

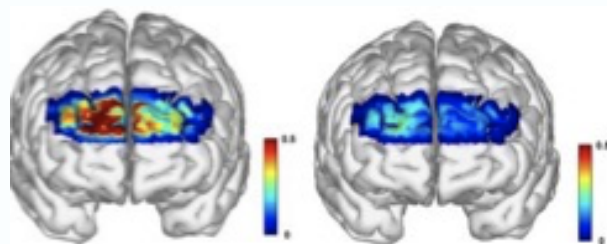
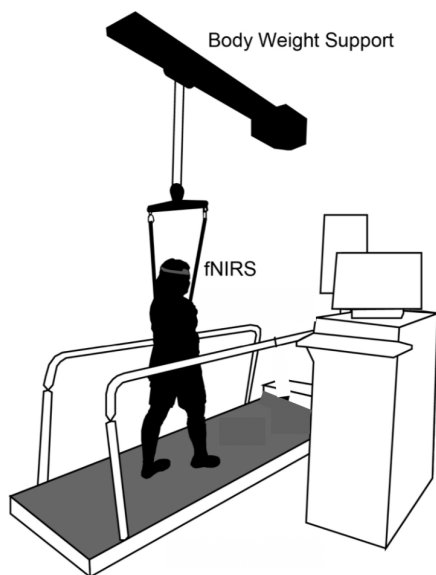
PARTICIPANTS NEEDED

Cognitive and Heart Impairment (CHI) Study

Studying how impaired heart health affects the brain while moving

Who do we need?

- ≥ 55 years old
- Do not have any diagnosed medical condition
- Willing to participate in walking and balance study



University of Illinois at Urbana-Champaign
Institutional Review Board



What can you expect?

- Performing simple tasks while maintaining balance or walking.
- Brain activity will be recorded with a headband containing small sensors that are placed on your forehead.
- This study does not involve any electric shocks, drugs, or any other potentially dangerous elements.
- One day session will take approximately 3.5 hours
- If you come with a spouse or companion, that person may also be eligible to participate in the study
- You will receive a **check payment of \$30** to be mailed later for your participation in this study

If you are interested

Please contact the researchers by phone or email at mhernand@illinois.edu or abishn2@illinois.edu or fill out the attached questionnaire and mail it to Dr. Hernandez

For more information

Please contact Dr. Hernandez at his office phone number: **(217) 244-8971** or lab phone number: **(217) 300 - 3080**

Mobility and Fall Prevention Research Laboratory CHI Study

NAME:

Phone Number:

Send To: Manuel Hernandez, Ph.D.
209 Louise Freer Hall, MC-052
906 South Goodwin Avenue
Urbana, IL 61801

Approval Date: April 13, 2021
Closure Date: April 12, 2026
IRB # 21619



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University of Illinois at Urbana-Champaign
Cognitive and Heart Impairment (CHI) Study
Informed Consent

You are being asked to participate in a research study conducted by Manuel Hernandez, Ph.D. at the Department of Kinesiology and Community Health. The purpose of this form is to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision.

Although you may not benefit directly from this research, we hope that the knowledge gained from this study will increase our understanding about how to improve the ability to dual-task, information that may be helpful to clinicians for decreasing the risk of falls in individuals with and without high blood pressure. You should feel free to ask the researchers any questions you may have.

Why am I being asked?

You are being asked to be a subject in a research study about how we can improve the ability to dual task. You have been asked to participate in the research because you are a healthy adult. Approximately 100 subjects may be involved in this research, out of which 50 subjects with lower heart rate reserve and 50 subjects with higher heart rate reserve will be participating in this study.

Your participation in this research is **voluntary**. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Urbana-Champaign (UIUC). **If you decide to participate, you are free to withdraw at any time without affecting your relationship with UIUC.**

What is the purpose of this research?

The purpose of this research is to better understand how the brain controls balance while we are busy thinking, and to find changes in persons with and without impaired heart rate reserve that can be changed in future exercise programs. Heart rate reserve is the difference between a person's resting heart rate and maximum heart rate, which has been found to be a risk factor for hypertension.

What procedures are involved?

Your participation will involve one study session consisting of up to 9 tasks. As described below, these tasks may include aerobic tasks, neuropsychiatric tests, videotaping, and recording of your movements in the laboratory, and sessions in which pictures of your brain activity are obtained (fNIRS). Each study session will last approximately 3.5 hours and will take place in room 10 (Mobility and Fall Prevention Research Laboratory) and 181 of Freer Hall on the UIUC campus. You may agree to

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some tasks, but not all of the tasks. Just place a checkmark on the small lines next to the tasks that you agree to participate in.

Should you be videotaped, you may stop videotaping at any time.

If you agree to be in this study, the following will happen to you:

___ 1. You will be asked questions about your medical background. This will only take a few minutes to complete.

___ 2. You will be asked to take part in a walking and balance task. We will record your heart rate and your perceived exertion at the end of the task. This test will not last more than 30-40 minutes.

___ 3. You will be asked to take part in collection of demographics and anthropometrics such as your age, height, weight, and blood pressure measurement.

___ 4. You will be given a series of paper and pencil-type tasks to test your memory, attention and cognitive processing. You will also be given questionnaires regarding your physical activity levels, balance confidence, self-reported physical function, psychiatric tests to evaluate your mood or anxiety depression, disease assessment (for Framingham cardiovascular disease assessment), and activities of daily living. These tasks will take approximately 60 minutes to administer.

___ 5. In other tasks, you will be asked to take part in a series of physical assessments examining your physical function, balance, lower leg strength, and walking speed. This will take approximately 20-30 minutes.

___ 6. In other tasks, we will test your brain function through a dual task walking paradigm. You will be asked to walk on the treadmill and step on specific visual targets on the treadmill at the same time. You will be given training on this task before testing begins to ensure that you are comfortable with the task.

___ 7. In other tasks, you will be asked to walk on a treadmill at your comfortable speed while performing a thinking task. You will wear a harness for safety purposes during all treadmill experiments. These tasks will take approximately 30 minutes.

___ 8. In certain tasks, you will be asked to wear a sensor containing small lights (light-emitting diodes) and light detectors placed on your forehead. Light shined on the scalp will pass through the scalp and skull and enter the brain, and then be reflected back to the scalp where it will be detected. This procedure is very safe and can be used at the same time as you are moving.

___ 9. In certain tasks, you will be asked to wear a heart rate monitor. A trained research team member will assist with placement of the non-invasive sensor.

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What are the potential risks and discomforts?

The likely risks and discomforts expected in this study are:

1. Fatigue or light-headedness while attending to the walk test and other treadmill conditions. You will be given frequent rest breaks to minimize any fatigue or light-headedness.
2. Stress due to testing such things as your mood and your memory and to being videotaped. We will try to reduce any stress that you may have by providing frequent rest periods.
3. When wearing the sensor with light-emitting diodes or heart rate monitor, there is a small risk of skin irritation. We will monitor comfort throughout study session, and provide breaks in the use of sensors with light-emitting diodes so as to minimize skin contact time.
4. There are no known risks associated with fNIRS procedures. Optical measures of brain activity (fNIRS) are recorded by shining small lights through the scalp into the brain and recording the pattern of light scattered back at the scalp. There is no harmful radiation used, only near infrared light. This procedure is completely safe.

The procedures used in these tasks/sessions are experimental. They may involve risks that are not known at this time. However, if any new risks become known in the future you will be informed of them.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

Although you may not benefit directly from this research, we hope that the knowledge gained from this study will increase our understanding about how to improve the ability to dual-task, information that may be helpful to clinicians for decreasing the risk of falls in individuals with and without high blood pressure.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary, to protect your rights or welfare (for example, if you are injured and need emergency care).

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Study information that identifies you and the consent form signed by you may be looked at and/or copied for examining the research by:

- UIUC Institutional Review Board, or
- State of Illinois Auditors

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research team. We will minimize the possibility of any loss of confidentiality in the following ways. First, your name will be assigned a code that will be used to reference your data. A log linking your code and your name will be kept locked inside the investigator's office. Second, neither your name nor initials will be used in any published reports. Third, if you are being videotaped, you can request that the tape be stopped and/or erased at any time.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

What are the costs for participating in this research?

There are no costs to you for participating in this research.

Will I be paid for my participation in this research?

You will receive \$30.00 for participating. If you choose to withdraw from the study early, your payment will be prorated.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your relationship with the University of Illinois at Urbana-Champaign.

The researchers also have the right to stop your participation in this study without your consent if Dr. Hernandez believes that it is in your best medical interest, or you do not follow the instructions given to you by the research personnel.

If you withdraw or are asked to leave the study, you will still be compensated as described above.

Who should I contact if I have questions?

Contact Dr. Hernandez, Director of the Mobility and Fall Prevention Research Laboratory at 217-244-8971 and mhernand@illinois.edu:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

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Who should I contact about my rights as a research subject?

If you have any questions about your rights as a participant in this study or any concerns or complaints, please contact the University of Illinois Institutional Review Board at 217-333-2670 or via email at irb@illinois.edu.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

Signature

Date

Printed Name

Signature of Person Obtaining Consent
subject's)

Date (must be same as

Printed Name of Person Obtaining Consent

