

Role of health education for parents on childhood obesity and body weight among school children

Submission date 02/08/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/01/2024	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 is now described as a disease and one of the most preventable diseases by changing diet and personal lifestyle. High body weight and obesity in childhood may have harmful consequences for this very vulnerable age group and are connected to an increased chance of obesity in adulthood. Children who are overweight or obese are at a higher risk of developing many health problems, such as high blood pressure, asthma and other respiratory problems, type 2 diabetes, liver disease and sleep disorders. Obesity may also cause psychological problems like depression, social isolation and low self-esteem. Education and early programs (e. g. in school or community-based intervention) are critical to addressing the obesity epidemic. Epidemiological and clinical studies have confirmed the role of a low-calorie diet, intensified physical activity, and cognitive strategies to change behaviours. These strategies include self-monitoring, problem-solving, planning, stress management, and gaining other children's social support in managing adolescent obesity and associated cardio-metabolic risks. Health education is required to recognize behaviour and, if necessary, replace it with new behaviour to develop an effective program. This study explores the effectiveness of a school-based educational intervention program and identifies factors associated with significant weight loss.

Who can participate?

Parents of school-age children aged between 6 to 15 years old (primary school) in Sulaimani province - Kurdistan region/Iraq

What does the study involve?

Measurement of child height, weight, and waist and hip circumference will be undertaken at a baseline measurement and before the end of the school year. Parents will be invited to participate in two different education sessions, one at the baseline measurement and another after ten weeks. The contents of the sessions will include brief introductory knowledge of childhood obesity, the cause and harms of childhood obesity, BMI references for screening overweight and obesity in school-age children, healthy eating (increasing consumption of vegetables and fruits, reducing consumption of non-healthy foods, fast foods, snacks, avoiding sugary drinks), and how to increase a child's physical activity (intensity, duration, reducing

sedentary time). Educational materials like paper-printed flyers will be distributed to the parents and their children. Furthermore, the researcher will ask for help to create a household-supportive environment for healthy eating and physical activity for their children. Parents are also required to encourage and supervise their children to have a healthy lifestyle.

What are the possible benefits and risks of participating?

Participant families will benefit from the education sessions, helping them to have a better quality of life by being more active than previously, which will lower body weight and decrease their BMI range. There are no risks for participants during the study period.

Where is the study run from?

The University of Sulaimani (Iraq)

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

April 2021 to April 2022

Who is funding the study?

Investigator-initiated and funded

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

7/5/9558

Study information

Scientific Title

Parental participation in reducing childhood obesity and overweight among basic school students: A randomized controlled trial

Study objectives

Health education of parents about obesity by various methods such as face-to-face group discussion, seminar presentations and providing paper print flyers is more effective in lowering obesity and weight levels than one method such as only providing a paper print flyer

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/08/2021, Ethical Committee of The College of Medicine (Sulaimani University, New Sulaimani, Street 27- Zone 29, Sulaymaniyah, Kurdistan Region, Iraq; +9640533270924; med@univsul.edu.iq), ref: 156

Study design

Interventional single-blind randomized controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Reducing obesity and body weight in primary school children

Interventions

Current interventions as of 30/03/2023:

The intervention program called 'I'm active' focuses on promoting a healthy lifestyle for overweight and obese children by providing two sessions of health education for parents. The study aims to recruit overweight or obese children whose body weight status was determined using age- and gender-specific body mass index (BMI) z-scores from one to nine grades in 15 primary schools. The schools are selected by applied stratified multistage cluster sampling from a total of 647 schools distributed into districts in the Sulaimani governorate. The schools are selected according to probability proportional to size (PPS) of the directorate of education in each district. From each of the selected schools, 20 overweight or obese children (both male and female) will be invited by convenience sampling to participate in this study. After anthropometric measurement, we will invite their parents to participate in two educational sessions and the parents will be divided randomly into two groups: a control group and the intervention group. Parents will be invited into school to participate in two education sessions ten weeks apart, the first session at the time of baseline measurements and the second session after ten weeks. Parents in the intervention group in each selected school will participate in a one-hour seminar presentation provided by the principal researcher and every parent will be provided with a paper-printed flyer containing the same information from the seminar. Parents in the control group in each selected school will be provided with the paper-printed flyer only without the seminar information. After ten weeks, a second similar session is run again for both groups. Further, there will be two rounds of anthropometric measurements, the first one is the baseline assessment and the second follow-up assessment is before the end of the school year.

Previous interventions:

The intervention program called 'I'm active' focuses on promoting a healthy lifestyle for overweight and obese children by providing two sessions of health education for parents. The study aims to recruit overweight or obese children whose body weight status was determined using age- and gender-specific body mass index (BMI) z-scores from one to nine grades in 15 Basic schools. The schools are selected by applied stratified multistage cluster sampling from a total of 647 schools distributed into districts in the Sulaimani governorate. The schools are

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Intervention Type

Behavioural

Primary outcome(s)

The measurements were taken in the student's classroom during school hours during a baseline assessment and a second follow-up assessment before the end of the school year after six months' duration:

1. Body mass index (BMI) measured, BMI was categorized using standard cut-points of BMI for age and sex percentile and BMI z-score for age and sex
2. Waist and hip circumference, and then waist-to-hip ratio (WHR)

Height was measured to the nearest 0.1 cm using an Anthroflex wall-mounted stadiometer with a wall plate with participants standing against the wall without shoes

Weight was measured to the nearest 0.1kg using a MEDEL 2316 Crystal International digital weighing scale with participants in lightweight cloth school uniform without shoes

Waist and hip circumference was measured to nearest 0.5 cm using an anthropometric tape with participants wearing light clothing, according to the World Health Organization (WHO) recommendations (W.H.O, 2011). Waist circumference was measured at the minimum circumference between the iliac crest and the rib cage. Hip circumference was measured at the maximum protuberance of the buttocks, and then the waist-to-hip ratio (WHR) was calculated.

Key secondary outcome(s)

1. Demographic characteristics measured using a questionnaire at baseline to include:
 - 1.1. Participant demographics: age, age group, gender, parent education level, parent occupation, and family size
 - 1.2. Residency (Sulaimani, Chamchamal, Rania, Pishdar, Sharazoor, Saidsadiq)
 - 1.3. Socioeconomic status (SES): based on a Dr Nameer scoring system. A total of a formulated 21-point scoring system was used to classify the children according to their socio-economic status (SES). The total score (21) was divided into three equal categories: 1-7 (low), 8-14 (medium), and 15-21 (high).
2. Eating behaviour measured using a questionnaire at baseline
3. Watching digital behaviours measured using a questionnaire at baseline
4. Sport activity, leisure time activity and school activity measured using a questionnaire at baseline, we summated all these points together so the grand total was between (0 – 120) score and grouped into three categories; low, moderate and high activity.

Completion date

28/04/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 30/03/2023:

1. Primary school children aged between 6 and 18 years old who are part of the sample that was invited to participate in the study
2. Overweight or obese. If there are two children in one family who meet the inclusion criteria, they are permitted to participate as two separate individuals

Pervious inclusion criteria:

1. Basic school children aged between 6 and 18 years old who are part of the sample that was invited to participate in the study
2. Overweight or obese. If there are two children in one family who meet the inclusion criteria, they are permitted to participate as two separate individuals

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

15 years

Sex

All

Total final enrolment

300

Key exclusion criteria

Current exclusion criteria as of 30/03/2023:

1. Primary school children aged 5 years old and younger and 19 years old and over
2. Children with disabilities
3. Parents who refused to participate in the study

Previous exclusion criteria:

1. Basic school children aged 5 years old and younger and 19 years old and over
2. Children with disabilities
3. Parents who refused to participate in the study

Date of first enrolment

19/09/2021

Date of final enrolment

31/10/2021

Locations

Countries of recruitment

Iraq

Study participating centre

Sulaimani general directorate of education

Kurdistan region

Sulaimani

Iraq

46001

Sponsor information

Organisation

University of Sulaymaniyah

ROR

<https://ror.org/00saanr69>

Funder(s)

Funder type

Other

Funder Name

Investigator-initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Mr Abdulrahman M. Ibrahim, abdulrahman.ibrahem@univsul.edu.iq. The data will be available for one year after publication for SPSS analysis and with no anonymisation or restriction.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 0	10/08/2022	10/08/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes