Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Effects of Dual-Task Training on Cognitive and Motor Learning and Cortical Activation in Healthy Young Adults

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Telephone #: 252-814-7312

Participant Full Name: _____Date of Birth: _____
Please PRINT clearly

Researchers at East Carolina University (ECU) study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to see how practicing a balance task and a cognitive task at the same time affects your performance, and if that performance improves in one or both areas after the dual-task (cognitive and motor) training. You are being invited to take part in this research because you are a healthy, young adult volunteer. The decision to take part in this research is yours to make. By doing this research, we hope to learn if dual practice of a motor task (involving balance) and a cognitive task (involving auditory reaction time) will counteract motor-cognitive task performance decrements that are likely to arise initially. We also hope to learn how your brain activation will change after practice of a dual-task.

If you volunteer to take part in this research, you will be one of about 20 people to do so.

Are there reasons I should not take part in this research?

Reasons for not taking part in the research include being outside the age range of 18-40 years. Also, you should agree not to take part in this study if you have cognitive deficits or communication problems, balance disorders, known cardiorespiratory dysfunctions, presence of lower extremity (leg) condition, injury, or surgery within the last three months (that could compromise training).

What other choices do I have if I do not take part in this research?

You can choose not to participate.

Where is the research going to take place and how long will it last?

The research will be conducted in the Pediatric Assessment and Rehabilitation Lab (PEARL) and Sensorimotor Testing and Rehabilitation (STAR) Lab at the ECU College of Allied Health Sciences building. You will need to come to the PEARL and STAR labs, Room 1445F and 1445E, respectively, for total 8 times during the study. The total amount of time you will be asked to volunteer for this study includes a pre-training visit, 5 consecutive days of training, a post-training visit, and a follow-up visit 1-week after the post-training visit. So, there are 8 visits in total for about 1-1.5 hours the first visit and 25 minutes each visit after.

What will I be asked to do?

You will be asked to do the following:

Visit 1:

1. Trained research personnel will obtain an informed consent.
2. If you are able to participate in the study and choose to sign the consent form, we will first record your demographic details such as name, age, date of birth, past medical history, medications, etc.
3. After that, we will test your baseline performance of the cognitive task alone, the motor task alone, and the dual-task (combined motor-cognitive task). This will include 6 blocks of 3 trials (18 trials total this day). Each trial will be 30 seconds in duration, with 30 seconds of rest following each trial. The following is an example of a testing block (order randomized): you will perform the auditory reaction time task by itself for 30 seconds, rest 30 seconds, balance on the dynamic stability platform for 30 seconds, rest 30 seconds, perform the auditory reaction time task while balancing on the platform for 30 seconds. Between each block, you will be given 2 minutes of rest. So, total testing time for this day will be 25 minutes.
4. We will simultaneously assess your brain activation using the functional near-infrared spectroscopy (**fNIRS**) neuroimaging technique. A head cap will be worn and small, button-like electrodes will be placed on your forehead and scalp that will correspond to specific brain areas. You will not feel any different sensations due to the electrodes on your forehead and scalp. **fNIRS** measures changes in the oxygenation in the form of concentration of oxyhemoglobin (HbO) within your brain blood flow. Increases in HbO indicates increased activation of brain neurons.
   Visit 1 will last for approximately 1-1.5 hours.

Visit 2:

1. You will engage in the first day of dual-task training. This involves performing the balance task and auditory reaction time task together for 3 blocks of 6 trials (18 trials total). Similar to testing, each training trial will be 30 seconds in duration followed by 30 seconds of rest. Between training blocks, 2 minutes of rest will be provided. Total training time for this day will be around 20-25 minutes.

Visit 3:

1. You will engage in day 2 of dual-task training. Total training time for this day will be 20-25 minutes.

Visit 4:

1. You will engage in day 3 of dual-task training. Total training time for this day will be 20-25 minutes.

Visit 5:

1. You will engage in day 4 of dual-task training. Total training time for this day will be 20-25 minutes.

Visit 6:

1. You will engage in day 5 of dual-task training. This is the final day of training. Total training time for this day will be 20-25 minutes.

Visit 7:

1. On this day, we will assess your post-training performance of the cognitive task alone, the motor task alone, and the dual-task. The testing format will be the same as used in Visit 1 (6 blocks of 3 trials), and brain activation will be assessed using the fNIRS. Total testing time for this day will be 30-60 minutes.
2. Using a non-invasive and safe neuroimaging technique, functional near-infrared spectroscopy (fNIRS), we will simultaneously record your brain activation while performing the above mentioned 18 trials of cognitive, motor, and dual-task performance.

Visit 8:

1. This is a follow-up visit 1-week after Visit 7. The purpose of this visit is to assess retention effects of the dual-task training.
2. The same method will be used to assess retention effects as used on the testing days (i.e. Visits 1 and 7). You will perform the same 6 blocks of 3 trials (18 trials total). So, total testing time for this day will be 30-60 minutes.
3. Using a non-invasive and safe neuroimaging technique, functional near-infrared spectroscopy (fNIRS), we will simultaneously record your brain activation while performing the above mentioned 18 trials of cognitive, motor, and dual-task performance.

Functional Near-Infrared Spectroscopy (fNIRS)- A head cap made of Velcro and plastic materials will be positioned on your head. This cap has several fiber optic cables attached to it. We will need to adjust any hair so that these light sensors can send and receive light from your scalp. This may require us to adjust the position of the cap and fibers to ensure good contact with the skin. The signals from each of the sensors will be verified and adjusted if needed. The setup will take about 15 minutes. This measurement will be done in the baseline and final testing.

Auditory choice reaction time task: You will be asked to perform a reaction time task while standing and holding two remotes. You will hear two different pitch of tones and you will push the right-hand button when you a tone in the right ear and push the left-hand button when you a tone in the left ear. This task will be performed in each visit.

What might I experience if I take part in the research?

This is a minimal risk study. Any risks that may occur with this research are no more than what you would experience in everyday life. The minimal risk associated with the balance task involves losing balance, but safety measures are in place to ensure you do not fall. Such safety measures include: a study team member will always be by the side of the study participant to guard the participant. Additionally, the participant will wear a safety belt around the waist and will be instructed to hold onto the handrails in the event of loss of balance. The minimal risk associated with the auditory task involve no to minimal discomfort in the ears since the pitch of the auditory stimuli is similar to listening to music or someone over the phone. There might be some discomfort with the fNIRS cap over the head; however, the discomfort will be minimized by using appropriately-sized head caps for the study participants.

We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you, but the information gained by doing this research may help others in the future.

Other people who have taken part in this type of research have experienced improved performance in situations involving a dual-task. These improvements include better balance and cognitive ability. These enhancements may positively translate to tasks in daily living that involve cognitive processing and postural stability or balance. By participating in this research study, you may also experience these benefits.

Will I be paid for taking part in this research?

Yes, you will be monetarily compensated for your participation. You will receive a compensation of total $75 in the form of an ECU Greenphire ClinCard at the end of the study, i.e. on visit 8. For some reason, if you are not able to complete all the study visits, each visit will be prorated at $9.37.

Will it cost me to take part in this research?
It will not cost you any money to be a part of the research.

Who will know that I took part in this research and learn personal information about me?
ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Research investigators to conduct and oversee the research project
- Principal Investigator and Faculty Investigator to participate in the research activities
- FDA or other regulatory agencies to provide regulatory oversight
- UMCIRB to provide continuing review of the research project
- Institutional officials in connection with duties for monitoring research activity
- Data and Safety Monitoring Board and its staff
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.

How will you keep the information you collect about me secure? How long will you keep it?
All the paper documents related to the study including this consent form will be kept in a locked file cabinet in a locked room in the Pediatric Assessment and Rehabilitation Laboratory (PEARL, Room 1445F) and only research team members will have access to it.
All other electronic data will be stored on secure, password protected, ECU approved electronic database REDCap. Only research team members will be able to access the data on REDCap.
All other raw data from **fNIR**S will be stored on password protected ECU study piratedrive.

Only the Principal Investigator (PI) will have a list of identifiers with the data information. This list will remain in the locked offices of their ECU password protected servers. After information is updated into the datasheet, then the PI will de-identify the data and save research on a password protected ECU piratedrive and REDCap. We will keep the data and de-identified information for 6 years.

What if I decide I don't want to continue in this research?
You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

Who should I contact if I have questions?
The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Study Coordinator, Tyler Phinizy, at 252-814-7312 Monday-Friday, between 9:00 am – 5:00 pm, or by email anytime at phinizyt17@students.ecu.edu. The Principal Investigator, Dr. Swati M. Surkar, may also be contacted at 252-744-6244 Monday-Friday between 9:00 am – 5:00 pm, or by email at surkars19@ecu.edu.

If you have questions about your rights as someone taking part in research, you may call the University & Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914.

Is there anything else I should know?
Identifiers might be removed from the identifiable private information or identifiable biospecimens and, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your Legally Authorized

Representative (LAR). However, there still may be a chance that someone could figure out the information is about you.

The research results about your dual-task performance (i.e. time spent in balance, reaction time) will be provided to you. These results will be shared with you upon request within 2 weeks after completion of the study.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

_____ _____

Participant's Name (PRINT) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

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Person Obtaining Consent (PRINT) **Signature** **Date**