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 fist 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
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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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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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No. 13, Irandost St, abuzar Blvd, piroozi Ave, Tehran City
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Person responsible for scientific inquiries

Contact
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Position
Master student
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Other areas of specialty/work
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Person responsible for updating data

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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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