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UNIVERSTIY OF NEW ENGLAND CONSENT FOR PARTCIPATION IN RESEARCH

Project Title: Does Sensory Sensitivity Affect Motor Learning?

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Approved for Use Between

11/21/14-

University of New England Institutional Review Board

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Introduction:

Please read this form, you may also request that the form is read to you. The purpose of this form is to provide you with information about this research study, and if you choose to participate, document your decision.

You are encouraged to ask any questions that you may have about this study, now, during or after the project is complete. You can take as much time as you need to decide whether or not you want to participate. Your participation is voluntary.

Purpose

People have a wide range of responses to the world around them. Some people respond a lot to bright lights, smells, muscle stretch or pain while others do not. People who feel sensations very strongly also feel sensations from their own bodies more strongly. Sensations from the body help us to learn how to do new physical activities such as sport movements or dancing. So, it may be that people who respond strongly to sensations may be better at learning new movements. This research study will see how much sensitivity to sensations including pain affects the way young healthy men and women learn a new movement.

Participants

We will include 20 people in this research study. You are being asked to take part because you are between the ages of 18-30 and are healthy. You will not be able to take part in the study if you have any of the following:

- Inability to follow spoken directions
- History of injury to the legs, back or spine that required the care of a doctor
- Fibromyalgia, diabetes, neurological problems, or history of unexplained falls
- Known heart disease or high blood pressure not controlled by medication
- Currently pregnancy

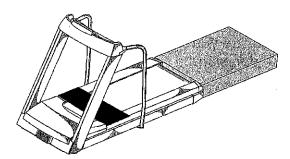
Study Details

You will need to wear loose fitting shorts and t-shirt, and athletic shoes with socks that leave the bones on the sides of your ankles bare. If you do not have those clothes they will be provided to you.

<u>Sensation sensitivity:</u> You will be asked to answer a series of questions about how sensitive you are to things you encounter in your daily life such as sounds, smells, textures etc. and how you deal with them. The questions will also ask about how you deal with stress in general.

Learning during a movement task: To measure how easily you learn a new movement, we will place small sensors on your skin over 7 muscles on your legs with special skin tape. The sensors will record when your muscles turn on and off and they will be wrapped with elastic straps so they do not move. Small flat sensors will be taped to the bottom of your shoes with tape to determine when your feet contact the ground. We will also put small balls (1/2" in diameter) on your arms, upper back, pelvis, legs and feet with sticky Velcro tabs or with elastic straps. The markers will be videotaped by 8 cameras as you move. You will perform an activity that is like stepping onto a moving walkway. The walkway will be simulated by a treadmill that will be still during some trials and moving at 2 miles per hour.

During the first movements you will stand on a board (shown in black in the picture) facing the back of the treadmill. When the tester says "go" you will step from the black platform onto the treadmill belt. If the belt is not moving, you will stand quietly for about 5 seconds. If the belt is moving, you will step onto the belt and let it move you toward the back of the treadmill. The treadmill will stop before you reach the end of the belt but a landing platform, shown in gray in the picture, will be positioned at the rear of the treadmill so you may step



onto it if you wish. The computer will record your muscle activity and movements as you repeat the activity up to 20 times with the belt still, 20 times with the belt moving, and again 20 times with the belt still.

<u>Pain sensitivity:</u> We will measure the amount of pressure you can stand when we press on your wrist with a small probe that is the size of a pencil eraser. We will slowly increase the pressure of the probe until you say that the pressure has turned to pain and the pressure will not exceed 23 lbs. We will record the amount of pressure applied. This will be repeated two times with at least 1 minute between measurements.

You will then put your opposite hand in a container of ice water up to your wrist. You will hold your hand in the ice water for 1 minute and tell the tester how much pain you are experiencing by you rating your pain on a scale of 0-10 where 0 is no pain and 10 is the worst pain you can imagine. You will rate your pain every 15 seconds and after 1 minute, or if you rate your pain as 10, you will remove your hand from the ice water, dry it off, and within the next 2 minutes the pressure pain measurement will be repeated on the hand that was not in the ice water.

Testing should last no more than 1 hour and 45 minutes and you will receive \$25 for your time and travel expenses.

Risks

The risks of injury are very small during this study however it is possible that you could lose your balance during the treadmill test when the belt is moving. However, you will have the chance to experience the movement before testing begins with the physical assistance of a tester.

You may feel stress during the pain testing but the pain from the cold water will go away within 1 minute after taking your hand out of the water. The pressure testing will be repeated only after you say you are ready and pressure will be stopped as soon as you experience pain. You could experience some bruising from the pressure test but the bruise would be no larger than the size of a pea.

Benefits

You will not benefit directly from taking part in this study however the information gained through this study will benefit people who get physical therapy treatments that involve learning a new movement or activity.

Privacy

If you agree to participate in this study you will be assigned a Study ID number and that number, not your name, will be used on all written and electronic materials that are part of the study. The link between your name and your Study ID will be kept on a secure computer that only the people that work for this study can access.

	If you would be willing to be contacted to learn about future research studies please check the
Ш	box.

If you checked the box above, your name, contact information and basic health information will be kept in a database on a secure computer until you tell us that you no longer want to be contacted about other research studies.

If you <u>did not</u> check the box, your name, contact information, basic health infomation and any identifying information will be deleted from the database 3 years after the research has been completed and published in medical and scientific journals. The information that we collect from you, without any way to link the information to you personally, will be kept indefinitely so we can compare it to future studies.

Rights

Your participation in this research study is voluntary. Your decision to participate will have no impact on your current or future relations with the University. If you are a student or employee of the

University, your decision to participate will not impact your standing as a student or your relationship with your employer in any way.

You may skip or refuse to answer any question or do any activity for any reason. If you choose not to participate there is no penalty to you and you will not lose any benefits that you are otherwise entitled to receive. You are free to withdraw from this research study at any time, for any reason. If you choose to withdraw from the research there will be no penalty to you and you will not lose any benefits that you are otherwise entitled to receive.

A copy of your signed consent form will be maintained by the principal investigator (K.S. Rudolph) for at least 3 years after the project is complete before it is destroyed. The consent forms will be stored in a secure location that only members of the research team will have access to and will not be linked to any data obtained during the project.

The researchers conducting this study are Dr. Katherine Rudolph, Chad Lyons, Sarah Cooper and Michael Lawrence. For questions or more information concerning this research please contact Dr. Katherine Rudolph at (207) 221-4113 or by e-mail krudolph@une.edu.

If you choose to participate in this research study and believe you may have suffered a research related injury, please contact Dr. Katherine Rudolph (207) 221-4113 or by e-mail at krudolph@une.edu.

If you have any questions or concerns about your rights as a research subject, you may call Olgun Guvench, M.D. Ph.D., Chair of the UNE Institutional Review Board at (207) 221-4171 or irb@une.edu.

You will be given a copy of this consent form.

Participant's Statement I understand the above description of this research and the risks and benefits associated with my participation as a research subject. I agree to take part in the research and do so voluntarily.			
Printed name			
Researcher's Statement The participant named above had sufficient tin ask questions, and voluntarily agreed to be in	ne to consider the information, had an opportunity to this study.		
Researcher's signature	Date		
Printed name			