

ACTIVITY COUNSELING TRIAL (ACT)
Screening and Randomization/Participation Consent

Purpose of the study

The objective of this study is to test the effectiveness of physical activity counseling in the physician office setting on the health status of persons who are sedentary (involved in limited physical activity). Approximately 810 men and women 35-75 years of age will be enrolled at three centers, located in California, Texas and Tennessee. Everyone will be encouraged to remain in the study for 2 years. Legal authority to conduct this research is provided by Section 419 [285b-1] of the Public Health Service Act.

Remaining screening procedures

During the remaining two screening visits to determine your eligibility for ACT, you will have a physical examination and will have your blood pressure measured. Blood will be drawn from a vein in your arm (less than 2 tablespoons) to check your levels of cholesterol, insulin, and specific blood clotting factors. Some of this blood will be frozen for later analysis and studies. In preparation for these blood tests, you will be asked to fast (to stop eating and drinking anything except water) for 12 hours before you come in for your third screening visit. At the next two visits, you will walk on an exercise treadmill, which is like walking on a conveyor belt. The treadmill will start going uphill very slowly. You will continue to walk on the treadmill as the uphill increases in steepness. For the first visit this will continue until you cannot proceed further. At the next visit you will walk on the treadmill but it will not be as hard. During this test, you will have your heart rate monitored and you will breath into a breathing tube. Your reactions to the exercise tests will be monitored to assure your safety. We will also ask you to complete some questionnaires that ask about your level of physical activity, what medications you are taking, the types of foods you eat, your smoking history and your quality of life. You will also have height and weight measurements taken.

Study procedures

If you are not eligible to participate in this study, the reason(s) will be explained to you. If you remain eligible for ACT after these next two screening visits, and you agree to participate in the study, you will be assigned by chance to one of the following programs, which involve:

- A. Advice from your doctor concerning increasing your level of physical activity and provision of written materials on how to increase your level of physical activity.
- B. Advice from your doctor concerning increasing your level of physical activity, provision of written materials on how to increase your level of physical activity, in-person counseling, viewing a video promoting increased physical activity, mailings, occasional phone calls, and referral to community resources. You will be asked to keep track of your physical activity on written "logs" over the two-year course of the study.
- C. Advice from your doctor concerning increasing your level of physical activity, provision of written materials on how to increase your level of physical activity, in-person counseling, viewing a video promoting physical activity, phone calls, mailings, written and visual materials, group classes and referral to community resources. You will be asked to keep track of your physical activity on written "logs" over the two-year course of the study.

For all three programs, if you ever have questions about your physical activity program, you can call your Health Educator, who will give you his/her phone number at the time of your first health educator visit.

For all three programs, you will need to return to have several special "measurement" visits. You will also be contacted by study staff by phone at 12 months to provide some information. During the one 6

and two 24 months visits, you will have the same types of tests and procedures that you will have during the next 2 screening visits. The 6- and 24-month "measurement" visits will last approximately 3 to 4 hours. These visits will include the following:

- completion of various questionnaires asking you about your current level of physical activity, your diet, smoking history and quality of life;
- blood pressure measurement;
- height and weight measurements taken;
- a blood test, where blood will be drawn from a vein in your group (less than 2 tablespoons) to check your levels of cholesterol, insulin, and specific blood clotting factors. In preparation for these blood tests, you will be asked to fast (to stop eating and drinking anything except water) for 12 hours before coming in for this visit; and
- exercise treadmill tests, which involve walking on a conveyor belt that starts going uphill very slowly. During these tests, you will have your heart rate monitored and you will breath into a breathing tube. These tests will be the same as at the beginning of the study.

In addition, a test to determine the degree of stiffness of the main arteries will be done. This test involves placing a pencil-like instrument over the blood vessels of the chest, groin, and/or neck. Recordings will be made on a computer while a partial electrocardiogram is being done. The measurements use high frequency sound waves that are harmless. The procedure will take about 10 minutes while you are lying down in a resting position. You can decline this optional test by crossing out this paragraph.

Risks/Discomforts

The risks of participating in ACT are small. You may experience temporary pain during the blood drawing, with later bruising at the puncture site. Only specially trained staff will be responsible for collection of blood samples. There exists the possibility of certain changes occurring during the treadmill test. These include abnormal blood pressure, fainting, disorder of heart beat and, in rare instances, heart attack, stroke and death. Every effort will be made to minimize these risks by reviewing information about your health and fitness before the test and by closely observing you during the treadmill procedure. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Possible risks associated with increasing physical activity include but are not limited to, injuries to the muscles, ligaments, tendons and joints of the body. Other risks associated with exercise include, but are not limited to, abnormal blood pressure, fainting, dizziness, disorders of heart rhythm, and very rare instances of heart attack, stroke, or even death.

Benefits

The physical examination, laboratory tests and treadmill tests may lead to the early diagnosis of disease, if present. The physical examination and the laboratory studies are all free of charge. It is expected that any increase in physical activity in people who are non-active will benefit their general health and cardiovascular status.

Alternatives to participation

To determine your blood levels of cholesterol, insulin and some clotting factors, you could visit your personal health care provider. You may choose to increase your activity level on your own without enrolling in this study. You may choose to have your own health trainer.

Voluntary participation

Participation in the ACT study is voluntary. Refusal to participate will involve no loss of benefits to which you are entitled. Further, you may withdraw from the study at any time without penalty.

Significant findings

You will be told of any significant findings that may occur during the course of this study that could relate to your willingness to continue to participate. Your blood pressure and blood cholesterol results will be sent to your physician. The investigator and the sponsor reserve the right to terminate the study and discontinue your participation at any time for any reason, in order to ensure your safety.

Confidentiality

Personal medical data will be kept confidential as required by the Privacy Act, 5 U.S.C. 552a. Details from your medical records will be stored on a private computer system, but your name will not be used in any computer files. Information stored on the computer may be seen by ACT clinic study staff or government staff at the National Heart, Lung and Blood Institute, which funds the study.

Questions

If you have any questions at any time during the study or if you believe you have sustained an injury related to the study, you can contact either Dr. _____ at _____ or the Health Educator at _____. If you have any questions about your rights as a research subject, contact Dr. _____, the Institutional Review Board Chairman, at _____.

Consent summary

I understand that I am not waiving any legal rights or releasing the local institution sponsoring this study or its agents from liability for negligence. I understand that in the event of physical injury resulting from the research procedures, the local institution sponsoring this study does not have funds budgeted for compensation either for lost wages or for medical treatment. Therefore, aside from the emergency care previously described, the local institution does not provide for treatment or reimbursements for such injuries.

I have read the description of this study and I freely volunteer to participate in it. I have had known possible side effects and adverse reactions explained as well as having had treatment alternatives explained. I have had an opportunity to ask questions to the ACT clinical staff and I have received acceptable answers. I understand that I may withdraw from this study at any time and I will still receive standard treatment for my condition.

Signature of participant

Date

Signature of witness

Date

Signature of Principal Investigator

Date