Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 Eftekhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3149 2229

Email address

rezaeft.nut@gmail.com

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 apetite 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
outoanalyzer bt3000

2

Description
low-density lipoprotein
Timepoint
low-density lipoprotein levels were measured before and after the study
Method of measurement
outoanalyzer bt3000

3

Description
cholesterol
Timepoint
cholesterol levels were measured before and after the study
Method of measurement
outoanalyzer bt3000

4

Description
triglyceride
Timepoint
triglyceride levels were measured before and after the study
Method of measurement
outoanalyzer 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
outoanalyzer bt3000

6

Description
fasting blood sugar
Timepoint
fasting blood sugar levels were measured before and after the study
Method of measurement
outoanalyzer 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
outoanalyzer bt3000

9

Description
Alanin Aminotransferase
Timepoint
Alanin Aminotransferase levels were measured before and after the study
Method of measurement
outoanalyzer 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
Street address
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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

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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9177948564

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ghayourm@mums.ac.ir

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