

Title of Study: Respiratory Effects of Obesity in Children
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The University of Texas Southwestern Medical Center at Dallas
Parkland Health & Hospital System
Children's Medical Center
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas – Institute for Exercise and Environmental
Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: Breathing Limitations in Overweight Children

Funding Agency/Sponsor: National Institutes of Health

Principal Investigator: Tony G. Babb, Ph.D.

You may call Dr. Babb or research personnel during regular office hours at 214-345-6574. At other times, you may call Dr. Babb at 214-534-1898.

Note: If you are a parent or guardian of a minor and have been asked to read and sign this form, the “you” in this document refers to the minor.

Instructions:

Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?

This study is being done to explore whether increased body weight (which can vary from individual to individual) reduces lung function in children and whether a reduction in body weight leads to an improvement in lung function.

Why is this considered research?

Little is known about the effects of weight on breathing among children and whether limitations in breathing can be improved by a weight loss intervention.

The following definitions may help you understand this study:

- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the Institute for Exercise and Environmental Medicine and its affiliated hospitals.



Why am I being asked to take part in this research study?

You are being asked to take part in this study because you are interested in the effect that increased weight has on breathing or to serve as a healthy volunteer for comparisons.

Do I have to take part in this research study?"

No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?

We will consent and screen one hundred and fifty-two [152] people in order to have one hundred and twenty-six [126] people who will take part in this study at Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine.

What is involved in the study?

If you volunteer to take part in this research study, you will be asked to sign this consent form and will complete the following tests and procedures. The procedures are being done solely for the purpose of this study. The tests performed in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your lungs or heart to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the tests done in this study are not for medical purposes, we will not issue official reports of the results. However we will provide you with a summary of the key findings that you can show to your doctor, and would be pleased to provide whatever further details that you or your doctor might wish. A more detailed description of all the tests and procedures we will perform is included below.

Procedures and Evaluations during the Research

You will undergo a pre-testing and a post-testing phase during this study. Each testing phase will involve **two** study-test visits that will last 4 – 4.5 hours and will be conducted over a period of 1-4 weeks. If you are overweight, then you will return to the laboratory for post-testing after you have lost a certain amount of weight or achieved an equivalent reduction in your BMI percentile (due to growth in height without losing weight) or at the end of 1 year, whichever is sooner. If you are not overweight, you will return to the laboratory for post-testing after one year.

Pre-testing:

Screening Visit One (4.5 hours in duration):

Screening Procedures

To help decide if you qualify to be in this study, the researchers may ask you questions



about your health, including medications you take and any surgeries you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Medical history;
- Pulmonary (Lung) Function Tests;
- Vital signs;
- Electrocardiogram (ECG), a tracing of the electrical activity of the heart; and

These procedures will be done to determine if you qualify for this research and could take up to 4.5 hours to complete.

During the first visit, you will also have the following evaluations:

Review of medical history (i.e., medications you take for any health problems, and any surgical procedures you have had), filling out a physical activity questionnaire, asthma screening questionnaires, and a sleep questionnaire. You will also complete a self-assessment of your pubertal status using drawings of different stages of breast, genital and pubic hair development. Your Parent/Legal Guardian may be present while you are providing the information to the nurse. The nurse will review the pictures with you. You will be able to complete and seal the form in a private place. Your Parent/Legal Guardian will have the opportunity to review this form. These procedures may be done even if you do not participate in this research.

Pregnancy Test: If you have started your period, a urine pregnancy test will be done (using a few drops of urine), and it must be negative before we conduct any testing. You cannot be pregnant during your participation in this study. If you become pregnant during the course of the study, you must immediately inform the staff, and withdraw from the investigation.

Pulmonary function tests or PFTs: These involve breathing exercises to measure your lung function. You will be asked to sit in a plastic, body box (body plethysmograph) for about 2 – 2.5 h and perform a number of breathing exercises. A body box is best described as an enclosed, clear chamber (you can see through the walls) where pulmonary function testing is performed. In order to screen for asthma you will be asked to inhale 4 puffs [90 mcg per actuation] of a drug (Albuterol) during your lung function tests. You will breathe through a mouthpiece and wear a nose clip during the tests.

Maximal exercise test: The goal of the test is for you to exercise as long as possible. You will start pedaling at a rate that is easy for you. Then, it will get harder at every stage. This will feel like you are riding up a hill. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm, blood pressure, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Most children cycle for 8 – 15 minutes; however, there is no set time limit for the test. You will only be asked to work to the best of your abilities. You may stop exercise when you wish, because you are feeling tired or uncomfortable.



Verification test: The goal of this test is for you to exercise as long as possible at a workload that is a little higher than the highest workload achieved during your maximal exercise test described above. We do this test to verify your maximal exercise capacity. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Most children cycle for 2 - 3 minutes at this high workload; however, there is no set time limit for the test. You will only be asked to work to the best of your abilities. You may stop exercise when you wish, because you are feeling tired or uncomfortable.

Study-Test Visit Two (4.5 hours in duration):

Dual-Energy X-Ray absorptiometry (DEXA): Your body composition (percentage of fat and lean tissue) will be determined by using an FDA-approved bone density measurement machine. The procedure is called Dual-energy X-ray Absorptiometry (DEXA). You will be asked to lie face up, on a padded bed for 7 minutes while the scanner arm of the DEXA machine passes over your entire body. The scanner will not enclose you or touch you, and you can wear my regular clothing (no metal allowed). This test takes about 15 minutes.

Moderate exercise: You will be asked to pedal on a stationary exercise cycle at a constant work rate (pedal resistance) for 10 minutes at the most. The exercise will not be too easy and it will not be too difficult, it will be somewhere in between. You will breathe through a mouthpiece and wear a nose clip during the test. Your breathing pattern, heart rhythm (ECG), blood pressure, and oxygen saturation level (via pulse oximetry) will be monitored during the test. Pulse oximetry is a method of determining the amount of oxygen in the blood by using a sensor placed on the skin. You may stop exercise when you wish, because of personal feelings of fatigue or discomfort.

Postural changes in lung function: You will be asked to perform several different breathing exercises while breathing through a mouthpiece and wearing a nose clip during the test. You will be coached on each breathing maneuvers while seated or lying on your back. We may repeat the supine measurements with a small 10 lb weight placed on your stomach so that we can test how weight on the stomach changes the way you breathe while lying down.

Voluntary Hyperventilation: You will be asked to breathe deep and fast. The breathing rate will be set by a metronome. A metronome is a device used to mark time by means of regular ticking sound. The ticks will help you pace your breathing. You will breathe through a mouthpiece and wear a nose clip during the test. Each voluntary hyperventilation test will last approximately 4 to 10 minutes. You may stop the test when you wish, because you are feeling tired or uncomfortable. Before and after the voluntary hyperventilation every few minutes, you will be asked to performed a breathing exercise so we can measure how your breathing changes in response to the hyperventilation. If there is a change in your breathing, you will be asked to inhale 2 puffs [90 mcg per actuation] of a drug (Albuterol) and the breathing exercises will be repeated after 10 minutes.



Gas mixtures: You will be asked to breathe different gas mixtures while seated upright, while lying down, during exercise, and during voluntary hyperventilation. These will include room air, mixture of acetylene, helium, nitrogen and oxygen for several breaths or 3%, 4% or 5% carbon dioxide mixtures with oxygen and nitrogen during the voluntary hyperventilation trials. You may be asked to breathe these gases during the course of this study or a combination of any of these gases may be used during the experiment. These gases are used to measure lung volumes or to help maintain a normal level of carbon dioxide in your blood.

Weight Loss and Exercise Program:

If you are under the guidance of physicians at the Center for Obesity And its Consequences in Health (COACH) Program at Children's Medical Center. We will keep in touch with you periodically after your pre-testing visits to help answer any questions that might arise during the weight loss and exercise program regarding diet and physical activity recommendations. If needed, we will demonstrate physical activity intensities on multiple exercise devices depending on your preferences (e.g., stationary cycle, treadmill, gaming, etc.). We will not interfere with the dietary and medical recommendations set forth by COACH, but we will provide monitoring and support throughout the study. If you are overweight and not enrolled with COACH, you will receive standard of care information regarding weight loss and regular physical activity and will be monitored and supported throughout the study.

After the weight loss and exercise program or at 1 year:

The 2 study-test visits performed during pre-testing will be repeated; the procedures for each of these visits will be exactly as described above. In addition, during post-testing, Visit 1 will include a pregnancy test if you have started your period.

How long can I expect to be in this study?

You will be in the study for 14 - 18 months. The study will consist of pre-testing and post-testing phases separated by approximately 1 year,

The primary investigator may ask you to repeat some tests, which may take up to 4 extra visits; as with all testing, you will have the option of whether or not you wish to complete these extra visits.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Albuterol

Albuterol (Ventolin®) has been known for many years as a well-tolerated drug that expands the airway, called a bronchodilator, and its list of known side effects is well described. The most common side effects of albuterol (Ventolin®) are palpitations (awareness of rapid or pounding heartbeat), chest pain, rapid heart rate, shakiness and



nervousness, as well as nausea, increased blood pressure, dizziness and heartburn. Allergic reactions may also occur. Serious allergic reactions may be life threatening.

Pulmonary Function Test

There are no known risks of performing pulmonary function tests.

Breathing Carbon Dioxide

The risk to you of breathing increased levels of carbon dioxide at rest or during exercise is minimal. You may feel your breathing rate increase, which may cause some feelings of shortness of breath, lightheadedness, and/or temporary headache or feeling hot. We will monitor end-tidal carbon dioxide levels when indicated to maintain concentrations within acceptable limits.

Maximal Exercise

During maximal exercise, you will experience discomforts similar to those associated with any type of heavy exercise. There is the possibility of certain changes occurring during the test. They include abnormal blood pressure, fainting, disorder of heartbeat, and in rare instances, heart attack. The risk of serious complication during maximal exercise testing is estimated to be less than 1 per 40,000 such tests in adults. Every effort will be made to minimize these through the preliminary interview and screening, and by observations during testing. A physician or his/her designee will be immediately available during the exercise test.

During sub-maximal (mild) exercise, you will experience discomforts similar to those associated with any type of sub-maximal exercise. Examples of these discomforts may include, but not limited to, shortness of breath, leg fatigue and soreness, and discomfort from sitting on a bike seat. These discomforts have been reported in 2-20% of subjects tested.

Voluntary Hyperventilation

There is a very small possibility of severe breathing problems during this test. If this occurs, you will be immediately treated with a medication (Albuterol) that will reduce your breathlessness. You may experience cough, shortness of breath, chest tightness, wheezing, chest soreness, or headache, however, most people have no symptoms. These symptoms typically disappear after administration of medication (Albuterol). We will monitor your breathing and other vital signs during the test to limit the risks.

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be



guaranteed.

DEXA:

Radiation exposure to a woman's reproductive organs may harm an embryo or fetus. Also, if radioactive materials are used for certain types of scans, harm may come to an embryo, fetus, or an infant who is breast feeding.

Pregnancy tests performed during the early stages of pregnancy do not always reveal pregnancy. Therefore, radiation exposure that includes the reproductive organs will be limited to the first ten days after a woman who can become pregnant has begun her most recent menstrual period. This is standard policy in clinics and hospitals within UT Southwestern. This policy applies unless there is an important medical reason requiring radiation outside this time frame.

If your parents or guardian asks, we will tell them the results of your pregnancy test or that you are using birth control.

Risks of Radiation – Diagnostic Test

This research study includes exposure to radiation from diagnostic tests in addition to that which you would receive from standard care. The additional radiation dose you will get is about 1% of the average radiation dose from all sources (natural background radiation, consumer appliances, radon gas, medical tests, etc.) that a person in the United States receives each year.

Other Risks

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?

During your participation in this research your study investigator and his staff will monitor you closely to determine whether there are problems that could disqualify you from participation. Trained personnel will monitor you for any problems or discomfort during testing. You will be removed from the study if there are any problems. You will be referred for treatment, counseling or necessary follow-up for any problems or abnormalities noted during testing procedures. The study design minimizes any potential risks or discomforts to the fullest extent possible by providing for the presence of trained personnel to closely monitor you, and by planning the testing protocol to minimize any discomfort to you.

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.



- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injuries or illnesses while you are in the study, even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?

If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?

If you agree to take part in this study, there may or may not be direct benefits to you. You will receive information regarding your lung function, body fat, and exercise tolerance. Information obtained in this study may help your primary care providers better understand your condition (i.e. obese, healthy, unfit, fit, etc.). There will be no charge for any tests required for the study. Results of the pulmonary function tests can be provided to your primary care provider upon request. The researchers cannot guarantee that you will benefit from participation in this research.

Your participation will help us learn more about the effects of body weight and weight loss on pulmonary function and exercise capacity. However, the study investigator will not know whether there are benefits to other children until all of the information obtained from this research has been collected and analyzed.

What options are available if I decide not to take part in this research study?

This is not a treatment study. You do not have to be part of it to get treatment for your condition.



Will I be paid if I take part in this research study?

Yes. You will be paid \$60.00 for visits one, and \$90.00 for visit two (\$60 for the exercise testing and \$30 for the DEXA scan) (total of \$150.00). If we cannot get the DEXA scan scheduled on visit 2, it will be performed on a separate visit. In that case, compensation for Visit 2 will be \$60 and the visit when the DEXA is done will be \$30. The two visits after the weight loss and exercise program or control intervention will be paid at the same rates. Your payment will be made in the form of gift cards. If you complete the tests before and after the program, you will be paid a total of \$300.00. Payments will be processed after completion of your visits. You will be paid at the end of each visit.

If you do not complete all visits, you will be paid according to your participation (i.e. if you participated in visit one only, you will be paid \$60.00). If you repeat some testing, you will be paid a pro-rated rate for each of your additional visits, depending on whether you need to repeat a part of the visit or the whole visit.

We do not pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Your Social Security Number (SSN) will be given to Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine in order to process your payment as required by law. This information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a "hold" on all State payments to you. Such a "hold" could result from your failure to make child support payments or pay student loans, etc. If this happens, UT Southwestern or Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the "hold."

Will my insurance provider or I be charged for the costs of any part of this research study?

No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care. Participating in this research project will not offset the costs of the weight reduction program through the COACH clinic.

What will happen if I am harmed as a result of taking part in this study?

It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not



available from the University of Texas Southwestern Medical Center at Dallas, Children's Medical Center-Dallas, or Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine.

You keep your legal rights during your participation in this research

Can I stop taking part in this research study?

Yes. If you decide to participate and later change your mind, you are free to stop your participation in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern, Children's Medical Center-Dallas, or Texas Health Presbyterian Hospital Dallas - Institute for Exercise and Environmental Medicine staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

If I agree to take part in this research study, can I be removed from the study without my consent?

Yes. The researchers may decide to take you off this study if:

- You do not meet our screening criteria.
- You develop a new medical condition or your medical condition worsens.
- The complications are intolerable.
- The investigator decides that participation in the research is no longer safe for you.
- The sponsor/FDA closes the research.
- You are unable to keep appointments or to follow the researcher's instructions.
- You have completed all study activities.

Will my information be kept confidential?

Information about you that is collected for this research study will remain confidential unless you give your permission to share it with others, or if we are required by law to release it. You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of government agencies, like the National Institutes of Health, U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.



In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Are there procedures I should follow after stopping participation in this research?

Yes. If you, the researchers, or the sponsor stops your participation in the research, you may be asked to do the following:

- Let the researchers know immediately that you wish to withdraw from the research.
- Return to the research center for tests that may be needed for your safety.
- Discuss your future medical care, if any, with the researchers and/or your personal doctor.

Whom do I call if I have questions or problems?

For questions about the study, Contact Tony G. Babb, Ph.D. at 214-345-4622 or the research nurse at 214-345-6574 during regular business hours. You may also contact Dr. Babb at 214-534-1898 after hours and on weekends and holidays.

The Chairman of the IRB is available to answer questions about your rights as a participant in research or to answer your questions about an injury or other complication resulting from your participation in this research. You may telephone the Chairman of the IRB during regular office hours at 214-648-3060.



SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

Legally authorized Representative's Name (printed)

Legally authorized Representative's Signature Date Time AM/PM

Legally authorized Representative's Name (printed)

Legally authorized Representative's Signature Date Time AM/PM

Name of person obtaining consent (printed)

Signature of person obtaining consent Date Time AM/PM

ASSENT OF A MINOR:

I have discussed this research study with my parent or legal guardian and the researchers, and I agree to participate.

Signature of participant (age 10 through 17) Date Time AM/PM

