

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of Internet-based Cognitive Behavioral Therapy in Weight Loss and Outcome of Virtual Group Therapy

Protocol summary

Study aim

Determining the effectiveness of Internet-based cognitive-behavioral therapy in weight loss and treatment outcome through virtual group

Design

This research is a quasi-experimental applied foundation with pre- and post-test between three intervention groups, routine obesity treatment and control group. The sample size based on G-Power is 90 people (30 people in the intervention group (iCBT), 30 people in the usual treatment of obesity (diet therapy) and 30 people in the waiting list control group) who are randomly placed in groups. The intervention group receives Internet-based cognitive-behavioral therapy, the as usual group undergoes a treatment regimen, and the control group's waiting list treatment is delayed until the end of the intervention group treatment.

Settings and conduct

This research does not require a physical location and only the initial interview is done at the Call of Life Counseling Center located in Neishabour.

Participants/Inclusion and exclusion criteria

Inclusion criteria include BMI ≥ 25 , age 18 to 50 years, having at least a ninth grade degree Fluency in Persian language, internet access and skill in using it. Exclusion criteria include menopause or pregnancy, lactation, psychosis and bipolar disorder diagnosed by a PhD student in psychology, certain diseases such as diabetes, thyroid, cancer, cardiovascular disease, and the use of psychotropic drugs or drugs that affect weight.

Intervention groups

The intervention group receives Internet-based cognitive-behavioral therapy, the as usual group undergoes a treatment regimen, and the control group's waiting list treatment is delayed until the end of the intervention group treatment.

Main outcome variables

Reducing body mass index Improve lifestyle self-efficacy Satisfaction with body image Improve eating-related

behaviors Depression, anxiety, stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210306050594N1**

Registration date: **2021-03-09, 1399/12/19**

Registration timing: **prospective**

Last update: **2021-03-09, 1399/12/19**

Update count: **0**

Registration date

2021-03-09, 1399/12/19

Registrant information

Name

NAJME ABEDI SHARGH

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4263 6798

Email address

abede.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-13, 1399/12/23

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Effectiveness of Internet-based Cognitive Behavioral Therapy in Weight Loss and Outcome of Virtual Group Therapy
Public title	Internet-based Cognitive Behavioral Therapy
Purpose	Education/Guidance
Inclusion/Exclusion criteria	
Inclusion criteria:	Age 18 to 50 years Have at least a ninth grade degree Internet access and skills in using it Fluency in Persian BMI ≥ 25
Exclusion criteria:	Menopause or pregnancy, lactation Psychosis and bipolar disorder diagnosed by a PhD student in psychology Certain diseases such as diabetes, thyroid, cancer, cardiovascular disease Taking psychotropic drugs or drugs that affect weight
Age	From 18 years old to 50 years old
Gender	Female
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 90
Randomization (investigator's opinion)	Randomized
Randomization description	The present research in the category is applied basic research in terms of purpose and semi-experimental in terms of collection method. The pre-test and post-test design template was between three groups of iCBT intervention, routine treatment (TAU) and waiting list control group (WL). The population of this study is overweight women with a body mass index of more than 25, Neishabour city in 1300-00. Of these, 82 are selected based on G * Power analysis to determine the size of the medium to large effect (alpha .05; power .80) and due to the possibility of shedding according to the research, which is online, 90 people are considered. شد. How to replace people after structured diagnostic interview based on DSM-5 (SCID-5) by a PhD student in psychology and review the inclusion and exclusion criteria in the first stage using the available sample of 90 people selected and replacing subjects in each intervention and control group It is simple random using a table of random numbers and is an individual randomization unit.
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

Iran University of Medical Sciences

Street address

Sattarkhan St., Maziar Mansouri St., Iran Psychiatric Institute

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2019-09-28, 1398/07/06

Ethics committee reference number

IR.IUMS.REC.1398.667

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Weight Loss

Timepoint

two months

Method of measurement

Body mass index is calculated

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :receive cognitive-behavioral therapy for weight loss. Cognitive-behavioral therapy sessions are based on Judith Beck's treatment plan for weight loss in 42 two-hour sessions over six weeks. This protocol is a treatment package that has been proven to be effective. Setsu and Zerwas research was also modeled on the

correct implementation of ICBT. The content of the sessions used in the present study includes familiarity with the logic of treatment, familiarity with destructive thoughts and challenges with them, familiarity with the ABC pattern, setting goals, starting a diet, examining destructive thoughts related to dieting and responding to them, overcoming challenges. The remaining destructive thoughts are adjusting and creating new skills, how to stop weight loss and stabilize new weight, and evaluate and summarize. CBT treatment is performed by a PhD student in clinical psychology who completed a CBT training course at the Tehran Psychiatric Institute. In this way, the therapist first forms two groups called psychotherapy in weight loss in WhatsApp (one intervention group 30 people, one control group waiting list 30 people) every morning audio file explaining psychotherapy sessions with exercise related to each session according to The goals of the program are recorded by a psychotherapist and placed in the virtual space created by the WhatsApp application, as well as the techniques are explained online. And to understand and perform correctly, the exercises of each person are examined (people have the opportunity to listen to the treatment file and perform the exercise and share it in the group until the evening) and for the exercises, feedback and answering questions for one hour. Every day from 6 to 7 pm, a consultation session can be held using online chat and WhatsApp voice and video calls. During the course, people communicate with each other and the therapist through online chat and support and give feedback to each other.

Category

Treatment - Other

2

Description

Control group 2: The control group did not apply any psychological treatment.

Category

N/A

3

Description

Control group 2: The as usual group undergoes treatment regimen once a week under the supervision of a nutritionist.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neishabour, Counseling Center

Full name of responsible person

Najmeh Abedi Sharghl

Street address

Iran Square, Attar St. 10

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Sattar Khan St., Maziar Mansouri St., Tehran Psychiatric Institute

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۱۴۴۹۶۱۴۵۳۵

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admins@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Najmeh Abedi Shargh

Position

tutor

Latest degree

Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Descriptive statistics information of all participants in the study Research results

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Be a research person in the field of research with the code of ethics

From where data/document is obtainable

Email address: NAJME.ABBEDI@GMAIL.COM

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

Submit your request via email. One week to one month

Comments