Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Effectiveness of Unified Protocol with and without Supplementary Protocol on Personality Dimensions and Symptoms in Patients with Emotional Disorders and Identifying Mechanisms of Change.

Protocol summary

Study aim

Comparative Effectiveness of Unified Protocol with and without Supplementary Protocol on Personality Dimensions and Symptoms in Patients with Emotional Disorders and Identifying Mechanisms of Change.

Design

This is a mixed-methods study. The quantitative phase uses a pretest–posttest design with two experimental groups and purposive non-random sampling. Twenty patients with emotional disorders will be randomly assigned to two groups. Each group will complete pretest, midtest, posttest, and two-month follow-up. The qualitative phase involves inductive latent content analysis to identify change mechanisms after treatment.

Settings and conduct

Participants: Patients with emotional disorders recruited from university-affiliated clinics and hospitals. Screening via interview and eligibility assessment; informed consent obtained; questionnaires administered at three time points; interventions delivered based on random assignment; 16 individual therapy sessions provided.

Participants/Inclusion and exclusion criteria

Inclusion: Age 25–45 years, at least high school diploma, medication stability for ≥6 weeks. Exclusion: Medication changes, psychotic disorders, personality disorders, concurrent treatments, suicide risk, substance use, recent psychotherapy.

Intervention groups

Unified Protocol: A transdiagnostic CBT-based intervention targeting negative emotion regulation. Complementary Module: An additional intervention focusing on positive emotion regulation.

Main outcome variables

Integrating personality dimensions into transdiagnostic CBT may simplify care, reduce therapist training burden, enhance treatment efficiency, align with real-world clinical presentations, enable simultaneous intervention for primary disorders and comorbidities, facilitate mechanism-based development of interventions, and support preventive efforts and early identification of at-risk individuals.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250421065413N1**
Registration date: **2025-04-28, 1404/02/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-28, 1404/02/08**
Update count: **0**

Registration date

2025-04-28, 1404/02/08

Registrant information

Name

Mahbubeh Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-26, 1404/02/06

Expected recruitment end date

2025-05-24, 1404/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Unified Protocol with and without Supplementary Protocol on Personality Dimensions and Symptoms in Patients with Emotional Disorders and Identifying Mechanisms of Change.

Public title

The Impact of Unified and Supplementary Protocols on Emotional Disorders.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 25 and 45 years educational level of high school diploma or higher if taking medication, the dosage must have remained stable for at least 6 weeks prior to entering treatment

Exclusion criteria:

Changes in medication or dosage during treatment Substance or alcohol dependence Full criteria for personality disorders Presence of psychotic disorders (such as schizophrenia or bipolar disorder) or Diagnosis of major depressive disorder with psychotic features Need for urgent treatment, such as acute suicidal ideation Concurrent treatments that may interfere with the research process Receiving psychotherapy for depression or anxiety within the past six months Symptoms due to medical conditions

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

To ensure the absence of medication interference with the research outcomes, the following conditions are mandatory: Participants who are currently taking medication must have maintained a stable dosage for a minimum of six weeks prior to study enrollment and throughout the treatment period. Individuals who are not taking medication at the time of study enrollment must not initiate any new psychotropic medication during the study period, spanning from the fulfillment of inclusion criteria until the completion of treatment. Considering that the participants will exhibit clinically significant symptoms, the non-initiation of new psychotropic medication or any alteration in the dosage or type of current medication (under psychiatric supervision) during the study duration is a prerequisite for both study entry and continued participation. Due to ethical considerations (the infeasibility of allocating patients to a wait-list control group for a duration of 5 to 6 months), this study will comprise two experimental groups, with each group receiving 16 sessions of individual psychotherapy:First experimental group (n=10): Recipients of the Unified Protocol (UP) with a focus on negative emotion regulation.Second experimental group (n=10): Recipients of a combination of the Unified Protocol and a supplementary protocol, where, in addition to the focus on negative emotion regulation, the enhancement of positive emotions is also incorporated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Committees of Iran University of Medical Sciences

Street address

Office of the Vice Chancellor for Research and Technology, Headquarters Building, Iran University of Medical Sciences (IUMS), Adjacent to Milad Tower, Hemmat Expressway, Tehran, Iran.

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1449614535

Approval date

2024-05-13, 1403/02/24

Ethics committee reference number

IR.IUMS.REC.1403.164

Health conditions studied

1

Description of health condition studied

Emotional Disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Emotional Disorders: Three primary characteristics define emotional disorders: a) the intense and frequent experience of negative emotions; b) aversive reactivity towards emotional experiences due to a reduced sense of control and negative self-evaluation; c) the individual's engagement in efforts to reduce, escape, or avoid emotional experiences by developing behaviors and strategies aimed at preventing these experiences. These three criteria, through their collaboration and interaction, help to define and identify emotional disorders, which are predominantly manifested as anxiety and depressed mood states.

Timepoint

1.Pre-test 2.Mid-test (end of the eleventh week) 3.Post-test (treatment completion) 4.Follow-up (two months after treatment completion)

Method of measurement

The score obtained by the participant on the Hospital Anxiety and Depression Scale (HADS). A clinical cut-off point of 6 in the 80th percentile was considered the criterion for the depression and anxiety subscales, with scores above this indicating a higher severity of depression and anxiety.

2

Description

Neuroticism: A personality trait defined by a tendency towards negative emotionality and a strong negative emotional response to various stressors. Individuals with this trait often tend to experience a range of negative emotions such as anxiety, fear, irritability, anger, and sadness. Furthermore, a distinguishing characteristic is a deep-rooted belief that leads them to perceive the world as a dangerous place, which in turn intensifies their negative emotions in response to stressors.

Timepoint

1.Pre-test 2.Mid-test (end of the eleventh week) 3.Post-test (treatment completion) 4.Follow-up (two months after treatment completion)

Method of measurement

The score obtained by the participant on the neuroticism dimension of the Eysenck Personality Questionnaire-Revised Short Form (EPQR-S).

3

Description

Aversive Reactivity: A functional mechanism that acts as a bridge between the personality trait of neuroticism and the development and maintenance of emotional disorders.

Timepoint

1.Pre-test 2.Mid-test (end of the eleventh week) 3.Post-test (treatment completion) 4.Follow-up (two months after treatment completion)

Method of measurement

The score obtained by the participant on the subscales of questionnaires assessing motivation and responsiveness to reward and punishment, and emotional beliefs.

4

Description

Extraversion: A personality trait defined by sociability, talkativeness, warmth, assertiveness, activity, and excitement-seeking, and overall the experience of positive affect. Deficits in extraversion, meaning both low and high levels of this trait, are associated with various psychopathological conditions.

Timepoint

1.Pre-test 2.Mid-test (end of the eleventh week) 3.Post-test (treatment completion) 4.Follow-up (two months after treatment completion)

Method of measurement

The score obtained by the participant on the extraversion dimension of the Eysenck Personality Questionnaire-Revised Short Form (EPQR-S).

5

Description

Sensitivity to Reward/Rejection: A proposed functional mechanism that acts as a bridge between the personality trait of extraversion and the development and maintenance of emotional disorders.

Timepoint

1.Pre-test 2.Mid-test (end of the eleventh week) 3.Post-test (treatment completion) 4.Follow-up (two months after treatment completion)

Method of measurement

The score obtained by the participant on the subscales of questionnaires assessing motivation and responsiveness to reward and punishment, and emotional beliefs.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Unified Protocol (UP) is a cognitive-behavioral therapy approach that applies the same therapeutic principles, without adapting the protocol to specific disorders, to address a broad range of anxiety and depressive states in emotional disorders. It is an intervention recently developed with the aim of directly impacting neurotic temperament for the transdiagnostic treatment of emotional disorders. In this study, the Unified Protocol, authored by Barlow and colleagues at Boston University as a transdiagnostic treatment for emotional disorders, will be used for 11 sessions in the first group and 16 sessions in the second group.

Category

Treatment - Other

2

Description

Intervention group: The supplementary protocol is a

proposed intervention aimed at engaging positive emotions. This protocol is designed as an adjunctive intervention for individuals with emotional disorders who have residual symptoms after a period focused on neuroticism (i.e., UP) and score low on the extraversion dimension. In this study, the supplementary protocol, authored by Carl, Gallagher, and Barlow at Boston University as a transdiagnostic and adjunctive treatment to the UP designed to regulate positive emotions, will be used in the final 4 sessions of the first group after receiving 11 UP sessions.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran University of Medical Sciences (IUMS)

Full name of responsible person
Mahbube Fallah

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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?
No

Title of funding source
Iran University of Medical Sciences (IUMS)

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
Iran University of Medical Sciences

Full name of responsible person
Mahbube Fallah

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Outcome-related data (data from questionnaires completed by subjects) is shareable after anonymization.

When the data will become available and for how long
Access period starts one year after publication of results.

To whom data/document is available
Researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used
Non-commercial use of data is permitted only.

From where data/document is obtainable
Researchers can submit their data requests to the following email address: mahbubeh.fallah.fm@gmail.com (Mahboube Fallah).

What processes are involved for a request to access data/document
Researchers must specify the intended use of the data in their email. If the stated purposes comply with the data sharing terms, the data will be sent to the applicant's email address within one month.

Comments