

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effectiveness of Reality Therapy Based on Choice Theory along with diet Therapy on Biochemical Indicators in Obese People: The Mediating Role of Bipolar Thinking and Body Image

#### Protocol summary

##### Study aim

1-Determination and comparison of mean anthropometric parameters (body mass index, weight, height, waist circumference, hip circumference, waist to hip ratio) between and within the study groups 2-Determining and comparison the mean score of dichotomous thinking and body image between and within the study groups 3-Determination and comparison of mean biochemical markers (total cholesterol, high-density lipoprotein, low-density lipoprotein, triglycerides, aspartate amino transferase, alanine amino transferase, whole blood test, high-sensitivity C-reactive protein, and low blood glucose) between and within the study groups

##### Design

Randomized clinical trials, intervention and control groups, randomization by balanced blocks, 50 participants

##### Settings and conduct

The purpose of this study was practical and semi-experimental method with pre, and post-test with control group and randomly assigned to intervention and control group. The population of the study were patients invited to Dietary Clinic in Mashhad.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years, body mass index between 25 and 35, one drug increases appetite does not eat, didn't use medicines and supplements for weight loss over the past two months, No bariatric surgery, not been in pregnant or breastfeeding during, have bipolar thinking or body image. exclusion criteria: Having depressive disorders, personality disorders

##### Intervention groups

The intervention package in this study was included reality therapy with diet therapy for the intervention group and only diet therapy for the control group

##### Main outcome variables

Dichotomous thinking; body image; weight; body mass

index; waist circumference; hip circumference; body fat mass; lean body mass

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190822044580N1**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **retrospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

##### Registration date

2020-03-19, 1398/12/29

##### Registrant information

##### Name

Reza Eftekhari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3149 2229

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-22, 1397/07/30

##### Expected recruitment end date

2018-12-19, 1397/09/28

##### Actual recruitment start date

2018-11-27, 1397/09/06

##### Actual recruitment end date

2018-12-19, 1397/09/28  
**Trial completion date**  
2019-03-18, 1397/12/27

### Scientific title

The Effectiveness of Reality Therapy Based on Choice Theory along with diet Therapy on Biochemical Indicators in Obese People: The Mediating Role of Bipolar Thinking and Body Image

### Public title

The Effectiveness of Reality Therapy Based on Choice Theory along with diet Therapy on lose weight of over weight People

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

age between 18 to 65 body mass index between 25 to 35 individuals don't use drugs that increasing appetite individual hasn't use drug or supplement for two month ago individual hasn't do bariatric surgery individual has not been pregnancy or lactation He/She had dichotomous thinking He/She had body image disorder

#### Exclusion criteria:

depression disorder personality disorder

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

Actual sample size reached: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Subjects from one to fifty were assigned to A and B and then divided into two groups: intervention and control with random allocation software

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee school of Public Health-Shahid Sadoghi University of Medical Sciences

### Street address

Shahid Sadoughi Blvd

### City

Yazd

### Province

Yazd

### Postal code

8916978477

### Approval date

2018-10-21, 1397/07/29

### Ethics committee reference number

IR.SSU.SPH.REC.1397.090

## Health conditions studied

### 1

#### Description of health condition studied

Overweight and obesity

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Dichotomous Thinking Scale in Dichotomous Thinking Questionnaire

#### Timepoint

"Measuring Dichotomous thinking at the beginning of the study (before the intervention) and at the end of the reality therapy intervention"

#### Method of measurement

Dichotomous Thinking Questionnaire

### 2

#### Description

Body Image Scale in Body Image Concern Inventory Questionnaire

#### Timepoint

"Measuring Body Image Concern Inventory at the beginning of the study (before the intervention) and at the end of the reality therapy intervention"

#### Method of measurement

Body Image Concern Inventory Questionnaire

### 3

#### Description

individuals body weight

#### Timepoint

measuring of body weight in 1, 4, 11 weeks

#### Method of measurement

By using inbody device

## Secondary outcomes

## 1

### **Description**

high-density lipoprotein

### **Timepoint**

High-density lipoprotein levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 2

### **Description**

low-density lipoprotein

### **Timepoint**

low-density lipoprotein levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 3

### **Description**

cholesterol

### **Timepoint**

cholesterol levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 4

### **Description**

triglyceride

### **Timepoint**

triglyceride levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 5

### **Description**

high-sensitivity C-reactive protein

### **Timepoint**

high-sensitivity C-reactive protein levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 6

### **Description**

fasting blood sugar

### **Timepoint**

fasting blood sugar levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 7

### **Description**

Complete blood count

## **Timepoint**

Complete blood count levels were measured before and after the study

### **Method of measurement**

Using approved kits and cell counter

## 8

### **Description**

Aspartate Aminotransferase

### **Timepoint**

Aspartate Aminotransferase levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 9

### **Description**

Alanin Aminotransferase

### **Timepoint**

Alanin Aminotransferase levels were measured before and after the study

### **Method of measurement**

autoanalyzer bt3000

## 10

### **Description**

hip circumference

### **Timepoint**

hip circumference were measured before, middle and after the study

### **Method of measurement**

By using inbody device

## 11

### **Description**

abdomen circumference

### **Timepoint**

abdomen circumference were measured before, middle and after the study

### **Method of measurement**

By using inbody device

## 12

### **Description**

body fat mass

### **Timepoint**

body fat mass were measured before, middle and after the study

### **Method of measurement**

By using inbody device

## 13

### **Description**

free fat mass

### **Timepoint**

free fat mass were measured before, middle and after the study

**Method of measurement**

By using inbody device

**14****Description**

body mass index

**Timepoint**

body mass index were measured before, middle and after the study

**Method of measurement**

By using inbody device

**15****Description**

Total Body Water

**Timepoint**

Total Body Water were measured before, middle and after the study

**Method of measurement**

By using inbody device

**16****Description**

minerals

**Timepoint**

minerals were measured before, middle and after the study

**Method of measurement**

By using inbody device

**Intervention groups****1****Description**

Intervention group:Reality Therapy according to the protocol specified by Psychologist for 8 sessions in the first three weeks of study combined with Low calorie diet that reduced 500 calorie per person by Nutritionist

**Category**

Treatment - Other

**2****Description**

Control group:Nutritionist gave Low calorie diet with 500 calorie limitation per person

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Dr. Majid Ghayour Mobarhan Clinc

**Full name of responsible person**

Dr. Hassan Mozaffari Khosravi

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Medical University of Yazd

**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**

thesis master degree

**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**

Medical University of Yazd

**Full name of responsible person**

Dr. Hassan Mozaffari Khosravi

**Position**

Professor  
**Latest degree**  
Specialist  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Medical University of Mashhad  
**Full name of responsible person**  
Dr. Majid Ghayour Mobarhan  
**Position**

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**Latest degree**  
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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

Not applicable

### Title and more details about the data/document

The data obtained for this study are available in journals

### When the data will become available and for how long

This data is presented as an article by the end of the year 2020

### To whom data/document is available

This data will be only available to researchers working in academia

### Under which criteria data/document could be used

The data in this study are only authorized with the permission of the design of other statistical analyzes

### From where data/document is obtainable

reza eftekhar email: rezaeft.nut@gmail.com cellphone number:00989150406372

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

Just send an email with full specifications of individual expression. you need 48 hours for getting data

### Comments