

Healthy Aging
in
Neighborhoods of
Diversity across
the
Life Span

MRI Brain Scans in
Diverse Populations



Contents

Introduction.....	1
Purpose of the study.....	2
Tests	3
Statement of Risks	5
Compensation	6

Introduction

We must have your written informed consent before we perform research tests or examinations.

We follow federal regulations for research with human subjects. These regulations require us to make sure that you understand what examinations we will perform and the risks that are involved, if there are any.



This booklet reviews the tests of brain structure that will help us study how risk factors for heart disease and aging affect the brain. We will also study how risk factors and aging relate to thinking processes and physical movement.

We perform these tests free of charge.

You should understand the purpose of this study before you agree to participate in this research. We welcome any questions that you might have about what to expect in this study. This is a study related to the HANDLS study. Like HANDLS, you may decide whether you want to do these tests. If you choose not to take these tests then it will not affect your status as a HANDLS participant.

While you are a part of this study we will ask you questions about your physical health. We will also ask you

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complete tests of concentration and hand movement. We will also ask you to perform a simple walking test that measures your overall level of physical fitness. We will ask questions about your health to determine if it is safe for you to undergo a brain scan known as a *magnetic resonance imaging* (MRI) scan. If it is safe for you, then we will perform the MRI scan.

We want to make sure you understand the tests in this study. We must witness your signature on the consent form. Please do not sign the form until you arrive at the General Clinical Research Center (GCRC) at the University of Maryland Medical Center.

Purpose of the study

Risk factors for heart disease such as high blood pressure and age also create risk for stroke and other changes in the brain. The first purpose of the study is measure changes in the brain that are associated with aging and stroke risk in people from different racial and ethnic backgrounds. We will look at the structure of your brain using an MRI scan. We will not ask you to take a contrast drug for this study.

Risk factors for heart disease also put people at risk for problems with thinking and movement. We will ask you to participate in tests that will look at your ability to concentrate, to use your hands, and to walk.

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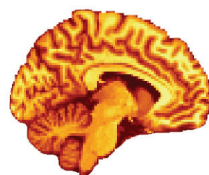
For this study you will visit the General Clinical Research Center and Department of Diagnostic Radiology at the University of Maryland Medical Center. The General Clinical Research Center is like a health clinic in the hospital. The Department of Diagnostic Radiology is where you will get your brain scan.

We call this part of the study HANDLS SCAN, *Healthy Aging in Neighborhood of Diversity across the Life Span: Scan*.

Tests

You may participate in some or all of our tests. You may stop at anytime you want even after you agree to do the tests or even if you started and want to stop.

We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts. Risks, if any, are stated and discussed with the description of the test, or in the section on *Assessment of Risks* in this booklet.



Health status. If you agree, you will meet first with a doctor or nurse at the General Clinical Research Center. He or she will ask whether you have had any changes in your health or medicines since you were

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seen last in the HANDLS study. The doctor or nurse will also ask other questions about your physical health and about your ability to take an MRI scan. The doctor or nurse will also take your blood pressure and pulse.

Tests of concentration and hand move-

ment. If you agree, we will ask you to do a test of your ability to concentrate and a test of your hand-eye coordination. The tests will be given in a quiet room with a tester who will help you do the best you can. These tests should take about 10 to 15 minutes. Sometimes people feel nervous when they are taking these tests. The testers are experienced and will help you feel relaxed. You can stop taking the tests at any time if you feel uncomfortable.



Corridor walk. We will ask you to walk up and down a hallway at the General Clinical Research Center as a way to examine your physical fitness. This part of the study will take about 10 minutes.

MRI. A doctor or nurse will ask you some questions about your health to make sure it is safe for you to get an MRI. You should answer the questions fully and honestly because we do not want you to be injured during the test. You will not be able to get an MRI if you have a pacemaker, an aneurysm clip, a metallic prosthesis or certain metal objects in your body.

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APPROVAL EXPIRES: **JAN 25 2011**

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If we determine that it is safe for you to get a MRI then a research assistant will escort you to the radiology department. We will ask you to lie on a table in front of the MRI. While you are lying on the table, you will go into a tube-like enclosure where the MRI scanner will take pictures of your brain. This part of the study will take about an hour. The MRI tube is quite small and sometimes people feel nervous in such close quarters. It is also quite loud inside the tube. You may stop the test at any time.

Statement of Risks

Although we do not anticipate any negative consequences, we want to make sure you understand the risks involved in taking the tests in this part of the study.

Blood Pressure. Some people experience minor discomfort in their arm when the blood pressure cuff is inflated. However, this lasts only a few minutes.

Tests of concentration and hand movement. Sometimes people feel nervous when they are taking these tests, but the testers are experienced and will help you feel relaxed. If you feel too uncomfortable during this part of the study, you can stop taking the tests at any time.

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APPROVAL EXPIRES: **JAN 25 2011**

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Corridor walk. Most people do not experience any discomfort of symptoms during this test. However, we want you to know there are some risks especially if you have heart disease. There is a small chance that you may fall, have chest pain, feel short of breath, or become dizzy during the test. We will stop the test if you have any symptoms that cause concern, such as chest pain. There is a small chance that you will experience muscle strains or muscle pulls.

MRI. The MRI tube is quite small and sometimes people feel nervous in such close quarters. It is also quite loud inside the tube. You may stop the test at any time.

Compensation

As a volunteer, we will pay you \$50 for participating in HANDLS SCAN. If you want it, we will also provide round-trip transportation from your home to the University of Maryland Medical Center. For example, we will pay for a taxi, your public transportation, or parking costs.

You are participating in a research study and our doctors and technicians are not your primary healthcare providers. We will provide medical feedback only if we find an abnormality in your MRI and we will then refer you to the appropriate type of doctor.

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