

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effectiveness of Integrative psychotherapy on Body Image, Self-esteem and Sexual Function in Patients with systemic sclerosis (Scleroderma)

Protocol summary

Study aim

Designing and determining the effectiveness of integrated therapy with the orientation of four common factors in reducing Body Image anxiety, increasing self-esteem and sexual function in patients with scleroderma. Determination of sustainability The effectiveness of integrated therapy with four common factors over time, on Body Image anxiety, self-esteem and sexual function variables in patients with scleroderma.

Design

In this study, 30 patients with systematic scleroderma (with entry requirements) are selected from the rheumatology department of Shariati Hospital in Tehran (Iran). patients are randomly divided into two control and intervention groups and a code are allocated to each one of them.

Settings and conduct

The Integrated Psychotherapy protocol is presented as group sessions for the intervention group at the Iranian Rheumatism Center (Tehran). The therapist is aware of the intervention, but the participants in the intervention and control group are unaware of the psychotherapy process.

Participants/Inclusion and exclusion criteria

All patients resident on Tehran with scleroderma, whose records have been recorded in the department of rheumatology of Shariati Hospital, one year have passed since their diagnosis, have not any psychiatric disorders and have not used any psychoactive drugs during the past three months. Complete the informed consent form for participation in the research.

Intervention groups

In this study, the design and evaluation of the effectiveness of integrated therapy based on the model of four common factors (therapeutic relationship, hope and expectation of treatment, awareness and behavioral ordering) on reducing image body anxiety, increasing

self-esteem and increasing sexual function in Scleroderma patients are treated. At first, dependent variables are evaluated by pre-test questionnaires that have valid and validated validity in both groups. Then, in group, the experimental group is under the intervention of psychotherapy, but the control group is expected during the research. After the intervention and evaluation of the experimental and control groups and the completion of the post-test and follow-up questionnaire, psychiatric intervention will also be implemented for the control group (due to ethical relations and, if desired).

Main outcome variables

Reduce of worry from body image ; Increase of self-esteem; Increase of sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171125037622N1**

Registration date: **2017-12-16, 1396/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-16, 1396/09/25**

Update count: **0**

Registration date

2017-12-16, 1396/09/25

Registrant information

Name

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2017-12-06, 1396/09/15

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Integrative psychotherapy on Body Image, Self-esteem and Sexual Function in Patients with systemic sclerosis (Scleroderma)

Public title

The Effectiveness of Integrative psychotherapy on Patients with Scleroderma

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients whose information is recorded in the Department of Rheumatology of the Shariati Hospital (based on the American College of Rheumatology package or formerly the American Rheumatism Association). At least one year has passed from diagnosing scleroderma. Residents in Tehran and its surroundings Complete the aware and voluntary consent form for participation in the research

Exclusion criteria:

Patients should not be afflicted with mental disorders (in accordance with DSM V). Do not have a history of taking psychoactive drugs over the past 3 months. Patients who have had three absences due to the nature of the illness during the intervention sessions

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

At first, available patients are selected and then randomly assigned (using sealed envelopes) to the two groups of test and control, and the individual randomization unit.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single-blind study is just for the participants, and since psychological intervention is directly taught by the researcher also the evaluation and control operations are conducted by him, the researcher is aware of the method of study.

Placebo

Used

Assignment

Parallel

Other design features

The design of a unified protocol for educational and psychotherapy based on a four-factor common model for patients with scleroderma.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of islamic azad univercity, karaj branch

Street address

Rajai Shahr, Moazzen Boulevard

City

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Postal code

3148635731

Approval date

2017-10-31, 1396/08/09

Ethics committee reference number

IR.IAU.K.REC.1396,54

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

systemic sclerosis (Scleroderma)

ICD-10 code

M34

ICD-10 code description

Systemic sclerosis [scleroderma]

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

Body image worry score in Littleton's body image worry questionnaire.

Timepoint

To measure the effectiveness of unified therapy psychotherapy on the amount of body image anxiety, we

measure the amount of body image anxiety before the intervention (pre test), after the intervention (post test) and one month after the last day of the intervention (follow up)

Method of measurement

To investigate the effect of integrated psychotherapy on body image anxiety, we use the Littleton's Physical Image Worry Questionnaire.

2

Description

Self-esteem score in Cooper Smith self-esteem questionnaire.

Timepoint

To evaluate the efficacy of integrated therapy for self-esteem, We measure the amount of self-esteem before the intervention (pre-test), after the intervention (post-test) and one month after the last day of the intervention (follow up).

Method of measurement

To investigate the effect of integrated psychotherapy on self-esteem, we use the Cooper Smith self-esteem questionnaire.

3

Description

Sexual Function Score in female Sexual Function Index (FSFI).

Timepoint

To evaluate the efficacy of integrated therapy for sexual performance, We measure the amount of sexual function before the intervention (pre -test) , after the intervention (post-test) and one month after the last day of the intervention (follow up).

Method of measurement

Function Index Female Sexual and International Index of Erectile Function

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Hoda kavosi

Street address

North Kargar St. Shariati Hospital

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Sponsors / Funding sources

1

Sponsor

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Layla Shamkoeyan

Position

PHD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Layla Shamkoeyan

Position

PHD Student

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after unidentifiable people.

When the data will become available and for how long

Since 2018/04

To whom data/document is available

Researchers and practitioners in the field of mental and physical health

Under which criteria data/document could be used

For scientific and research use of students, professors and researchers is permitted.

From where data/document is obtainable

Referring to the library of Islamic Azad University, Karaj Branch; Sending a message to a private mail; l.shamkoeyan@gmail.com

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

Send a message to your personal and e-mail and Answer during 5 days

Comments