Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 71 3272 5447

Email address

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
Age
From **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
City
Shiraz
Province
Fars
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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Shiraz
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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
Street address
Unit 3-Second Floor, Mani Building, facing Karim Khani Citadel, Jomhouri Boulevard
City
Shiraz
Province
Fars
Postal code
1433671348
Phone
+98 71 3230 5410
Email
amr1034352@gmail.com
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

Ph.D.

Other areas of specialty/work

Psychology

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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