Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of cognitive- behavioral stress management group therapy on chronic stress, depression and quality of life of female patients with systemic lupus erythematosus

Protocol summary

Summary

The purpose of this study was to determine the efficacy of cognitive- behavioral stress management group therapy on chronic stress, depression and quality of life of female patients with systemic lupus erythematosus. A total of 24 female patients with SLE who received this diagnosis, according the ACR criteria, were randomly selected and assigned into experimental or control group. The experimental group received 10 weekly sessions in the clinic of rheumatology in Alzahra Hospital. The Cohen Perceived Stress Scale, Quality of Life Questionnaire (WHOQOL-BREF) and Beck Depression Inventory (BDI) were used as the pretest, post-pest and follow-up. The follow-up measurements were conducted two months after the end of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010114909N1**
Registration date: **2011-01-01, 1389/10/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-01, 1389/10/11

Registrant information

Name

Fateme Neissiani Habib Abadi

Name of organization / entity

Isfahan University

Country

Iran (Islamic Republic of)

Phone

+98 31 1433 3761

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-03-19, 1388/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of cognitive- behavioral stress management group therapy on chronic stress, depression and quality of life of female patients with systemic lupus erythematosus

Public title

Effectiveness of cognitive- behavioral therapy on SLE

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being female, age 18-55 years, having at least diploma degree Exclusion criteria: treatment for a psychiatric pathology

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Isfahan University

Street address

Hezar garib st, Azadi sq, Isfahan

City

Isfahan

Postal code

8174673441

Approval date

2010-03-15, 1388/12/24

Ethics committee reference number

89/6427

Health conditions studied

1

Description of health condition studied

Systemic lupus erythematesus

ICD-10 code

M32

ICD-10 code description

Primary outcomes

1

Description

chronic stress

Timepoint

before intervention- 2 months after intervention- 4 months after intervention

Method of measurement

The Cohen Perceived Stress Scale

Secondary outcomes

1

Description

depression

Timepoint

before intervention- 2 months after intervention- 4 months after intervention

Method of measurement

Beck Depression Inventory (BDI)

2

Description

quality of life

Timepoint

before intervention- 2 months after intervention- 4 months after intervention

Method of measurement

Quality of Life Questionnaire (WHOQOL-BREF)

Intervention groups

1

Description

Control group: No intervention.

Category

N/A

2

Description

Intervention group: cognitive- behavioral stress management group therapy. The therapy consisted of ten consecutive weekly sessions and each sessions lasted 90 minutes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Street address

Sofe Blvd., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University

Full name of responsible person

Fateme Neissiani Habib Abadi

Street address

No72- 4 Golchin Lane, Ostad Shahriar Ave., 1 Robat St., Jomhori Sq

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University

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

Name of organization / entity

Isfahan University

Full name of responsible person

Fateme Neissiani Habib Abadi

Position

Clinical Psychology M.A

Other areas of specialty/work

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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