ISRCTN69072933 https://doi.org/10.1186/ISRCTN69072933

Body composition and its association with nutrition and health factors in adolescents in the Middle East

Submission date 15/09/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 26/09/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 21/07/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study includes 210 national adolescents aged 15-18 years from each participating country and aims to examine their body fat percentage, nutrition, and health. The study will assess body composition through several techniques to better understand its association with nutrition and health factors. The study is conducted in several Arab countries, including Jordan, Lebanon, Kuwait and Syria, to allow for inter-country comparisons.

Who can participate?
Children aged 15-18 years old who are nationals in the participating countries

What does the study involve?
How participants will be approached:
Participants will be approached in local schools in each country, as follows:
All secondary school students, i.e. students in grades 10-12, will be approached. The research team members will explain the study to potential participants. They will be given a copy of the parental consent and adolescent assent forms. Parents who agree to allow their child to participate will then return the signed parental consent form to the school. The adolescents' assent form signed by the participating subject, should be returned to the school. Following a specific protocol, eligibility of adolescents who agree to be part of the study, and whose parents /legal guardians have consented, will be confirmed based on age, nationality, health status, puberty stage, measured weight and height (and body mass index consequently). For participants aged 18 years old, their consent will be sought, without the need for the consent of parents/legal guardians, after which the same screening protocol will be applied.

In an interview setting, trained researchers will administer a multi-component questionnaire, inquiring about demographic and socioeconomic characteristics (age, sex, parental education level). The questionnaire will also inquire about lifestyle characteristics, including smoking, dietary behavior and physical activity. Participants will also be asked about the foods/drinks they have consumed in the past 24 hours.
The following measurements will be obtained: weight, height, waist circumference, mid-upper

arm circumference, calf measurement and blood pressure.
A blood sample will be withdrawn from each participant (provided that they have fasted for 8 hours). Prior to blood withdrawal, finger-prick glucose will be assessed to make sure the participants are fasting.
Body fat will be assessed using two procedures:
- Deuterium Dilution Technique: Participants will be asked to give a saliva sample, after which they will be given a small amount of water labeled with the stable isotope deuterium oxide. Another saliva sample will be collected 3 hours after drinking the water provided. During the waiting time, participants will be offered a small breakfast.
- Bioelectrical impedance analysis whereby the measurement will be taken on the right side of the body, while the participant is lying down and by placing the device in contact with his/her feet and hands for a few seconds.

What are the possible benefits and risks of participating?
There are no direct benefits to being in the study. However, participants can be given a brief dietary consultation and a brief educational session to help maintain a healthy body weight. Moreover, by being part of this study they will be contributing to research and knowledge on adolescents' body composition in relation to nutrition and health.
As for the risks, participants might feel a very small amount of pain, bruising, or bleeding at the site of the blood prick. Finally, the deuterium oxide water, used for the measurement of body fat, is completely safe, tastes like normal water, and does not cause any adverse effects.

Where is the study run from?
The American University of Beirut (Lebanon)

When is the study starting and how long is it expected to run for?
November 2020 to March 2025

Who is funding the study?
The International Atomic Energy Agency (IAEA) (Europe)

Who is the main contact?
Dr Cornelia Loechl, C.U.Loechl@iaea.org

Contact information

Type(s)
Principal Investigator

Contact name
Prof Lara Nasreddine

ORCID ID
https://orcid.org/0000-0003-3707-8218

Contact details
Faculty of Agricultural and Food Sciences
Department of Nutrition and Food Sciences
American University of Beirut
P.O. Box 11-0236, Riad El Solh
Beirut

Lebanon
1107-2020
+961 1 354547
ln10@aub.edu.lb

Type(s)
Public, Scientific

Contact name
Ms Cornelia Loechl

ORCID ID
https://orcid.org/0000-0001-7959-6270

Contact details
Nutritional and Health-related Environmental Studies Section
Division of Human Health
Department of Nuclear Sciences and Applications
International Atomic Energy Agency
Vienna International Centre
PO Box 100
Vienna
Austria
1400
+43-1 2600-21635
C.U.Loechl@iaea.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Nutrition and Health in Arab Adolescents (NaHAR): Determination of ethnic-specific body fat and anthropometric cut-offs to identify metabolic syndrome in adolescents

Acronym
NaHAR

Study objectives

Current public health surveillance and clinical management of adolescents in the Middle East depend on standard methods based on definitions and cut-offs derived largely from populations of European descent. Whether these definitions and cut-offs are optimal for adolescents in the Middle East is unclear. It is in this context that the multi-country “Nutrition and Health in Arab Adolescents” (NaHAR) study is being launched in several countries of the Middle East, including Kuwait, Jordan, Lebanon and Syria. The objective of this study is to determine the optimal gender-specific cut-off values for BMI z-score, waist circumference percentile, weight for height ratio and mid-upper arm circumference (MUAC) for the prediction of Metabolic Syndrome and body fat among 210 national adolescents in each of the participating countries. A secondary objective is to examine the validity of Bioelectrical Impendence Vector Analysis (BIVA) in estimating body fat against the deuterium dilution technique (DD).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 17/11/2021, Institutional Review Board of the American University of Beirut (P.O. Box 11-0236, Riad El Solh, Beirut, 1107-2020, Lebanon; +961 1 35 5445; irb@aub.edu.lb), ref: BIO-2021-0022

2. Approved 01/10/2022, Institutional Review Board (General Department of Health Affairs, King Abdullah Bin Abdulaziz University Hospital, Riyadh, 11564, Saudi Arabia; +966 548867916; ohkasule@kaauh.edu.sa), ref: 22-0029

3. Approved 01/09/2021, Institutional Committee of Bioethics (Atomic Energy Commission of Syria, Damascus, 6091, Syria; +963 11 213 2580; atomic@aec.org.sy), ref: RAS6094

4. Approved 11/12/2022, Ministry of Health for Planning and Quality Affairs (P.O. Box (5), Ministry of Health, Safat, 13001, Kuwait; +96524622228; health@moh.gov.kw), ref: 2134/2022

5. Approved 03/06/2021, Ministry of Health (Ministry of Health, Amman, 11118, Jordan; +962 6 520 0230; info@moh.gov.jo), ref: 23221 /8/1/2

Study design
Multi-country cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
School, Other

Study type(s)
Other, Prevention, Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prediction of metabolic syndrome among 210 national adolescents in each of the participating countries.

Interventions
This multi-country observational cross-sectional study will be conducted in several Middle-Eastern countries, including Kuwait, Jordan, Lebanon and Syria. The study objectives are to:
1. Determine the optimal gender-specific cut-off values for body fat, BMI z-score, waist circumference (WC) percentile, weight-to-height ratio (WHtR) and mid-upper arm circumference (MUAC) for the prediction of MetS among 210 national adolescents in each of the participating countries
2. Examine the applicability and validity of the Bioelectrical Impendence Vector Analysis (BIVA) in estimating BF against the deuterium dilution technique among adolescents in the region.

1. In brief, the deuterium dilution technique will be performed on the participants aged 15=18 years. Body fat is determined using the deuterium dilution technique. Following Standard Operating Procedures, participants will be administered an oral dose of approximately 0.1 g D_2O /kg body weight (Cortecnet, Voisins-le-Bretonneux, France), after a 10% dilution in water. A saliva sample will be obtained prior to the dose and at 3 hours post-dose when the deuterium has reached equilibrium with the total body water, using a cotton swab. The deuterium enrichment in post-dose saliva is determined by Fourier Transform Infrared (FTIR) spectrometry (portable Agilent FTIR 4500s, Agilent, Santa Clara, United States). The dilution space is derived from the post-dose enrichment, and converted to total body water (TBW) after adjustment for the non-aqueous exchange of hydrogen atoms in the body (TBW=Dilution Space/1.04). Fat-free mass (FFM) and fat mass (FM) can then be derived. The deuterium dilution technique will be performed by trained research members who have received extensive training on the technique prior to data collection. The technique will be performed through face-to-face encounters in schools and during one day only.

2. Anthropometric measurements include weight, height, WC, MUAC and calf circumference using standardized protocols. For weight measurement, participants will be instructed to be in light indoor clothing, barefoot or wearing stockings. The weight will be measured using a standard calibrated balance (Seca 869 Digital Floor Scale, Seca, Hamburg, Germany). Height will be measured using a wall-mounted Seca stadiometer (Seca 213, Seca, Hamburg, Germany), and without shoes. Weight and height are to be measured to the nearest 0.1 kg and 0.1 cm, respectively. The measurements will be taken twice and repeated a third time if the first two measurements differ by more than 0.3 kg (weight) or 0.5 cm (height). Waist circumference will be measured to the nearest 0.5 cm, using a non-stretching measuring tape (Seca 201, Seca, Hamburg, Germany) at the midpoint between the bottom of the rib cage and above the top of the iliac crest while the participants stand and follow normal expiration. The measurement will be taken twice and the average of both values will be used. MUAC will be measured using a non-stretching measuring tape (Seca 201, Seca, Hamburg, Germany) and by taking half the distance between the acromion process at the back of the shoulder and the olecranon at the elbow level. It is measured to the nearest 1 mm. Calf circumference (CC) will also be measured (to the nearest 0.1 cm) by sliding the measuring tape (Seca 201, Seca, Hamburg, Germany) up and down to find the widest area on the right calf while the person remains seated. BMI will be calculated from the weight and height obtained, and BMI z-scores will be derived using the WHO Anthroplus software.
Moreover, body composition will also be assessed using the BIVA device (BIA 101, Akern, Via Lisbona, Italy). The measurement will be taken on the right side of the body while the participant is standing and by placing the device in contact with the feet and hands for a few seconds.

All measurements will be done by trained research members through face-to-face encounters in schools and during one day only.

3. Metabolic syndrome will be measured using the definition of the International Diabetes Federation (IDF) whereby participants will be classified as having the Metabolic Syndrome if they have 3 out of the 5 following cardiometabolic abnormalities:
For subjects aged 16 years and above:
1. Elevated TG level (≥150 mg/dl)
2. Low HDL-C level (<40 mg/dl for boys and <50 mg/dl for girls)
3. Elevated BP (systolic BP ≥130 mm Hg and/or diastolic BP ≥ 85 mm Hg)
4. Elevated fasting glucose level (≥100 mg/dl); and (v) elevated WC (≥94 cm for men, ≥80 cm for women).
For subjects aged < 16 years: the IDF recommends using the same cut-offs with the exception of WC and HDL. The cut-offs to be considered instead are as follows: WC ≥ 90th percentile for age and sex, HDL < 40 mg/dl. TG, HDL and fasting glucose levels will be assessed by withdrawing a blood sample from the participants after fasting for 8 hours. Blood withdrawal will be performed by a certified phlebotomist who will be with the research members in the school setting. BP measurements will be obtained using a standard mercury sphygmomanometer (Omron 7 Series Upper Arm Blood Pressure machine monitor BP760); after participants are seated and rested for at least 5 minutes. The measurement will be taken twice and the average of both values will be used. Measurements will be done by trained research members through face-to-face encounters in schools and during one day only. As for the waist circumference, it will be measured to the nearest 0.5 cm, using a non-stretching measuring tape (Seca 201, Seca, Hamburg, Germany) at the midpoint between the bottom of the rib cage and above the top of the iliac crest while the participants stand and follow normal expiration. The measurement will be taken twice and the average of both values will be used. Measurements will be done by trained research members through face-to-face encounters in schools and during one day only.

Intervention Type
Mixed

Primary outcome measure
1. Metabolic syndrome measured using the definition of the International Diabetes Federation (IDF) at one timepoint
2. Body fat measured using the deuterium dilution technique at one timepoint
3. Anthropometric measurements, including weight, height, waist circumference, mid-upper arm circumference and calf circumference, measured using standardized protocols to calculate BMI and BMI z-scores at one timepoint

Secondary outcome measures
Total body water, fat mass and fat-free mass measured using bioimpedance vector analysis (BIVA) at one timepoint

Overall study start date
15/11/2020

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. 15-18 years of age
2. Nationals to one of the participating countries, i.e. not refugees or foreigners
3. Healthy
4. At the 4th or 5th Tanner stage of puberty

Participant type(s)
Learner/student

Age group
Child

Lower age limit
15 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
210 from each participating country; so a total of 840 students

Total final enrolment
929

Key exclusion criteria
1. Inborn errors of metabolism, use of medications that may alter body composition, blood pressure, glucose, or lipid metabolism
2. Adolescents who did not reach Tanner stage 4 or 5, since hormonal changes during puberty may play a role in influencing insulin sensitivity and lipoprotein profile
3. Underweight (defined as BMI < -2 z-score)

Date of first enrolment
01/05/2023

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Jordan

Kuwait

Lebanon

Syria

Study participating centre
Local schools in Lebanon
Lebanon
Not applicable.

Study participating centre
Local schools in Syria
Syria
Not applicable.

Study participating centre
Local schools in Kuwait
Kuwait
Not applicable.

Study participating centre
Local schools in Jordan
Jordan
Not applicable.

Sponsor information

Organisation
American University of Beirut

Sponsor details
Faculty of Agricultural and Food Sciences, Department of Nutrition and Food Sciences
P.O. Box 11-0236. Riad El Solh
Beirut
Lebanon
1107-2020
+961 1 354400
fafs@aub.edu.lb

Sponsor type
University/education

Website
http://www.aub.edu.lb/main/Pages/index.aspx

ROR
https://ror.org/04pznsd21

Organisation
International Atomic Energy Agency

Sponsor details
Division of Human Health
Department of Nuclear Sciences and Applications
Vienna International Centre PO Box 100
Vienna
Austria
100, 1400
+43 (1) 2600-0
nahu@iaea.org

Sponsor type
Government

Website
https://www.iaea.org/

ROR
https://ror.org/00gtfax65

Organisation
University of Strathclyde

Sponsor details
School of Psychological Sciences and Health
Physical Activity for Health Group
16 Richmond St
Glasgow
Scotland
United Kingdom
G1 1XQ
+44 (0)141 552 4400
hass-courses-psh@strath.ac.uk

Sponsor type
University/education

Website
http://www.strath.ac.uk/

ROR

https://ror.org/00n3w3b69

Funder(s)

Funder type
Government

Funder Name
International Atomic Energy Agency

Alternative Name(s)
IAEA

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Austria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The International Atomic Energy Agency (IAEA)’s International Research Integration System (IRIS) will be used for data management. IRIS is an online direct data capture platform that allows to collect data of various structure and complexity with a data export and basic analysis possibility. Hence, all participating countries will be using the same data entry system. IRIS can be used as direct data entry via a browser if internet is accessible when collecting data, or it can be used to enter data from paper records. Data entry and access is password protected and storage is cloud-based. Data will be de-identified before analysis.
The link to IRIS is https://iris.iaea.org/#pages/welcome.html .

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		23/05/2023	26/09/2023	No	Yes
Participant information sheet		13/06/2023	26/09/2023	No	Yes
Protocol article		23/02/2024	18/03/2025	Yes	No