

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of treatment on compassion in reducing emotional repression and Perception of the suffering of women with vitiligo undergoing phototherapy.

Protocol summary

Study aim

Investigating the effect of treatment on compassion on emotional suppression and perception of suffering in vitiligo patients.

Design

In order to assign people to two experimental groups, the block randomization method is considered by considering blocks 4, 6 and 8. To generate a sequence of random numbers, the software on the web at <https://www.sealedenvelope.com/simple-randomiser/v1/lits> was used. The sample size is 40 patients with vitiligo. The clinical trial has a control group.

Settings and conduct

The place where the intervention will be performed is in Razi Skin Superspeciality Hospital in Tehran, it will be done in person and virtually. The treatment method is group therapy (focused therapy).

Participants/Inclusion and exclusion criteria

Entry criteria: 1. Not taking psychiatric drugs. 2. No disease except vitiligo. 3. Not suffering from acute mental illness. 4. female gender. 5. Vitiligo diagnosis by the attending physician. 6. Age range between 18 and 40 years. 7. Minimum education of diploma. 8. When receiving this treatment, the client should not receive any other psychological treatment and must have completed the previous psychological treatments one month before entering the treatment. 9. Informed consent to participate in research. Output criteria: 1. Absence of more than two sessions. 2. Non-cooperation. 3. It should be determined that the patient has a mental disorder or is taking psychiatric medication.

Intervention groups

The intervention group consists of 20 women with vitiligo undergoing phototherapy, which is a treatment on compassion twice a week. The control group includes 20 women with vitiligo undergoing phototherapy who will not receive any psychological and

psychiatric treatment.

Main outcome variables

Reducing emotional suppression in vitiligo patients;
reducing the perception of suffering in vitiligo patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220403054398N1**

Registration date: **2022-10-30, 1401/08/08**

Registration timing: **prospective**

Last update: **2022-10-30, 1401/08/08**

Update count: **0**

Registration date

2022-10-30, 1401/08/08

Registrant information

Name

Saeid Einali

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-02-08, 1401/11/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of treatment on compassion in reducing emotional repression and Perception of the suffering of women with vitiligo undergoing phototherapy.

Public title
The effect of compassion therapy on emotional repression and perception of suffering of female patients with vitiligo.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Vitiligo diagnosis by the attending physician is a condition for entering the study. The age range between 18 and 40 years is the condition for entering the study. Female gender is a condition for entering the study.
Exclusion criteria:
The use of psychiatric drugs is not included in the study. Co-occurring with vitiligo is a reason not to enter the study. Suffering from psychiatric diseases is the reason for not entering the study.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to assign individuals to two experimental groups, the block randomization method was considered by considering blocks 4, 6 and 8. To generate a sequence of random numbers, the web-based software at <https://www.sealedenvelope.com/simple-randomiser/v1/lists> has been used.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features
The sample population was divided into two experimental and control groups, and in one group, the intervention (compassion therapy) was implemented, and in the intervention control group, the intervention could not be done, after that, the specified

questionnaires were tested in the pre-test and post-test And follow up and analyze, compare and draw conclusions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Medical School-Tehran
University of Medical Sciences

Street address

No.12, Vahdat Eslami Ave.

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Tehran

Province

Tehran

Postal code

1199663911

Approval date

2022-08-30, 1401/06/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.414

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

2

Description of health condition studied

Perception of Suffering

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Emotional Repression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of the Weinberger Adaptability Questionnaire (WAI) .

Timepoint

Before the start of the intervention, after the end of the intervention, one month after the end of the intervention.

Method of measurement

Weinberger Adaptability Questionnaire (WAI).

2

Description

The score of the Scholz Suffering Questionnaire.

Timepoint

Before the start of the intervention, after the end of the intervention, one month after the end of the intervention.

Method of measurement

Scholz Suffering Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group of compassion-focused therapy had 8 sessions as two 90-minute sessions in four consecutive weeks, which used techniques (such as: meditation and recognition of emotions and cognitive errors). . Description of Compassion-Focused Therapy (CFT) Sessions The first session: establishing initial communication, grouping, overview of the structure of the sessions, getting to know the general principles of CFT therapy and distinguishing compassion from self-pity; Evaluating the amount of emotional abuse, describing and explaining emotional abuse and factors related to its symptoms and conceptualizing self-compassion training. Second session: Mindfulness training along with physical examination and breathing exercises, familiarity with brain systems based on compassion, empathy training; Teaching to understand how people feel to follow things with an empathic attitude and homework. The third session: getting to know the characteristics of people with compassion, compassion towards others, cultivating a feeling of warmth and kindness towards oneself, cultivating and understanding that others also have defects and problems (cultivating a sense of human commonality) in front of self-destructive feelings and shame, training Sympathy; and providing homework. The fourth session: reviewing the exercise of the previous session, encouraging the subjects to self-identify and examine their personality as a "compassionate" or "non-compassionate" person according to educational topics, identification and application of "compassionate mind training" exercises (the value of self-compassion, empathy and Compassion towards oneself and others, (physiotherapist metaphor training), forgiveness training and homework. Fifth session: review of the exercise of the previous session, familiarity and application of "compassionate mind exercises" (forgiveness, non-judgmental acceptance and tolerance training), training

to accept problems. Accepting upcoming changes and enduring difficult and challenging conditions due to the variability of the life process. The sixth session: review of the exercise of the previous session, practical exercise of creating compassionate images, teaching the styles and methods of expressing compassion (verbal compassion, practical compassion, cross-sectional compassion and continuous compassion) and applying these methods in daily life and for parents, friends, Teachers and acquaintances, teaching the development of valuable and sublime feelings and homework. . Seventh session: Reviewing the practice of the previous session, teaching how to write compassionate letters for yourself and others, teaching the method of "recording and keeping a diary of real situations based on compassion and the person's performance in that situation". The eighth session: training and practicing skills; Reviewing and practicing the skills presented in the previous sessions to help the subjects to deal with the different conditions of their lives in different ways and finally summarizing and providing solutions to maintain and apply this treatment method in everyday life.

Category

Behavior

2

Description

Control group: does not receive any treatment.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Zainab Aryanian

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Sponsors / Funding sources

1

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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
 Tehran University of Medical Sciences
Proportion provided by this source
 90
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

2

Sponsor
Name of organization / entity
 Shahab Danesh University.
Full name of responsible person
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Web page address
 https://shdu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shahab Danesh University.

Proportion provided by this source
 10
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
 Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The result of the article will be available in full.

When the data will become available and for how long

Taking into account the execution time and the requirements of printing the article, it is expected that 2023 data will be available.

To whom data/document is available

Access will be possible for the general researchers.

Under which criteria data/document could be used

Conducting further research.

From where data/document is obtainable

Request from authors Dr. Zainab Arianian
z_arianian@yahoo.com Dr. Azam Bayanlou
a.bayanlou@yahoo.com Saeid Einali
saeideinali.psy@gmail.com

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

Requests for data will be sent to researchers and will be sent within two weeks if possible.

Comments