

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effect of an intervention on nutrition based on a digital game with physical activity and group cognitive behavioral therapy on anthropometric and biochemical parameters in obese and overweight elementary school girls

Protocol summary

Study aim

Determining the Effect of Nutrition Intervention Based on Digital Game Plus Cognitive Behavioral Therapy and Physical Activity on Anthropometric and Biochemical Parameters in Obese and Overweight Elementary School Girls

Design

The randomized clinical trial is community-based, practice-oriented control group, with parallel groups,

Settings and conduct

In this study, Shiraz will be divided into 3 districts according to urban geographic regions, we will accept each area as a cluster. Then we will select a school randomly from each cluster. 62 students will be selected and randomly assigned (randomized block method) into two intervention and control groups (31 in each group). This study will be performed as a randomized, controlled clinical trial for 10 weeks, and the impact of digital nutrition and psychological intervention and physical activity will be assessed. Anthropometric and biochemical measurements will be evaluated at the end of the period.

Participants/Inclusion and exclusion criteria

Obese and Overweight Elementary School Girls

Intervention groups

During 10 weeks of the intervention, digital games will be given to children. At the beginning of the game, information about the causes of obesity, complications of obesity, amount of calories in various foods, food sources of fiber and vitamins, banned foods during the intervention, and etc. will be presented to children in a video. In each game a person can play for no more than 45 minutes. The game is opened step-by-step, but when they enter the next stage, the previous stage can also be opened. The sports program is out of school, asking parents to obtain parental consent and set weekly hours

outside the school program to bring their children to the gym. Sports program will be done under the supervision of a coach weekly.

Main outcome variables

weight

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190508043531N1**

Registration date: **2019-07-10, 1398/04/19**

Registration timing: **prospective**

Last update: **2019-07-10, 1398/04/19**

Update count: **0**

Registration date

2019-07-10, 1398/04/19

Registrant information

Name

Sara Salahshoornezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 7014

Email address

salahshoor@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of an intervention on nutrition based on a digital game with physical activity and group cognitive behavioral therapy on anthropometric and biochemical parameters in obese and overweight elementary school girls

Public title

Evaluating the effect of an intervention on nutrition based on digital game with physical activity and group cognitive behavioral therapy on anthropometric and biochemical parameters in obese and overweight elementary school girl

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

8-12 years old overweight or obese school girls who can use a smart phone or tablet

Exclusion criteria:

depression students who already have a diet any medicine which affect body weight students (or students' parents) who don't want to involve in this research

AgeFrom **9 years** old to **12 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **62****Randomization (investigator's opinion)**

Randomized

Randomization description

Overweight and obese students are selected using a randomized block method from the screened students from the fourth, fifth and sixth grade of selected schools (schools are selected using a cluster randomization method).

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 of Shiraz University of Medical Sciences

Street address

Nutrition and Food Science College, Razi Blvd., Shiraz, Iran

City

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Province

Fars

Postal code

7153675541

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SUMS.REC.1397.870

Health conditions studied**1****Description of health condition studied**

obesity

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

waist circumference

Timepoint

At the beginning of the study (before the intervention) and 10 weeks after the start of psychological intervention and physical activity intervention and computer game intervention.

Method of measurement

The body weight is measured and recorded at both test times, with a minimum coverage and without shoes, with a seca type scales with a minimum of 0.1 to a maximum of 150 kg and an error of 100 grams in the morning. The scale is standardized before each measurement

Secondary outcomes**1****Description**

serum leptin

Timepoint

At the beginning of the study (before the intervention) and 10 weeks after the start of the intervention

Method of measurement

The leptin hormone will be measured according to the ELISA method with the help of the kit, which will be

measured in accordance with the instructions and using a standard curve and control at a specified time

Intervention groups

1

Description

Intervention group: During the ten weeks of intervention, children will be provided with information on the causes of obesity, the complications of obesity, the amount of calories in various foods, sources of fiber and vitamins, banned foods during the intervention, and ... presented to students as a video game. Each week, three aerobic exercise sessions will be held for 45 minutes each student by a Master of Sport Physiology. A Master of Psychology will hold a Cognitive-Behavioral Therapy session a week in a groups of 10 to 12 people at the school.

Category

Behavior

2

Description

Control group: In the control group, the intervention includes routine healthy nutrition education (lecture, pamphlets, etc.) for students and their parents.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz schools

Full name of responsible person

Sara Salahshoornezhad

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16th alley, chamran Blvd., Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sara Salahshoornezhad

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable