

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison Effectiveness of Treatment Based on Acceptance and Commitment, Compassion-Based Therapy and Combination Therapy on Depression, Anxiety, Chronic Pain, Quality of Life, Ineffective Attitudes, Compliance Therapy and Clinical Syndrome in Patients with Systemic Lupus

Protocol summary

Study aim

Comparison of the effectiveness of group therapy based on acceptance and commitment, compassion and combination on depression, anxiety (clinical symptoms), chronic pain, quality of life, dysfunctional attitudes and follow-up treatment of patients with systemic lupus

Design

Clinical trials with control groups, with parallel groups, are not blind, randomized, and have been performed on 100 patients.

Settings and conduct

Samples used by people referred to Hafez Hospital in Shiraz and Dr. Aflaki's Rheumatology Clinic. In order to conduct training and psychological interventions, it was done using the sessions of the investigator's counseling and psychotherapy clinic. The present research method was quasi-experimental and its design was pre-experimental-post-experimental and quarterly follow-up with the control group. After determining the research sample, by examining the general characteristics of the subjects, according to the stratified sampling method, four groups of 20 people were separated from the study population.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 25 to 40 years old; at least 6 months and a maximum of 2 years from the time of diagnosis; not having another physical illness other than lupus; not taking psychiatric drugs; the motivation to participate in the program during the initial interview; no participation in other psychological courses at the same time.

Intervention groups

Research groups have learned the third wave of psychological therapies, including acceptance-based

therapy and commitment and compassion-based therapy, to reduce the psychological effects of depression, anxiety, chronic pain, dysfunctional attitudes, and their adherence to specific therapies.

Main outcome variables

Depression; anxiety; chronic pain; quality of life; dysfunctional attitudes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046500N1**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **retrospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Ali Mohammad Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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ramin3677s@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-03-19, 1398/12/29

Scientific title

Comparison Effectiveness of Treatment Based on Acceptance and Commitment, Compassion-Based Therapy and Combination Therapy on Depression, Anxiety, Chronic Pain, Quality of Life, Ineffective Attitudes, Compliance Therapy and Clinical Syndrome in Patients with Systemic Lupus

Public title

Comparison Effectiveness of Treatment Based on Acceptance and Commitment, Compassion-Based Therapy and Combination Therapy on Depression, Anxiety

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

At least 6 months and a maximum of 2 years have elapsed since the diagnosis Lack of physical illness other than lupus Do not use psychiatric medications Having the motivation to participate in the program during the initial interview Lack of simultaneous participation in other psychological courses

Exclusion criteria:

Absence of more than two sessions There are physical problems that prevent the patient from attending treatment sessions

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **750**Actual sample size reached: **80****Randomization (investigator's opinion)**

Not 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**

Islamic Azad university-shahrekord Branch

Street address

Unit 3-Second Floor -- Mani Building - facing Karim Khani Citadel -- Jomhouri Boulevard-Shiraz

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Postal code

7144914118

Approval date

2020-02-05, 1398/11/16

Ethics committee reference number

IR.IAU.SHK.REC.1399.002

Health conditions studied**1****Description of health condition studied**

Systemic lupus

ICD-10 code

M32.0

ICD-10 code description

Drug-induced systemic lupus erythematosus

Primary outcomes**1****Description**

The percentage of people with a Beck questionnaire score above 15.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

Beck Depression Questionnaire

2**Description**

The percentage of people with a Zong anxiety score above 44.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

Zong Anxiety Questionnaire

3

Description

The percentage of people with chronic pain scores above 30.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

Revised Chronic Pain Questionnaire

4

Description

The percentage of people whose quality of life score is below 15.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

World Health Organization Quality of Life Questionnaire

5

Description

The percentage of people whose scores of dysfunction are higher than 54.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

Weizmann & Beck's Ineffective Attitudes Questionnaire

6

Description

The percentage of people whose treatment adherence score is less than 25.

Timepoint

Measurement period before the start of the intervention and three months after the start of treatment

Method of measurement

Treatment Follow-up Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: in 12 sessions of group therapy based on two treatment approaches, compassion-based therapy and treatment based on acceptance and commitment on a weekly basis, two 90-minute sessions (treatment based on acceptance and commitment) and 120 minutes (treatment-based therapy). They performed at the Counseling and Psychotherapy Center. In the group meetings, after motivating the treatment and the sense of trust between the members of the group, the rules and techniques of treatment methods were taught.

Category

Treatment - Other

2

Description

Second intervention group: The experimental treatment group participated in 16 90-minute combination therapy sessions twice a week in the secret counseling center. The members of the group also learned verbal aikido skills after motivating them.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital in Shiraz

Full name of responsible person

Dr. Elham Aflaki

Street address

Chamran Boulevard-Hafez Hospital

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3478671946

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ramin3677s@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raaz Counseling Center

Full name of responsible person

Mehrnaz Mazarei

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Unit 3-Second Floor, Mani Building, facing Karim Khani Citadel, Jomhouri Boulevard

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1433671348

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Grant name

Grant code / Reference number

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

No
Title of funding source
Mehrnaz Mazarei
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Arsanjan Azad University
Full name of responsible person
Ali Mohammad Rezaie
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only a part of the data, such as information about the main consequence or the like, can be shared.

When the data will become available and for how long

Start of access period from 1399

To whom data/document is available

Data will only be available to researchers working at academic and scientific institutions

Under which criteria data/document could be used

Only general data for guidance

From where data/document is obtainable

I am Dr. Ali Mohammad Rezaei-Secret Counseling Center-
Shiraz, Ordibehesht St., Nab Coffee Building
09178843677

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

The applicant must send his / her request to my e-mail
with a complete explanation of why and what to do
RAMIN3677S@YAHOO.COM

Comments