

ADOLESCENTS ASSENT FORM TO PARTICIPATE IN A RESEARCH STUDY "Nutrition and Health in Arab Adolescents (NaHAR)"

Principle Investigator:

Dr. Lara Nasreddine-Faculty of Agricultural and Food Sciences

Co-Investigators:

Dr. Elie-Jacques Fares- Faculty of Agricultural and Food Sciences Ms. Mandy Taktouk- Faculty of Agricultural and Food Sciences

Address: American University of Beirut

Bliss Street Beirut, Lebanon

Phone: +961-1-350000 Ext: 4547

- You are being asked to be in a research study. Research studies are a special way to find out about something. We are trying to better understand adolescents' body composition in relation with nutrition and health.
- This form will tell you about the study to help you decide whether or not you want to participate. Please take time to read the following information carefully before you decide.
- You should ask any questions you have before making up your mind. You can think about it and discuss it with your family before you decide.
- It is okay to say "No" if you don't want to be part of the study. If you say "Yes" you can change your mind and quit at any time without getting in trouble.
- If you decide you want to be in the study, your parents (or legal guardians) will also need to give permission for you to be in the study, if you are not yet 18 years old.

1) What is this study about?

This study includes 210 Lebanese adolescents aged 15-18 years and aims to examine body fat percentage, nutrition, and health. We are assessing body composition through several techniques to better understand its association with nutrition and health factors.

Moreover, this study is conducted in several Arab countries, including Jordan, Lebanon, Qatar and Syria, to allow for inter-country comparisons.

2) How can participate in this study?

We will approach participants in two ways:

a. Flyers will be posted at the Department of Nutrition and Food Sciences, in various locations within the Faculty of Agriculture and Food Sciences and on social media platforms.

American University of Beirut Institutional Review Board 26 May 2023 APPROVED



Subjects who are interested to participate in the study will be invited to visit the Department of Nutrition and Food Sciences, at a specific date and time, for the screening stage.

b. Visiting public schools: The screening stage will take place at the schools.

All secondary school students, i.e. students in grades 10-12, will be approached. Our research team members will explain the study for you. Your participation is completely voluntary and we will ask for your assent. You will be given a copy of the parental consent and adolescents assent forms, as well as the screening form to take home with you. Take the time to carefully read the adolescents assent form and contact the research team in case you have any question, before you decide to participate in the study and sign the adolescents assent form. Your parents or legal guardians will also need to give permission by signing the parental consent form, since you are not yet 18 years old. Following a specific protocol, eligibility of children who assented 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).

Considering the sensitivity of some questions related to puberty, and in order to avoid any discomfort in answering those questions at school, a copy of the screening form will also be given to you, along with the parental consent and adolescents assent forms. You will be asked to fill the screening form at the privacy of your home and then return it to the school or to the Department of Nutrition and Food Sciences, along with the signed parental consent and adolescents assent forms. Once returned, your weight and height (and body mass index consequently) will be measured. This will require 10 minutes and will be done at school or at the Department of Nutrition and Food Sciences by a trained nutritionist. After confirming your eligibility to participate in this study, you will be asked to visit the Department of Nutrition and Food Sciences at the American University of Beirut (AUB), at a time and date convenient for you.

You can participate if you are Lebanese, aged 15-17.9 years old, at a specific stage of puberty, healthy without any inborn errors of metabolism, not using any medications that may affect your body composition, blood pressure, blood glucose, or lipid metabolism, and not underweight.

3) What will I need to do if I participate in this study?

If you decide to participate in this study, we will ask you questions about your parents' (or legal guardians') education and the number of members and rooms in the household, as well as questions about your lifestyle in regards to smoking, physical activity, and dietary behavior, during your visit to the Department of Nutrition and Food Sciences at AUB. We would like to ask about the foods/drinks you have consumed in the past 24 hours. We would also like to measure your weight, height, waist circumference, mid-upper arm circumference, calf measurement (back of the leg, below the knee) and blood pressure. These will be performed by a trained nutritionist at the Department of Nutrition and Food Sciences. The measurements may be taken twice or thrice in order to obtain accurate results. Moreover, we would like to measure some indicators in your blood, such as cholesterol, triglycerides, and glucose levels. This will be done by withdrawing blood samples (12 mL, which is equivalent to 3 tubes) by a certified and trained nurse or

American University of Beirut Institutional Review Board 26 May 2023 APPROVED



practitioner, considering that you have fasted for 8 hours. Prior to blood withdrawal, fingerprick glucose will be assessed to make sure that you are fasting.

Finally, we would like to check your body composition, specifically body fat, by following the below procedures:

A. Deuterium Dilution Technique:

- You will be asked not to eat or drink anything at least 30 minutes before the study starts.
- We will collect a saliva sample by placing a cotton wool ball in your mouth to soak up saliva for 1-2 minutes. You will be asked to move the cotton wool ball around the mouth, while keeping the mouth closed.
- You will then be asked to drink, using a straw, a certain amount of water labeled with deuterium oxide (around 60 mL). Deuterium oxide is naturally present in your body, so we will only be adding a bit more by asking you to drink the provided water. This water contains a very small amount of deuterium oxide (6 g); it is completely safe and has been used before internationally on children and adolescents. Drs. Lara Nasreddine and Elie-Jacques Fares, who are extensively trained, will perform this technique.
- At least 30 minutes after drinking this amount of water, you will be given a snack.
- 3 hours later, we will collect another saliva sample. We need to be sure that you do not eat or drink anything at least 30 minutes before collecting the sample. The same procedure will be followed i.e. using a cotton wool ball.
- In case you do not consume the given amount of water entirely, you will be excluded from the study, since the protocol of the study required the full consumption of the dose.
- B. Body composition will also be assessed using the bioelectrical impedance analysis (BIA 101 device), whereby the measurement will be taken on the right side of the body, while you are standing and by placing the device in contact with your feet and hands for a few seconds. This will be performed by a trained nutritionist and will require 5 minutes of your time.

4) How much time will I spend in the study?

Since the saliva sample collection requires around 3 hours, then you will be asked to stay approximately 3 hours at the Department of Nutrition and Food Sciences. During these 3 hours and while waiting for the collection of the second saliva sample, we will ask you the required questions, take the necessary measurements, and collect the blood sample.

5) Can I stop being in the study?

You may stop being in the study at any time, and this is not a problem at all as it will not affect your relationship or your parents'/guardians' relationship with AUB or AUBMC.

6) Is my information going to be a secret?

American University of Beirut Institutional Review Board 26 May 2023 APPROVED



Every information you share with us will be kept strictly confidential and we will make sure no one can breach your privacy. You will be given a random number to further assure the confidentiality of your files. Only the research team will have access to the files and information which will be used only for research. The data collection sheets will be locked in a cabinet at the researcher's office. Electronic versions of the data will also be secured and locked by a password. This data will be stored on the principal's investigator's computer.

We will keep your records confidential unless we are required by law to share any information. It is important to note that data from all the participating countries will be shared with the main research team, as de-identified data, in order to allow for inter-country comparisons. This means that there will be no link between your identity and the collected data, thus ensuring total privacy and anonymity.

7) What bad things (risks and discomforts) might happen to me if I participate in the study? The questions we might ask you may bother you or you may find them embarrassing, but you should not worry since everything will be kept strictly confidential. You have the right to abstain from answering questions that may cause you any discomfort.

Also, you might feel a very small amount of pain, bruising, or bleeding at the site of the blood prick. You don't have to worry because a nurse or trained practitioner will do it and it will not last more than a minute. Finally, the deuterium oxide water, used during the saliva sample collection, is completely safe, tastes like normal water, and does not cause any adverse effects.

In case you weren't able to entirely consume the given amount of water or provide us with enough blood and in case you refuse to take anthropometric measurements, you might not be eligible to participate in the study.

8) What good things (benefits) might happen to me if I participate in the study?

There are no direct benefits for being in the study. However, you will be given a brief dietary consultation and a brief educational session to help you maintain a healthy body weight. You will also receive monetary compensation in cash (12-20 USD, depending on the area you are coming from) as a compensation for your time.

Moreover, by being part of this study you will be contributing to research and knowledge on adolescents' body composition in relation with nutrition and health.

9) What other options are there?

There are no other options to reach the aim of the study. However, you may choose not to be part of the study.

10) What are the costs of being in the study?

There are no costs associated with your participation in the study. Moreover, you will not get paid to participate in the study.

American University of Beirut Institutional Review Board 26 May 2023 APPROVED



11) Who can I talk to about the study?

For questions about the study you may contact:

Dr. Lara Nasreddine, Faculty of Agricultural and Food Sciences-AUB

Tel: +961-1-350000 (Ext 4547) Email: <u>ln10@aub.edu.lb</u>

Dr. Elie-Jacques Fares, Faculty of Agricultural and Food Sciences-AUB

Tel: +961-1-350000 (Ext 4926) Email: ef08@aub.edu.lb

Ms. Mandy Taktouk, Faculty of Agricultural and Food Sciences-AUB

Tel: +961-1-350000 (Ext 4557) Email: mt86@aub.edu.lb

To discuss other study-related questions with someone who is not part of the research team, you may contact the AUB Institutional Review Board for human rights at:

Tel: +961-1-350000 (Ext 5445) Email: irb@aub.edu.lb

12) Your rights:

Your participation is completely voluntary and the informed adolescents assent will be obtained from you. If you don't want to participate, it will not affect your relationship with AUB or AUBMC and you can stop taking part at any time you want. Your decision will not result in any penalty or loss of benefits that you have now.

13) Investigator's statement:						
,	dolescents assent document for this research study with					
(Name of participant) the purpose of the study and its risks and benefits. I have answered all the participant's questions clearly. I will inform the participant in case of any changes to the research.						
Name of Investigator or Designee	Signature of Investigator or Designee					
Date & Time						
American University of Beirut Institutional Review Board 26 May 2023						



14) A	greement	to	be	in	the	study	٠:

Your signature below means that you have read (or someone has read to you) the above information about the study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a copy of this adolescents assent form. By signing this adolescents assent form you are not giving up any of your legal rights.

Name of Participant	Age
Signature of Participant	Date & Time
Witnessing of assent (in case participant is illiterate): I have witnessed the interviewer reading the above behalf of the participant who has voluntarily agreed to	text to the participant, and I am signing on
Name of Witness, Relationship to Participant	
Signature of Witness	Date & Time
15) Future studies:	
Can we contact you to invite you for future studies?	
Yes No	
If yes, kindly provide us with a phone number:	

American University of Beirut Institutional Review Board 26 May 2023 APPROVED