

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

A Comparison of the Effectiveness of Unified Transdiagnostic Treatment (UP) and Application of Roy's adaptation model on Blood Pressure, Alexithymia, Psychological Distress and Diet Adherence in People with Hypertension Comorbid with Stress

Protocol summary

Study aim

A Comparison of the Effectiveness of Unified Transdiagnostic Treatment (UP) and Application of Roy's adaptation model on Blood Pressure Reduction, Alexithymia, Psychological Distress and Diet Adherence in People with Hypertension Patients Comorbid with Stress

Design

This study is a randomized Clinical trial with one control group and two parallel intervention groups, designed for 45 patients, using SPSS software to analyze the data. This is not a blinded study.

Settings and conduct

This study is performed on People with Hypertension Patients Comorbid with Stress. The patients visited the Aligoodarz 17 Shahrivar Civil Health Care Center (The location of the study: the Aligoodarz 17 Shahrivar Civil Health Care Center; It is not a blinded study).

Participants/Inclusion and exclusion criteria

Inclusion criteria: achieving at least the score of 19 in stress sub-scale of DASS - 21 scale; having more than 18 years old; hypertension equal or higher than 140 mm mercury; diastolic hypertension equal or more than 90 mm mercury; Using hypertension drugs in more than six months; be willing to participate. Non inclusion criteria: participating in the psychological interventions simultaneously; having a history of mental illness and drug abuse

Intervention groups

The intervention group 1: Treatment sessions based on Unified Transdiagnostic Treatment book of Barlow et al will be performed according to the protocol (1 session per week, each session about 90 minutes - totally 8 sessions during 2 months). The intervention group 2: Treatment sessions based on Application of Roy's adaptation model will be performed according to the

protocol (1 session per week, each session about 60 minutes - totally 8 sessions during 2 months). Control group: doesn't receive any intervention.

Main outcome variables

Psychological distress, Alexithymia, Diet Adherence, Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210717051911N1**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Marziyeh Kolivand

Name of organization / entity

The University of Lorestan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-12, 1400/09/21

Expected recruitment end date

2021-12-15, 1400/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the Effectiveness of Unified Transdiagnostic Treatment (UP) and Application of Roy's adaptation model on Blood Pressure, Alexithymia, Psychological Distress and Diet Adherence in People with Hypertension Comorbid with Stress

Public title

Effect of Unified Transdiagnostic Treatment (UP) and Roy's adaptation model in treatment of hypertension

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Have a minimum score of 19 or higher on the stress subscale of the DASS-21 questionnaire Being over 18 years old Having the minimum physical and cognitive abilities necessary to participate in the interventions Systolic blood pressure equal to or greater than 140 and diastolic blood pressure equal to or greater than 90 mm Hg Have a history of at least six months of medication for high blood pressure treatment Tendency to participate in treatment sessions

Exclusion criteria:

Participate in other psychological interventions Having a history of mental illness and taking psychotropic drugs

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The block randomization method is performed by the statistical consultant as follows: randomization is performed in three groups: unified transdiagnostic treatment, application of Roy's adaptation model and control. First, a list of eligible individuals is provided and coded. We first code the groups in Latin letters as follows: A = unified transdiagnostic treatment, B= application of Roy's adaptation model and C = control group. In this study with three groups A, B, and C, we create the following six groups and assign a number from 1 to 6 to each group: ABC-ACB-BAC-BCA-CAB-CBA, Then, using the table of random numbers, we contract

that if the numbers 1, 2, 3, 4, 5, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be void and move on to the next selection. We have obtained a random sequence of numbers with a table of random numbers that for each number we consider the desired order of assignment. In this way, the number of people in the groups will be approximately 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 Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Shahid Anooshirvan Rezaei Square, Khorramabad, Lorestan.

City

Khorramabad

Province

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6813833946

Approval date

2021-07-05, 1400/04/14

Ethics committee reference number

IR.LUMS.REC.1400.100

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**

Psychological distress

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Depression Anxiety and Stress Scale

2

Description

Alexithymia

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Toronto Alexithymia Scale

3

Description

Diet Adherence

Timepoint

Before intervention, The middle of intervention and after intervention

Method of measurement

Diet information registration form

4

Description

The amount of blood pressure systolic

Timepoint

Before intervention, The middle of intervention and after intervention

Method of measurement

Digital sphygmomanometer

5

Description

The amount of blood pressure diastolic

Timepoint

Before intervention, The middle of intervention and after intervention

Method of measurement

Digital sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: after taking part in a pre-test in a separate meeting, the participants will have the Unified Transdiagnostic treatment which includes 8 basic treatment factors and targets important aspects of the processing and regulating emotions. Eight collective treatment sessions will focus on different factors and take 90 minutes long. These factors briefly include 1. Motivational development and education if needed 2. Psychological training and monitoring emotional experiences 3. Training on the awareness of the emotions 4. Re-cognitive assessment training 5. Avoidance of excitement 6. Understanding and tolerance

of physical sensations 7. Situation-based emotional encounters 8. Prevention of recurrence of the symptoms.

Category

Diagnosis

2

Description

The second intervention group: the Roy's adaptation model is implemented according to the steps of the nursing process, which are as follow: 1. Evaluation and recognition; 2. Nursing diagnosis; 3. Planning; 4. Implementation; 5. Assessment. In addition to the implementation of pre-tests, which is carried out on both the intervention and control group. In the intervention group, the first step is the evaluation and recognition form of Roy as well as the in-person interviews. Next, according to the obtained information, identification of incompatible behaviors, associated stimulations, and prioritizing these behaviors for the maladjusted and reformable behaviors, the objectives are determined and a suitable treatment program will be provided. The participants in the Roy's adaptation model intervention will be engaged in eight weekly treatment sessions for about an hour. Treatment steps details with respect to the identified stimuli in the implementation section are: 1. Hypertension disease familiarity (trained by a general doctor). 2. Evaluating the important physiological parameters related to high blood pressure, such as nutrition and its effect on hypertension, and proposing solutions and behavioral trains by nutrition expert 3. Evaluating the other physiological parameters related to high blood pressure such as exercise, BMI, their effects on hypertension and education, and conducting suitable behavioral training by the general practitioner. 4. Proposing the methods for reducing stress, anxiety, and relaxing techniques by psychologist 5. Training methods to control anger, increase self-confidence, and positive self-assumption providing by psychologist 6. Teaching issues related to roles, responsibilities, social support, and taking drugs regularly 7. Convene training sessions related to taking part in social and religious events and avoiding isolation 8. Reviewing previous meetings

Category

Rehabilitation

3

Description

The control group: 15 subjects will be randomly assigned to this group and do not receive any treatment for two months. At the end of the study, the subjects will receive whether Roy's adaptation model treatment or Unified Transdiagnostic treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar Comprehensive Urban Health Service Center

Full name of responsible person

Marziyeh Kolivand

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Latest degree

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

The University of Lorestan

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

The University of Lorestan

Full name of responsible person

Marziyeh Kolivand

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for updating data**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

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

After deleting participants' identifying factors details, the information about the main consequences will be shared

When the data will become available and for how long

As the results are published

To whom data/document is available

Researchers working in universities and medical centers

Under which criteria data/document could be used

In clinical and therapeutic work

From where data/document is obtainable

Lorestan University Central Library, Adress: 5th Kilometer of Khorramabad-Boroujerd Highway, Khorramabad, Lorestan. Phone:06633120661 researcher, Marziyeh Kolivand, Email marzikolivand@yahoo.com

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

If you are working in a university or scientific institution, it is necessary to provide the relevant document, and the reason for the need for the requested information and the type of relationship with the other study is requested.

Comments