

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effectiveness of stress inoculation and Compassion-Focused therapy on resiliency and anger rumination and perceived stress in the hypertensive women

Protocol summary

Study aim

Comparison of the effectiveness of stress inoculation and Compassion-Focused therapy on resiliency and anger rumination and perceived stress in the hypertensive women

Design

A randomized controlled clinical trial with parallel groups, Randomized block, sample size 45 (15 persons per group)

Settings and conduct

Prior to the meetings and licensing, all three groups completed resilience questionnaires, anger rumination, and perceived stress. Then, the experimental group A (immunization against stress) and the experimental group B (compassion-based treatment) were grouped weekly among women in Tehran's medical clinics. The control group did not intervene. The study will be held at Mehr Medical Clinic in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria include a maximum age of 60 years, high blood pressure, a desire to participate in medical intervention, a minimum of literacy, a normal listening ability, and conscious consent to attend treatment sessions. Exclusion criteria included chronic hypertension such as diabetes, severe depression, mental disorders requiring immediate treatment, disruption of the normal course of treatment, lack of cooperation, amputation, and severe physical disability.

Intervention groups

For the first group stress inoculation, for the second group Compassion-Focused therapy, and in the third group, no intervention will be performed. All groups receive medical treatment for high blood pressure.

Main outcome variables

Resiliency and anger rumination and perceived stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200307046713N1**

Registration date: **2020-05-19, 1399/02/30**

Registration timing: **retrospective**

Last update: **2020-05-19, 1399/02/30**

Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

Elahe Sadeghlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8457 9643

Email address

e.sadeghlou@iaukishint.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-05-14, 1399/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of stress inoculation and Compassion-Focused therapy on resiliency and anger rumination and perceived stress in the hypertensive women

Public title

Comparison of the effectiveness of stress inoculation and Compassion-Focused therapy on resiliency and anger rumination and perceived stress in the hypertensive women

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Maximum age 60 high blood pressure willingness to participate in medical intervention minimal literacy ability to listen normally conscious consent to attend therapy sessions

Exclusion criteria:

Having chronic physical illness with high blood pressure such as diabetes having severe depression having mental disorders requiring immediate treatment disrupting the normal course of treatment amputation and severe physical disability lack of cooperation

Age

To **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization method by the statistical consultant, the following randomization is done in 3 groups of stress immunization, compassion-based treatment and control: First, the list of names of qualified people is provided and coded. In block randomization, the number of participants in all groups will be very close, this is done by building blocks of sequences and intersections so that the same number of participants are allocated to study groups within each group. First, we encode the groups based on the Latin letters as follows: A = immunization against stress, B = compassionate treatment and C control group In this study, with three groups A, B and C, we create the following six groups and assign the numbers 1 to 6 to each: ABC-ACB-BAC-BCA-CAB-CBA Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, 6, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be null and void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers, which we consider the order of the assigned allocation for each number. In this way, the number of people in the groups will be almost equal.

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**

Ethics committee of Hormozgan University of Medical Sciences

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No. 64, Janbazan Ave., North Karegar Street

City

Tehran

Province

Tehran

Postal code

1437697419

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.HUMS.REC.1398.338

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

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

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

Resilience

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Connor and Davidson Resilience Scale

2**Description**

Anger Rumination

Timepoint

Measurement will be done in pre-test, post-test and

follow-up three months after post-test

Method of measurement

Anger Rumination Questionnaire

3

Description

Perceived stress

Timepoint

Measurement will be done in pre-test, post-test and follow-up three months after post-test

Method of measurement

Perceived stress scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: In the present study, the meaning of immunization against stress is 10 treatment sessions based on immunization intervention against stress Habibi et al.'s (2014), which are two sessions per week (for one and a half months) and each session. 90 minutes were held. The group also receives medical treatment for high blood pressure.

Category

Treatment - Other

2

Description

Intervention group II: Compassion focused therapy and a 90 minute 10 session treatment plan twice a week (for a month and a half) based on Compassion focused therapy Neff (2004) protocol and designed as a group experimental group subjects are provided. The group also receives medical treatment for high blood pressure.

Category

Treatment - Other

3

Description

Control group: No Intervention, but the group also receives medical treatment for high blood pressure.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Medical Clinics

Full name of responsible person

Elahe Sadeghlou

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Roosta

Street address

Kish Island, Sana'i Boulevard, Free Zone Organization Square, Islamic Azad University of Kish International Branch.

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Hormozgan

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Info@iaukishint.ac.ir

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

Elahe Sadeghlou

Position

Ph.D student
Latest degree
Master
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is 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

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any type of analysis on the data delivered is permitted

From where data/document is obtainable

Elahe Sadeghlou Address: No. 11, West Azerbaijan Ave., Valiasr Blvd. Tel: +98 21 8457 9643

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

The request will be sent by email to:

e.sadeghlou@iaukishint.ac.ir

Comments