Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2303 1548
Email
a.masjediarani@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:
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9951
Email
info@sbmu.ac.ir
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
Street address
Tehran - Shahid Chamran Highway - Yemen Street - next to Taleghani Hospital - Shahid Beheshti

University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
a.masjediarani@sbmu.ac.ir

Person responsible for scientific 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

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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
a.masjediarani@sbmu.ac.ir

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2303 1548

Email
a.masjediarani@sbmu.ir

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.