Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of four transdiagnostic treatments on reduction of symptoms of emotional disorders and Cluster B personality disorders among adults and adolescences

Protocol summary

Study aim

Comparing the effectiveness of Unified protocol, Mentalization- Based treatment,Dialectical Behavior Therapy and Self-acceptance group therapy for emotional disorders and Cluster B personality disorders ' symptom reduction among adults Comparing the effectiveness adaptation version of Unified protocol, Mentalization- Based treatment,Dialectical Behavior Therapy and Self-acceptance group therapy for emotional disorders among adolesents

Design

four arm parallel groups randomised trial with blinded assessors, therapists and and outcome analysis for adult group and adolescent group.assessment will be applied at baseline, post-treatment, 6,12,18,24 and 36 months follow-up.

Settings and conduct

this study will be occurred at clinical psychology office in Taleghani Hospital. At first, potential participants will screened by phone call, those who will meet inclusion criteria will be assessed by blinded psychologists . Moreover psychotherapists who will administer treatments and data analysts will be blinded

Participants/Inclusion and exclusion criteria

age:11-18 years old for adolescents sample and 18-65 years old for adults sample-meet full criteria for at least one emotional disorders-able to read and speak Farsi fluently-able to participate in in-person psychotherapy sessions Exclusion Criteria:-active suicidal plan-substance dependency-meet full criteria of schizophrenia or neurological diseases-using psychiatry medicine-missing psychotherapy session more than 3 times repeatedly

Intervention groups

For adolescents sample there will be four treatment groups: a)Unified protocol for adolescents -b)Dialectical behaviour therapy for adolescents (DBT-A), c)Mentalization based-treatment for adolescents (MBT-A) D)Self-Acceptance Therapy (SAGT).Moreover, adults protocol has same structures.

Main outcome variables

severity of Depression,anxiety, BPD, ASPD, emotion dysregulation and shame

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231106059970N1**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Banafsheh Mohajerin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of four transdiagnostic treatments on reduction of symptoms of emotional disorders and Cluster B personality disorders among adults and adolescences

Public title

Comparing the effectiveness of four transdiagnostic among adults and adolescences

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 11-18 in adolescence sample Age between 18 to 65 in adults group Be able to read and speak Farsi fluently, participant in in-person psychotherapy sessions Adolescence sample meet full criteria for at least one emotional disorders In Adult sample: meet full criteria for at least one emotional disorders and /or cluster B personality disorders

Exclusion criteria:

active suicidal plan substance dependency, meet criteria as schizophrenia and neurological diseases psychiatry medicines miss more than three psychotherapy session repeatedly

Age

From **11 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **360**

More than 1 sample in each individual

Number of samples in each individual: **45**

In adolescents sample: there will be four groups and 45 individuals will be allocated in each group. in adults sample size: 180 participants will randomly assigned in 4 groups and at each group there will be 45 participants

Randomization (investigator's opinion)

Randomized

Randomization description

The G*Power software will be used for calculating sample size by indicating the margin of error of 0.05 and power of 0.95 total sample size will be 180 for adolescent and 180for adult sample size. 180 participants of adolescents will be randomly allocated in four groups by using https://www.dcode.fr/random-selection and after that each group will received one of the treatments randomly. this will be done for adult group, too.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current study, participants will received a code for registering in study, after allocation randomly in treatment groups, therapists who will be blinded to participants diagnosis, will apply treatments. After intervention finish, the assessors who will be blind to participants diagnosis and type of intervention will analysis data. Finally, the observer, the only person who know who receive which treatment will write the report.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me

Street address

Ethic commitee of Shahid Beheshti University of Medical Sciences, 6 floor, 2th Building, Arabi St, Velenjak,Tehran, Iran

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Province

Tehran

Postal code

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Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.426

Health conditions studied

1

Description of health condition studied

Individuals who meet the full criteria of emotional disorders including mood disorders, anxiety disorders, OCD, PTSD,and eating disorder

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

2

Description of health condition studied

Individuals who meet the full criteria of emotional

disorders including mood disorders, anxiety disorders, OCD, PTSD, and eating disorders

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3

Description of health condition studied

Individuals who meet the full criteria of emotional disorders including mood disorders, anxiety disorders, OCD, PTSD, and eating disorders

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

4

Description of health condition studied

Individuals who meet the full criteria of emotional disorders including mood disorders, anxiety disorders, OCD, PTSD,and eating disorders

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

5

Description of health condition studied

Individuals who meet the full criteria of emotional disorders including mood disorders, anxiety disorders, OCD, PTSD, and eating disorders

ICD-10 code

F50

ICD-10 code description

Eating disorders

6

Description of health condition studied

Individuals who meet the full criteria of cluster B personality disorders consists of antisocial personality disorder, borderline personality disorder, narcissistic personality

ICD-10 code

F60.2

ICD-10 code description

Antisocial personality disorder

7

Description of health condition studied

Individuals who meet the full criteria of cluster B personality disorders consists of antisocial personality disorder, borderline personality disorder, narcissistic personality

ICD-10 code

F60.3

ICD-10 code description

Borderline personality disorder

8

Description of health condition studied

Individuals who meet the full criteria of cluster B personality disorders consists of antisocial personality disorder, borderline personality disorder, narcissistic personality

ICD-10 code

F60.81

ICD-10 code description

Narcissistic personality disorder

9

Description of health condition studied

Individuals who meet the full criteria of cluster B personality disorders consists of antisocial personality disorder, borderline personality disorder, narcissistic personality

ICD-10 code

F60.4

ICD-10 code description

Histrionic personality disorder

Primary outcomes

1

Description

scores of Beck's Depression Inventory (BDI-II)

Timepoint

questionnaires will be assessed at baseline, post-treatment, 6,12,18,24 and 36-month follow-up

Method of measurement

Beck's Depression Inventory (BDI-II)

2

Description

scores of Beck's anxiety Inventory (BAI)

Timepoint

questionnaires will be assessed at baseline, post-treatment, 6,12,18,24 and 36-month follow-up

Method of measurement

Beck's anxiety Inventory (BAI)

3

Description

scores of the Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004)

Timepoint

questionnaires will be assessed at baseline, post-treatment, 6,12,18,24 and 36-month follow-up

Method of measurement

The Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004)

4

Description

scores of the Positive and Negative Affect Schedule (PANAS)

Timepoint
questionnaires will be assessed at baseline, post-treatment, 6,12,18,24 and 36-month follow-up
Method of measurement
The Positive and Negative Affect Schedule (PANAS) (Watson, Clark, & Tellegen, 1988)

Secondary outcomes

1

Description
scores of Shame severity
Timepoint
baseline, post- treatment, 6,12,18,24 and 36 months follow-up
Method of measurement
The Experience of Shame Scale (ESS, Andrews et al, 2002)

Intervention groups

1

Description
Intervention group: Adaptation of Unified protocol for adolescents which consists 8 - 15weekly45-60 minutes session. Primary care-giver can participate in this treatment weekly either 2-5 individuals sessions
Category
Treatment - Other

2

Description
Intervention group: Unified protocol consists 8-14 weekly session that last between 45-60 minutes. main modules based on each participants conceptualization will be applied
Category
Treatment - Other

3

Description
Intervention group: Modified Dialectical behaviour therapy (DBT) for adolescents consists of weekly individual therapy sessions (approximately 1 hour), a weekly group skills training session (approximately 1.5–2.5 hours), and a therapist consultation team meeting (approximately 1–2 hours) that can last for 20 sessions
Category
Treatment - Other

4

Description
Intervention group: Dialectical behaviour therapy (DBT)The standard DBT treatment package consists of weekly individual therapy sessions (approximately 1 hour), a weekly group skills training session (approximately 1.5–2.5 hours), and a therapist consultation team meeting (approximately 1–2 hours)
Category
Treatment - Other

5

Description
Intervention group: Modified mentalization-based treatment for adolescents (MBT-A) is a manualized, psychodynamic psychotherapy based on attachment theory . It consists of 50 minutes of individual weekly and family monthly sessions and lasts for one -year.
Category
Treatment - Other

6

Description
Intervention group: Mentalization-based treatment for adults is a manualized, psychodynamic psychotherapy based on attachment theory . It consists of 50 minutes of individual weekly and family monthly sessions and lasts for one -year.
Category
Treatment - Other

7

Description
Intervention group: m̃odification version of Self-Acceptance Group Therapy (SAGT) is 12, 90-minute weekly sessions and will be applied in small groups of six participants and focuses on shame, acceptance and emotion regulation
Category
Treatment - Other

8

Description
Intervention group: Self-Acceptance Group Therapy (SAGT) is 12, 90-minute weekly sessions and will be applied in small groups of six participants and focuses on shame, acceptance and emotion regulation
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleqani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
none
Grant code / Reference number
none
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
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
Shahid Beheshti University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
demographic information and computed data of measures for reasonable requests as SPSS and/or Excel will be shared by sending email to corresponded project

When the data will become available and for how long
It is 36-month follow-up study, after results will be published by journals, the data will be shared

To whom data/document is available
the data will be only available for researchers working in academic institutions

Under which criteria data/document could be used
The data will be shared as computed scores of measures only for meta-analysis and review articles for researches after they provide information about their project, identity, data of their project and how they select the current project

From where data/document is obtainable
Researchers by sending a email to corresponded project will have an access to data, please send email to bmohajerin@sbmu.ac.ir banafshehmohajerin@gmail.com

What processes are involved for a request to access data/document
after the results of these data will be published by journals, researchers by sending an email and provide reasonable request for their project, will have data by a week

Comments