

A family-based lifestyle intervention program for Jordanian obese children aged 6-9 years

Submission date 29/04/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/05/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity in children has become an epidemic in developed and developing countries because it is the leading cause of morbidity and premature mortality. A randomized controlled trial was conducted to test the effect of a family-based lifestyle intervention program on body mass index, dietary habits, and physical activity for obese children aged 6-9 years in Jordan.

Who can participate?

Children aged 6-9 years who are obese and have a sedentary lifestyle.

What does the study involve?

Participants will be randomly allocated to receive a three-month family-based lifestyle intervention program on body mass index (BMI), dietary habits, and physical activity for obese children aged 6-9 years in Jordan, or no intervention.

What are the possible benefits and risks of participating?

There should be direct benefit to the student participant from this study, as it will raise awareness of a healthy lifestyle change, and provide information that may prevent you long-term from developing any complications related to obesity.

There are no further risks or discomforts anticipated from participation.

Where is the study run from?

Alzaytoonah University of Jordan and four schools in Amman (Jordan)

When is the study starting and how long is it expected to run for?

May 2020 to September 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Ayman Bani Salameh, A.salameh@zuj.edu.jo

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

03/145/2018-2019

Study information

Scientific Title

Randomized controlled trial of a family-based lifestyle intervention program for Jordanian obese children aged 6-9 years

Acronym

RCT- FBLIPJOCA6-9Y

Study objectives

1. There will be an effect of a family-based lifestyle intervention program on body mass index (BMI) among obese children aged 6-9 years in Jordan
2. There will be an effect of a family-based lifestyle intervention program on dietary habits among obese children aged 6-9 years in Jordan
3. There will be an effect of a family-based lifestyle intervention program on and physical activity among obese children aged 6-9 years in Jordan

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/12/2019, Institutional Review Board (IRB) at Al-Zaytoonah University of Jordan (Faculty of Nursing, Dean/Head of Research Committee, P.O.Box 130, Amman, 11733, Jordan; +962-6-4291511. (Ext. 369); nursing@zuj.edu.jo), ref: 03/145/2018-2019

Study design

Two-group single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Obesity in children

Interventions

A two-group, single-blinded, randomized controlled trial study will be conducted at Amman city, at four schools. The students will randomly be allocated to intervention group to receive a family-based lifestyle intervention program or control group with no care. All participants will be followed for three months.

Randomization

Four schools were selected randomly using a cluster sampling method. Then, two schools were selected randomly to be in the intervention arm and the other two schools were selected to be in the control arm. Sequentially, the researchers reviewed the students' health records that are existed in these schools. The eligible students and caregivers (guardians and parents) who were willing to participate will be provided with consent forms, and children gave assent. Thereafter, the researchers randomly will pull out the names of potential participants who met the inclusion criteria to be either in intervention group or in control group. The file names will keep concealed in closed envelopes. All subjects were blinded to their allocations.

intervention

The intervention is a lifestyle teaching program. The program consists of encouraging children to select a healthy diet and increase PA. The intervention was originally adopted from a 'Swap It Don't Stop It' (SIDSI) program (originally developed by the Australian government), which was culturally adapted and modified by Bani Salameh and had been tested on Jordanian adolescents

in 2012-2013. Participants will deliver the modified version.

Those children and their parents will be educated about interventional behavioral approaches to increase PA to around 7 hours per week and to decrease sedentary lifestyle, such as screen games and watching television, to less than 14 hours per week. Behavioural methods included lifestyle changes, self-control, SIDS weekly and monthly established targets, and positive reinforcement to achieve planned goals. Other instructions such as promoting body image and reducing emotional eating will be also provided.

The program will be delivered over 3 months in the schools' auditorium. A letter of invitation to parents, whose cooperation and understanding was vital, will be sent out with the participants three days before each session. Children and their parents attended the fortnightly sessions at the schools after the school classes were over. The program consisted of six group sessions (30 minutes fortnightly and 10-12 participants in each one), which will be followed by a phone call for reassurance if needed. The participants and their parents in each group will offer complementary education materials, such as manual of the daily diet and PA.

Intervention Type

Behavioural

Primary outcome measure

Body Mass Index will be measured by calculating height (m) and body weight (kg) at baseline and 3 months. Body mass index z-scores or BMI standard deviation (S.D) scores, which are considered as measures of child' weight according to age and sex. Also, body mass index percentile, which is a measure of weight according to child's age. It will be classified as follows: underweight (BMI is less than 5th percentile), normal weight (BMI is 5th - (BMI is 5th -85th percentile, overweight (BMI is at or above the 85th percentile but less than 95th percentile), and obesity (BMI is at or above the 95th percentile). The height and weight will be measured based on the guidelines provided by WHO. Children will be weighed without shoes in daily or routinely light clothes using, a digital scale (Garmin Index Smart Scale). A fixed height board will be used for height measurements.

Secondary outcome measures

Dietary habits and physical activity assessed by a questionnaire consists of questions related to dietary habits (seven questions) and physical activity (nine questions) at baseline and 3 months

Overall study start date

17/11/2019

Completion date

01/09/2020

Eligibility

Key inclusion criteria

1. Children aged 6-9 years
2. Obese (BMI of 95th percentile and more)
3. A sedentary lifestyle

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

6 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

170

Key exclusion criteria

1. Unable to participate in an arranged interventional program activity
2. Undertaken any obesity management program
3. Diagnosed with a developmental or mental disorder, autism or psychosis, genetic obesity syndrome, and any other contraindication

Date of first enrolment

17/05/2020

Date of final enrolment

18/08/2020

Locations

Countries of recruitment

Jordan

Study participating centre

Aldor Almanthor School

Marj alhamam

Amman

Jordan

11732

Study participating centre

Al Radwan School

Alyadodeh

Amman

Jordan

11610

Study participating centre
Al-Khamael School
Bayader
Amman
Jordan
11814

Study participating centre
Mashrek School
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Sponsor information

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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

10/10/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other