

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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:Mindfulness 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

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Psychiatry ward,Hajar Hospital,Shahrekord ,Iran

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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

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

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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