Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of Mindfulness – based Cognitive Therapy on psychology symptoms and quality of life in Systemic Lupus Erythematosus patients

Protocol summary

Summary

The aim of this study is to consider the effect of Mindfulness – based Cognitive Therapy (CT) on psychiatric symptoms and quality of life in patients with SLE.This was an experimental study with randomized clinical trial design, which included 46 patients with SLE who attended Shahrekord's Imam Ali clinic and performed at one year. The inclusion Criteria were Patients with at least 4 American College of Rheumatology criteria; The minimum level of literacy in primary; Participate of volunteered in the project and the exclusion Criteria were: The use psychiatric drugs; Receiving psychological treatment in 6 mounts ago.The patients were randomly chronologically, based on time of entrance into study, assigned to two trial and control groups. Both two groups were taken usual medical care and moreover trial group was taken singly Mindfulness – based Cognitive Therapy in 8 sessions. Participants were assessed at baseline, post-intervention and at six month intervals with General Health Questionnaire (GHQ-28) and Short form 36-items Health Survey Questionnaire (SF-36(V2)).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412018253N3**
Registration date: **2014-12-11, 1393/09/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-11, 1393/09/20

Registrant information

Name

Sayed Kamal Solati

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38133338157

Email address

kamal_solati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2012-08-12, 1391/05/22

Expected recruitment end date

2013-08-13, 1392/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Mindfulness – based Cognitive Therapy on psychology symptoms and quality of life in Systemic Lupus Erythematosus patients

Public title

The effect psychological intervention on quality of life and psychology symptoms lupus patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria:Patients with at least 4 American College of Rheumatology criteria ; The minimum level of

literacy in primary; Participate of volunteered in the project. Exclusion Criteria:The use psychiatric drugs;Receiving psychological treatment in 6 mounts ago.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University of Medical Sciences

Street address
Psychiatry ward,Hajar Hospital,Shahrekord ,Iran

City
Shahrekord

Postal code

Approval date
2012-08-12, 1391/05/22

Ethics committee reference number
11-3-91

Health conditions studied

1

Description of health condition studied
Systemic Lupus Erythematosus

ICD-10 code
L93

ICD-10 code description
Lupus Erythematosus

Primary outcomes

1

Description
Quality of Life

Timepoint
Before of intervention,After of intervention,Follow-up

Method of measurement
SF-36 Scale

2

Description
Psychology Symptoms

Timepoint
Before of intervention,After of intervention,Follow-up

Method of measurement
GHQ-28 Scale

Secondary outcomes

1

Description
Not have

Timepoint
Not have

Method of measurement
Not have

Intervention groups

1

Description
Intervention group:Mindfullness based on Cognitive Therapy with drug therapy

Category
Behavior

2

Description
Control group: Drug therapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali clinic

Full name of responsible person
Dr.Sayed Kamal Solati

Street address
Psychiatry ward,Hajar Hospital,Shahrekord ,Iran

City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Dr.Sayed Kamal Solati
Street address
Psychiatry ward,Hajar Hospital,Shahrekord ,Iran
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty