

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effectiveness of Compassion-Focused Therapy (CFT) on Self Criticism, Internalized Shame, Resilience and Quality of Life in Patients with Vitiligo

Protocol summary

Study aim

The general purpose of this study is to evaluate the effectiveness of treatment focused on self-critical compassion, internalized shame, resilience, and quality of life in patients with vitiligo.

Design

The clinical trial has a control group and is studied on 40 patients who are assigned to two groups based on a random table.

Settings and conduct

A quasi-experimental clinical trial is performed in Razi Hospital on 40 patients who were randomly selected and randomly assigned to a group of 20 people and a double-blinding method is used in which patients and researchers do not know how to allocate patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of the disease based on clinical evidence such as the appearance of skin lesions and, if necessary, skin biopsy and confirmation of vitiligo by a dermatologist - Age range 20 to 45 years Having at least a basic education At least six months of history of the disease - Completing the informed consent form based on voluntary participation in the study and not receiving psychological services outside the treatment session Exclusion criteria: Having diagnostic criteria for obvious psychiatric disorders based on clinical interview Addiction or alcohol consumption History of being hospitalized in psychiatric wards - Consumption of psychiatric drugs Participate in compassion-focused treatment programs over the past six months

Intervention groups

The group receives a therapy package based on the principles, foundations, and techniques of compassion-focused therapy in 8 two-hour sessions based on Gilbert's book on compassion-focused therapy.

Main outcome variables

Self-critical, internalized shame, resilience and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201103049252N1**

Registration date: **2020-11-17, 1399/08/27**

Registration timing: **prospective**

Last update: **2020-11-17, 1399/08/27**

Update count: **0**

Registration date

2020-11-17, 1399/08/27

Registrant information

Name

Abbas Masjediarani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1548

Email address

a.masjediarani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2022-01-12, 1400/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Compassion-Focused Therapy (CFT) on Self Criticism, Internalized Shame, Resilience and Quality of Life in Patients with Vitiligo

Public title

The Effect of Compassion-Focused Therapy (CFT) in Patients with Vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Diagnosis of the disease based on clinical evidence such as the appearance of skin lesions and, if necessary, by skin sampling and confirmation of vitiligo by a dermatologist 2. Age range 20 to 45 years 3. Having at least primary education 4. At least six months of disease history 5. Completing the informed consent form based on voluntary participation in the study and not receiving psychological services outside the treatment session

Exclusion criteria:

1. Have diagnostic criteria for obvious psychiatric disorders based on clinical interview 2. Addiction or alcohol consumption 3. History of being hospitalized in psychiatric wards 4. Consumption of psychiatric drugs 5. Participate in treatment programs related to compassion-focused treatment during the past six months

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample is selected as available, after identifying 40 samples based on the inclusion criteria that have referred to Razi Hospital, using a simple randomization method individually using a random number table of 20 people for the treatment group and 20 people for the group Selected and specialized controls are given.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the purpose of the study is first explained to the patients and they participate in the study if they are satisfied, but the participants are not given information about how to be in the group, and even the researchers who are doing the patient evaluation work. They will not have any information about assigning the subjects to the information group.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University
Medical Sciences

Street address

Evin, Daneshjoo Blvd., Shahid Beheshti University of
Medical Sciences

City

Tehran

Province

Tehran

Postal code

3311123322

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.SBMU.MSP.REC.1399.343

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

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

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

Self-critical

Timepoint

The variable is measured before performing the protocol. After performing the protocol, the variable is measured and then measured again three weeks later

Method of measurement

Thomson and Zarov self-critical levels scale

2**Description**

Internalized shame

Timepoint

The variable is measured before performing the protocol. After performing the protocol, the variable is measured and then measured again three weeks later

Method of measurement

Internalized Shame Scale

3

Description

Resilience

Timepoint

The variable is measured before performing the protocol. After performing the protocol, the variable is measured and then measured again three weeks later

Method of measurement

Connor & Davidson Resilience Scale

4

Description

Quality of Life

Timepoint

The variable is measured before performing the protocol. After performing the protocol, the variable is measured and then measured again three weeks later

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The treatment package was based on the principles, foundations and techniques of compassion-focused treatment in 8 two-hour sessions based on the book of compassion-focused treatment written by Gilbert and will be performed for the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

razi hospital

Full name of responsible person

abbas masjedi arani

Street address

Tehran - Shahid Chamran Highway - Yemen Street - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences

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Email

a.masjedarani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Zayayi

Street address

Tehran - Shahid Chamran Highway - Yemen Street - Next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences Postal Code:

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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

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Masjedi Arani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

After the intervention and the results of the research, the results are shared in general without mentioning the names of the people.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

All students and professors of psychology

Under which criteria data/document could be used

Can be used for review and meta-analysis research.

From where data/document is obtainable

Refer to Shahid Beheshti University of Medical Sciences and then to Dr. Masjedi Arani.

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

After collecting the sample and then analyzing the data and then publishing the article, people can access the results through Google Scholar.

Comments

The above information is sufficient.