

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The Effect of Continuous Care Model on Self-Management In patients with Systemic Lupus Erythematosus

#### Protocol summary

##### Study aim

Investigate the effect of continuous care model on self management, disease related knowledge, partnership in treatment, recognition and symptoms management and coping in patients with Systemic lupus erythematosus before the intervention and during eight weeks after intervention in intervention and control groups.

##### Design

Clinical randomised trial with parallel control group, not blinded on 87 samples, Randomising with random number table and all the permutation compounds of A and B.

##### Settings and conduct

Investigating on patients with Systemic lupus erythematosus admitted in Shariati hospital without blinding. Allocating the samples in intervention and control group.

##### Participants/Inclusion and exclusion criteria

Over 20 years Old, Their disease diagnosed less than a year, Ability to Read and Write, Willing to participate in the study, Ability to comprehend Persian, Be able to make contact for the follow up stage, Lack of motion Defect. If they are reluctant to continue research and incidence of any debilitating complication during research, they will be excluded from research.

##### Intervention groups

First stage and first session for intervention group and completing questionnaires, Stage 2 including 3 educational sessions, Stage 3 is 8 weeks of follow up and weekly completion of the questionnaire, Evaluating the process, failures and successions a week after completion of weekly phone calls and final completion of the questionnaire. Completion of questionnaire in first session for control group, making weekly phone calls to remind them to complete questionnaire and presenting the educational booklet at the end of the study.

##### Main outcome variables

Self management Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200810048354N1**

Registration date: **2020-09-12, 1399/06/22**

Registration timing: **retrospective**

Last update: **2020-09-12, 1399/06/22**

Update count: **0**

##### Registration date

2020-09-12, 1399/06/22

##### Registrant information

##### Name

Negin Hosseini hamze

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3306 6727

##### Email address

n-hosseinihamze@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

2019-11-22, 1398/09/01

##### Actual recruitment end date

2020-04-29, 1399/02/10

##### Trial completion date

2020-05-21, 1399/03/01

##### Scientific title

The Effect of Continuous Care Model on Self-Management In patients with Systemic Lupus Erythematosus

#### Public title

Effect of Continuous Care Model on Self-management in patients with systemic lupus erythematosus

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Adults Over 20 years Old  
Their disease diagnosed less than a year  
Ability to Read and Write  
Willing to participate in the study  
Ability to comprehend Persian  
Be able to make contact for the follow-up stage of the study  
Lack of motion Defect

##### Exclusion criteria:

Reluctance to continue research  
Incidence of debilitating complication during research

#### Age

From **20 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **88**

Actual sample size reached: **87**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Eligible samples enter the study by block sampling and then allocated in control and intervention groups. Letter A is for intervention Group and letter B is for control group. We consider all the possible permutation compounds of A and B which is consisted of six different compounds on six cards. 1. AABB 2. ABBA 3. ABAB 4. BAAB 5. BABA 6. BBAA Then we Choose a number between one to six by using the random numbers table. For example if the option two was chosen, it means the first sample enters the intervention group and the next two samples place in control group and the fourth sample will be in intervention group. We Continue as so to complete the sample size.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

National Research Ethics Committee

##### Street address

No.13, Irandost St, Abuzar Blvd, Piroozi Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1767677973

#### Approval date

2019-10-13, 1398/07/21

#### Ethics committee reference number

IR.TUMS.FNM.REC.1398.132

### Health conditions studied

#### 1

#### Description of health condition studied

Systemic Lupus Erythematosus

#### ICD-10 code

M32

#### ICD-10 code description

Systemic lupus erythematosus (SLE)

### Primary outcomes

#### 1

#### Description

Self management score based on PIH questionnaire

#### Timepoint

Evaluating self management score before the intervention and during eight weeks of intervention

#### Method of measurement

Partners in Health questionnaire

### Secondary outcomes

#### 1

#### Description

knowledge score

#### Timepoint

Evaluating knowledge score before the intervention and during eight weeks of intervention

#### Method of measurement

Partners in Health questionnaire

#### 2

#### Description

Recognition and management of symptoms score

#### Timepoint

Evaluating recognition and management of symptoms score before the intervention and during eight weeks of intervention

#### Method of measurement

Partners in Health questionnaire

### **3**

#### **Description**

Coping score

#### **Timepoint**

Evaluating coping score before the intervention and during eight weeks of intervention

#### **Method of measurement**

Partners in Health questionnaire

### **4**

#### **Description**

Partnership in treatment

#### **Timepoint**

Evaluating Partnership in treatment score before the intervention and during eight weeks of intervention

#### **Method of measurement**

Partners in Health questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Intervention group: before starting the research and intervention, Informed consent form would be completed by patients and they will be informed about research method. Research tools is a questionnaire which consists two sections. Section one is the demographic information questionnaire and section two is PIH (Partners in health) questionnaire which is completed by patients themselves. Samples of intervention group will be instructed based on the continuous care model. The first session of instruction that is the orientation stage of the model will be held through a lecture by researcher and answering the questions in about thirty to sixty minutes. Aims of this session is introducing patients and their family to researcher, talking about patient education methods, explaining the different steps of patient's education and explaining the mutual expectations between the patient and the nurse. In this stage both questionnaires will be completed. Second stage of the continuous care model which is sensitization, aimed to involve patient and family in continuous care and increasing the information and knowledge of patient and family to gain self management ability including: Disease related knowledge, pharmaceutical treatment and health conditions. Partnership in treatment including: Medical adherence, therapeutic decision makings and treatment follow ups. Recognition and management of symptoms including: Recognition warning signs and managing symptoms. And coping which is including: managing physical activities, managing mental and psychological conditions, managing the social life and life style. Educational sessions in this stage will be held through lectures and asking question by patients in three sessions a week for maximum of two hours. In the first session, researched explains about the chronic nature of

lupus, Its definition, signs and symptoms, accurate recognition of health problems and boosters of disease, the importance and advantages of phone consultancy and changing life style and also answering the patient's questions with underlining the risk factors. In the second session main drugs of the disease, Side effects, the importance of medical and therapeutic adherence and different prescription methods of lupus drugs will be introduced and the third session will be about maintaining the proper regimen, the importance of physical activity, recommendations on skin care, increasing the coping level and introducing the non-medical ways of stress reduction. At the end of the third session, the educational booklet will be available to patients of intervention group. In the control stage and with a week interval with the last session, the researcher contact the samples for eight weeks to consult the patients in order to complete the face to face meetings. In these sessions, patient's questions will be answered and they will be guided in performing the instructions. The patients will be instructed to complete the questionnaire once a week and reporting the results to researcher. Finally after the end of telephone sessions, the process of patient's care and successions and failures will be evaluated and at the end of the eighth week the questionnaire will be completed for the last time.

#### **Category**

Behavior

### **2**

#### **Description**

Control group: before starting the research and intervention, Informed consent form would be completed by patients and they will be informed about research method. Research tools is a questionnaire which consists two sections. Section one is the demographic information questionnaire and section two is PIH (Partners in health) questionnaire which is completed by patients themselves. In the control group after introducing the patient and explaining the aim of research, the PIH questionnaire will be completed. To prevent contamination of samples, the educational booklet will be available for control group at the end of the study. We will have weekly phone call with the samples of control group too. There won't be any professional consultants in these calla and phone calls are just for reminding to complete the questionnaire. In this way samples will be prevented from falling. The PIH questionnaire will be completed same as intervention group.

#### **Category**

Behavior

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shariati Hospital

##### **Full name of responsible person**

Negin Hosseini Hamze  
**Street address**  
No. 13, Irandost St, Abuzar Blvd, Piroozi Ave, Tehran  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Ali Sahraian  
**Street address**  
No.13 , Irandost St, Abuzar Blvd, Piroozi Ave, Tehran  
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n-hosseinihamze@razi.tums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Negin Hosseini hamze  
**Position**

Master student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Participants answers to Partners in health questionnaires can be shared.

**When the data will become available and for how long**

Results can be shared two month after printing the final study.

**To whom data/document is available**

Researchers in Academic and Scientific fields

**Under which criteria data/document could be used**

Using datas and results of current study for future similar studies.

**From where data/document is obtainable**

Contact the authors of the study via E mail. Contact Negin Hosseini Hamze via n-hosseinihamze@razi.tums.ac.ir Contact Dr. Shokhoh Varaei Via shvaraei@tums.ac.ir

**What processes are involved for a request to access data/document**

Applier will Send an E mail to authors. The request will be checked and after confirmation of applier's identity, requested documents will be sent to him/her.

**Comments**