

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The impact of group schema therapy on depression, anxiety and stress in patients with insulin-dependent diabetes

Protocol summary

Summary

The goal of this clinical trial is to determine the impact of group schema therapy on depression, anxiety and stress in patients with insulin-dependent diabetes. Among all the diabetic patients referred to Yasuj Clinic University of Medical Sciences, 64 patients with insulin-dependent diabetes will be selected and according to the questionnaire (DASS-42) who has moderate to severe depression, anxiety and stress will be enrolled in this study. This means after the introduction of the researcher, explaining the objectives of the study and how research will be done, informed consent is obtained, then questionnaires such as demographic, depression, anxiety and stress (DASS-42) (1995) and the short form of the Young Schema 75 items (SQ-SE) (1994) will give to the subjects that after their completion randomly allocated to two groups of subjects and control. After ensuring consistency between the two groups, the treatment process for intervention group will take place during 10 sessions of 90 minutes over a period of 5 weeks. During this meetings we will use techniques of schema therapy such as imagery, experimental techniques, providing a list of supporting evidence Schema, assessing the advantages and disadvantages of coping styles, Empty chair technique to establish a dialogue between the "Healthy aspect" and "Schema aspects", schema educational card, while a control group will not receive interventions considered in this study except routine services till taking the post test. Also, after a month of completion of the training, the above questionnaire completed by both groups will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102124620N6**

Registration date: **2016-02-02, 1394/11/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-02, 1394/11/13

Registrant information

Name

Azadeh Eghbalmanesh

Name of organization / entity

Yasuj university of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of group schema therapy on depression, anxiety and stress in patients with insulin-dependent diabetes

Public title

Schema therapy in in patients with insulin-dependent diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: hearing ability and acceptable speech; lack of depression and anxiety according to diagnostic criteria of DSM-IV; willingness to participate in study; diagnosis of moderate to severe depression (score 14-28); moderate to severe anxiety (score 10 -27); moderate to severe stress (score 14-34) after filling out the questionnaire DASS-42; no use of psychiatric drugs from 4 months ago till now; having a history of diabetes more than a year; having a history of suicide attempts and substance abuse and alcohol; at least having a cycle. Exclusion criteria: cognitive disorders and mental illness after beginning of the study; having a defect that seriously hamper the patients to participate in group therapy; failure to participate in three sessions of Schema Therapy; participating in other group psychotherapy at the same time; death and emigration of the patients.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Yasuj University of Medical Science

Secondary trial Id
yums.REC.1394.70

Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee

Yasuj University of Medical Sciences

Street address
Yasuj University of Medical Sciences, Shahid Motahari Blvd.

City
Yasuj

Postal code

Approval date
2015-09-09, 1394/06/18

Ethics committee reference number
yums.REC.1394.70

Health conditions studied

1

Description of health condition studied
Schemathereapy in patients with insulin-dependent diabetes

ICD-10 code
E10

ICD-10 code description
Insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Depression

Timepoint
At the begining of the study, last session of group schematherapy of intervention and one month after group schematherapy intervention

Method of measurement
Quesstionnare dass-42(1996)

2

Description
Anxiety

Timepoint
At the begining of the study, last session of group schematherapy of intervention and one month after group schematherapy intervention

Method of measurement
Quesstionnare DASS-42(1996)

3

Description
Primary malladaptive schemas

Timepoint
At the begining of the study, last session of group schematherapy of intervention and one month after group schematherapy intervention

Method of measurement
Young Schema Questionnaire-Short Form 75-item (SE-SQ) (1994)

4

Description

Stress

Timepoint

At the beginning of the study, last session of group schematherapy of intervention and one month after group schematherapy intervention

Method of measurement

Quesstionnare DASS-42(1996)

Secondary outcomes

empty

Intervention groups

1

Description

subjects in experimental group will have group schematherapy including : imagery, experimental techniques, providing a list of supporting evidence Schema, Assessing the advantages and disadvantages of coping styles, Empty chair technique to establish a dialogue between the " Healthy aspect" and " Schema aspects ",schema educational card during 10 sessions of 90 minutes over a period of 5 weeks.

Category

Behavior

2

Description

A control group will not receive interventions considered in this study (group schematherapy) except routine services till taking the post test.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasuj Clinical University of Medical Scincevs Clinic (Shahid Mofateh)

Full name of responsible person

Street address

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mehdi Akbartabar Turi

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd.

City

Yasuj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Zoladl

Position

Psychiatric Nursing Ph.D/ Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mohammad Zoladl

Position

Psychiatric Nursing Ph.D/ Associate Professor.

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Yasuj University of Medical Sciences

Full name of responsible person

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Position

MA student of psychiatric nursing

Other areas of specialty/work**Street address**

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City

Yasuj

Postal code**Phone****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