Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Unified Protocol for Transdiagnostic Treatment on Symptoms and Emotional and Cognitive indices of Adults with Separation Anxiety Disorder Comorbid with Emotional Disorders: A Randomized Controlled Trial

Protocol summary

Study aim
Investigate the effectiveness of unified protocol for transdiagnostic treatment on emotional and cognitive symptoms and indicators of adults with separation anxiety disorder comorbidity with emotional disorders

Design
The clinical trial has a wait-list group and an experimental group, which is double-blind and randomized using the minimization method.The sample size is 34 people.

Settings and conduct
Allocation of participants will be administered by someone other than a therapist. For the allocation of the participants, randomization minimization and a coin toss method method will be used. Referrals for the treatment and wait-list groups will be from the counseling center of the University of Kurdistan and mental health professionals.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having the diagnostic criteria for separation anxiety disorder and comorbid emotional disorders, consent to participate in the research, being at least 18 years old, Having at least a diploma, Speak Persian fluently, Ability to participate in all assessment and treatment sessions Exclusion criteria: receiving any other type of psychological treatment, having any type of personality disorder and diagnosing any type of psychiatric disorder and diagnosing any type of psychiatric disorder (except for emotional disorders) and substance abuse and taking medication related to disorder and Having serious thoughts about Suicide

Intervention groups
The individuals suffering from adult separation anxiety disorder (ASA) with comorbid emotional disorders will randomly be assigned to two groups including UP and wait-list. The treatment includes a maximum of 10 45-minute sessions that target emotional experiences.

Main outcome variables
Adult separation anxiety disorder; anxiety; cognitive fusion; anxiety sensitivity; difficulties in emotion regulation; intolerance of uncertainty

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240227061119N1**
Registration date: **2024-07-23, 1403/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-23, 1403/05/02**
Update count: **0**

Registration date
2024-07-23, 1403/05/02

Registrant information

Name
saeideh sobhani

Name of organization / entity
University of Kurdistan

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-07-10, 1403/04/20

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Unified Protocol for Transdiagnostic Treatment on Symptoms and Emotional and Cognitive indices of Adults with Separation Anxiety Disorder Comorbid with Emotional Disorders: A Randomized Controlled Trial

Public title

The Effectiveness of Unified Protocol for Transdiagnostic Treatment on people with Separation Anxiety Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having the diagnostic criteria DSM-5-TR for separation anxiety disorder and comorbid emotional disorders, and not taking drugs related to disorder. Consent to participate in the research Being at least 18 years old Having at least a diploma Not receiving any type of treatment related to the disorder during the past year Speak Persian fluently Ability to participate in all assessment and treatment sessions

Exclusion criteria:

Receiving any other type of psychological treatment Having any type of personality disorder and diagnosing any type of psychiatric disorder (except for emotional disorders) Substance abuse Having serious thoughts about Suicide Taking medications related to disorders

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants with SAD and comorbid emotional disordes will assigne to treatment groups and wait- list group on the basis of covariate adaptive randomization (minimisation). The purpose of this method is to control gender variable. So if the first participant be female, she will assigne in group number one. When the second participant be a man, he will assigne in the first group. When the third participant be female, she will assigne to the second group. If the fourth participant be female, she will assigne to third group and then the rest of the participants will place in the groups by adjusting the gender variable.

Blinding (investigator's opinion)

Double blinded

Blinding description

Interviews will conduct by an expert clinical therapist to assess the inclusion and exclusion criteria. After that, individuals randomly will assign to treatment group and wait- list group. Allocation of participants, will administer by someone other than therapist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in biological research

Street address

Central organization., University of Kurdistan., Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

15175-66177

Approval date

2024-04-27, 1403/02/08

Ethics committee reference number

IR.UOK.REC.1403.017

Health conditions studied

1

Description of health condition studied

Adult separation anxiety disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Separation anxiety score in adult separation anxiety questionnaire

Timepoint

Pre-treatment; post-treatment; follow-up

Method of measurement

Adult Separation Anxiety Questionnaire (ASA-27)

2

Description
Cognitive fusion score in cognitive fusion questionnaire
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Cognitive fusion Questionnaire (CFQ)

3

Description
Anxiety sensitivity score in anxiety sensitivity questionnaire
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Anxiety Sensitivity Questionnaire (ASI)

4

Description
Intolerance of uncertainty score in intolerance of uncertainty questionnaire
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Intolerance Uncertainty Questionnaire (IUS)

5

Description
Emotion regulation score in the emotion regulation difficulty scale
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Difficulties Emotion Regulation scale (DERS)

6

Description
Anxiety score in dass21 questionnaire
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Dass21 questionnaire

7

Description
Depression score in dass21 questionnaire
Timepoint
Pre-treatment; post-treatment; follow-up
Method of measurement
Dass21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: UP group. Unified protocol for transdiagnostic of emotional disorders consists of a maximum of 10, 45-minute individual treatment sessions. The UP targets and regulates emotional experiences by increasing emotion awareness and cognitive flexibility; identifying emotion-driven behaviors (EDBs) and replacing them with adaptive behaviors; identifying and preventing patterns of emotion avoidance; increasing awareness and confronting physical sensations, and facing emotions in situations. The treatment is preceded by enhancing the motivation and readiness of individuals for change and treatment engagement. Finally, the treatment ends by considering the progress of treatment and developing relapse prevention strategies.
Category
Treatment - Other

2

Description
Control group: wait-list group for Unified protocol. After completion of follow-up sessions of intervention groups, the UP treatment will be applied as intervention group 1.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The University of Kurdestan
Full name of responsible person
Farzad Nasiri
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Sponsors / Funding sources

1

Sponsor
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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 Kurdestan
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
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Person responsible for updating data

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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

Part of the data including information about the main consequence can be shared.

When the data will become available and for how long

Start of accessibility will be one year after printing the results.

To whom data/document is available

Data will only be available to researchers working in academic institutions.

Under which criteria data/document could be used

Requests for data are only permitted for intercultural studies or the studies of meta-analysis.

From where data/document is obtainable

Researchers can use the mentioned communication channel to receive the desired documents or data. Email: f.nasiri@uok.ac.ir

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

Data will be provided by email or post after evaluation of the request.

Comments