Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized clinical trial comparing cognitive behavior therapy and intensive short-term dynamic psychotherapy for medically unexplained pain

Protocol summary

Summary

Aims: This study evaluates intensive short-term dynamic psychotherapy (ISTDP) as a treatment for MUP outpatients by comparing it to the established evidence-based treatment cognitive behavioral therapy (CBT) in a randomized clinical trial. The authors hypothesized insignificant differences in ISTDP relative to CBT. Design: This study was a randomized controlled trial with an allocation ratio of 1:1 for CBT and ISTDP. Method: A total of 341 adults with MUP were randomly assigned to 16 sessions of individual manualized CBT (N = 164) or ISTDP (N = 177). The groups were assessed at baseline, after 16 weeks of treatment, and at the three-month follow-up. Interventions: Participants are randomly allocated to either CBT or ISTDP. Both are individual psychotherapies encompassing 16 sessions within 22 weeks. Randomization: Patients were randomized in blocks by a computer algorithm. Block size was randomly chosen to include either three or six patients. Blinding: The research assessor administering the observer-rated scales was blinded to the group assignment at baseline and three-month follow-up. Outcome measures: The primary outcome was perceived pain assessed using the Numeric Pain Rating Scale (NPRS). The secondary outcomes were psychological distress, depression, and cognitive variables. The cognitive variables included self-efficacy, catastrophizing, and coping strategies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091329810N1**
Registration date: **2016-11-09, 1395/08/19**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2016-11-09, 1395/08/19

Registrant information

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Recruitment status

Not enough for processing

Funding source

Vice chancellor for research of Baqiyatallah University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2014-12-01, 1393/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial comparing cognitive behavior therapy and intensive short-term dynamic psychotherapy for medically unexplained pain

Public title

Comparing the effectiveness of cognitive behavioral

therapy and intensive short-term dynamic psychotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: "18–45 years of age"; "at least one MUP with a duration of six months"; "fluency in Farsi". Exclusion criteria: "acute drug/alcohol abuse"; "psychotic disorder"; "bipolar disorder"; "anorexia nervosa disorder"; "acute suicidality"; "pregnancy".

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **341**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will randomize in blocks by a computer algorithm. Block size was randomly chosen to include either three or six patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Baqiyatallah University of Medical Sciences

Street address

Mollasadra Avenue, Vanak square

City

Tehran

Postal code

Tehran

Approval date

2013-07-01, 1392/04/10

Ethics committee reference number

130/1720/d/91

Health conditions studied

1

Description of health condition studied

Pain disorders related to psychological factors

ICD-10 code

F45.4

ICD-10 code description

A category of psychiatric disorders which are characterized by the presence of physical symptoms that suggest a medical condition but are not fully explained by any known medical reasons. Disorders characterized by bodily symptoms caused by psychological

Primary outcomes

1

Description

Pain intensity

Timepoint

at Baseline, Post-treatment (week 16) and at the Three-month Follow-up

Method of measurement

Numerical Pain Rating Scale (NPRS)

Secondary outcomes

1

Description

Secondary outcome measure 2: anxiety

Timepoint

We will take the measurement at three timepoints: at a baseline assessment (before randomization); immediately post of treatment (after 16 sessions); and after three months of follow-up.

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

2

Description

Secondary outcome measure 1: depression

Timepoint

We will take the measurement at three timepoints: at a baseline assessment (before randomization); immediately post of treatment (after 16 sessions); and after three months of follow-up.

Method of measurement

Beck Depression Inventory-II (BDI-II)

3

Description

Secondary outcome measure 3: catastrophizing

Timepoint

We will take the measurement at three timepoints: at a baseline assessment (before randomization); immediately post of treatment (after 16 sessions); and after three months of follow-up.

Method of measurement

Pain Catastrophizing Scale (PCS)

4

Description
Secondary outcome measure 4: self-efficacy
Timepoint
We will take the measurement at three timepoints: at a baseline assessment (before randomization); immediately post of treatment (after 16 sessions); and after three months of follow-up.
Method of measurement
Chronic Pain Self-Efficacy Scale (CPSS)

5

Description
Secondary outcome measure 5: chronic pain coping
Timepoint
We will take the measurement at three timepoints: at a baseline assessment (before randomization); immediately post of treatment (after 16 sessions); and after three months of follow-up.
Method of measurement
Chronic Pain Coping Inventory (CPCI)

Intervention groups

1

Description
Control group: cognitive behavioral therapy is a short-term, goal-oriented psychotherapy treatment that takes a hands-on, practical approach to problem-solving. Its goal is to change patterns of thinking or behavior that are behind people's difficulties, and so change the way they feel.
Category
Behavior

2

Description
Intervention group: Intensive Short-Term Dynamic Psychotherapy (ISTDP) is a unique form of psychodynamic treatment. ISTDP interventions are specifically designed to experience the emotion cognitively, and somatic matorically (physically in the body).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Dr. Mehdi Saberi
Street address
Tehran Province, Tehran, Mollasadra Avenue
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr. Hedayat Sahraei
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Artesh Boulevard, Aghdasieh
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Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Baqiyatallah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Neuroscience Research Center, Baqiyatallah University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty