Influence of Self-Management Instruction on Outcomes of Health for Systemic Lupus Erythematosus Patients. *Egyptian Journal of Nursing and Health Sciences*, 3(1), 391-408.
- [14] El said, A., Fathy, R., and Mahmoud, H. (2019): "The Effect of Implementing A protocol of Nursing Care on SLE Patients' Knowledge and Health Related Quality of Life". *International Journal of Novel Research in Health care and*

- Nursing. 6 (1), pp: (831-836), January-April 2019, Available at: [www.Noveltyjournals.com](http://www.Noveltyjournals.com).
- [15] El Saman, A., Mohamed, E., Khalifa, A., Meghezal, and El Radwan, A. (2020): Evaluation of Awareness, Knowledge and Attitudes ,The Egyptian Journal of Community Medicine; 38 (2):1-22. The Egyptian Journal of Community Medicine. Vol. 38, No. 2. Available at: <https://ejcm.journals.ekb.eg>
- [16] Elsayed, D., & Mesbah, S. (2018): Effect of Health Education based Intervention on Self-care among Systemic Lupus Erythematosus Clients". American Journal of Nursing Research, 6(3), 105-112.
- [17] Galoppini, G., Marangoni, A., Cirilli, F., Ruffilli, F., Garaffoni, C., Govoni, M., ... & Bortoluzzi, A. (2023): Optimizing Patient Care: A Systematic Review of Multidisciplinary Approaches for SLE Management. Journal of Clinical Medicine, 12(12), 4059.
- [18] García, L. C., Quesada, C. D., Vargas, A. I. R., Martín, E. T., and Martín, J. M. M. (2023):Nursing Recommendations in the Management of Systemic Lupus Erythematosus: A Delphi Consensus. Hispanic health care international: the official journal of the National Association of Hispanic Nurses. 4;15404153231176001. @<https://pubmed.ncbi.nlm.nih.gov/37272038/>
- [19] Gomez, A., Hani Butrus, F., Johansson, P., Åkerström, E., Soukka, S., Emamikia, S., & Parodis, I. (2021): Impact of overweight and obesity on patient-reported health-related quality of life in systemic lupus erythematosus. Rheumatology, 60(3), 1260-1272.
- [20] Haikel, K. A. B., & Al Tulaihi, B. (2019): Awareness of systemic lupus erythematosus among primary health care patients in Riyadh, Saudi Arabia. Saudi Medical Journal, 40(2), 177.
- [21] Kankaya, H., & Karadakovan, A. (2020): Effects of web-based education and counselling for patients with systemic lupus erythematosus: self-efficacy, fatigue and assessment of care. Lupus, 29(8), 884-891.
- [22] Kawka, L., Schlencker, A., Mertz, P., Martin, T., & Arnaud, L. (2021): Fatigue in systemic lupus erythematosus: an update on its impact, determinants and therapeutic management. Journal of Clinical Medicine, 10(17), 3996.
- [23] Martin-Mercado, T. M. (2022): An investigation of the Role of Precision Medicine in the Treatment of Systemic Lupus Erythematosus Journal of Clinical &Diagnostic Research.1(22), pp.45.
- [24] Mendoza-Pinto, C., García-Carrasco, M., Campos-Rivera, S., Munguía-Realpozo, P., Etchegaray-Morales, I., Ayón-Aguilar, J., ... & Méndez-Martínez, S. (2021): Medication adherence is influenced by resilience in patients with systemic lupus erythematosus. Lupus, 30(7), 1051-1057.
- [25] Metry, A. M., Al Salmi, I., Al Balushi, F., Yousef, M. A., Al Ismaili, F., Hola, A., & Hannawi, S. (2019): Systemic lupus erythematosus: symptoms and signs at initial presentations. Anti-Inflammatory & Anti-Allergy Agents in Medicinal Chemistry (Formerly Current Medicinal Chemistry-Anti-Inflammatory and Anti-Allergy Agents), 18(2), 142-150.
- [26] Mohamad, Z. A. E. L., Abo-ElNoor, E. I., & Abd-Elal, H. A. E. (2020): Effect of Nursing Education on Knowledge and Self Care for Patient's with Systemic Lupus Erythematosus. Assiut Scientific Nursing Journal, 8(23), 113-121.
- [27] Mohamady, S. H., Srouf, O. A. A., & Saad, N. S. E. (2022): Effect of Self-Care management on Health Outcomes and Symptoms for Females with Systemic Lupus Erythematosus. Tanta Scientific Nursing Journal, 25(2), 130-151.
- [28] Mohamed Elmetwaly, R., Younis Ahmed, A., & Mohamed Mohamed, Y. (2021): Effect of nurse-led lifestyle intervention protocol on associated symptoms and self-efficacy among patients with systematic lupus erythematosus. Egyptian Journal of Health Care, 12(1), 814-830.
- [29] Mohamed El-Zayat, O. S., Ahmed Elkattan, B. A., & Ahmed Hassan, R. A. (2022): Effect of telenursing instructions on improvement of awareness among systemic lupus erythematosus patients. Tanta Scientific Nursing Journal, 27(4), 261-284.
- [30] Mohamed, O., Ragheb, M., and Mohamed, H., (2020): Effect of self-care management program on pain and disability for patient with Systemic Lupus Erythematosus in Egypt. Submitted in partial of the doctoral degree in nursing science (medical-surgical Nursing) Benha University.
- [31] Mohammed Abdelzاهر, G., Samir Kamel, S., & Abd ELrahman Abd ELrahman, A. (2023): Biopsychosocial Needs among Patients with Systemic Lupus Erythematosus. Egyptian Journal of Health Care, 14(2), 220-233.
- [32] O'Riordan, R., Doran, M., & Connolly, D. (2017): Fatigue and activity management education for individuals with systemic lupus erythematosus. Occupational therapy international, 2017.
- [33] Putterman, C., Caricchio, R., Davidson, A. & Perlman, H. (2022): Clinical and Developmental Immunology Volume 2022, Article ID 437282, 2 pages doi:10.1155/2012/437282.
- [34] Sayadi, L., Faezi, S. T., Hasanpour, M., & Alahmadi, S. J. (2021): The relationship of lifestyle with disease activity among patients with systemic lupus erythematosus: a descriptive-correlational study. Mediterranean Journal of Rheumatology, 32(2), 124. Switzerland, 170.

- [35] Sullivan, S. L. (2016): Development of a systemic lupus erythematosus knowledge questionnaire: The relationship among disease proximity, educational exposure, and knowledge (Doctoral dissertation, The University of Wisconsin-Milwaukee).
- [36] Sumpter, I. J., Phillips, S. M & Magwood, G. S. (2022): Approaches to reducing fragmented care in systemic lupus erythematosus (SLE) and other multimorbid conditions: A realist review. *International Journal of Care Coordination*, 25(4), 103-114.
- [37] Wattiaux, A., Bettendorf, B., Block, L., Gilmore-Bykovskiy, A., Ramly, E., Piper, M. E., ... & Bartels, C. M. (2020): Patient perspectives on smoking cessation and interventions in rheumatology clinics. *Arthritis care & research*, 72(3), 369-377.
- [38] Yousef, A. E. A. M., El-Azeez, A., Gomaa, N., & Ali Ameen, D. (2018): Effect of Health Promotion Program on Quality of Life for Patients with Systemic Lupus Erythematosus. *Egyptian Journal of Health Care*, 9(4), 10-27.
- [39] Zhang, L., Luan, W., Geng, S., Ye, S., Wang, X., Qian, L., ... & Jiang, A. (2019): Lack of patient education is risk factor of disease flare in patients with systemic lupus erythematosus in China. *BMC Health Services Research*, 19, 1-8.