The Effect of Exercise Training on Musculoskeletal Health in Individuals with Cerebral Palsy

NCT05070117

IRB approval on 8/23/2018

INFORMED CONSENT DOCUMENT

TITLE OF STUDY
The Effect of Exercise Training on Musculoskeletal Health in Individuals with Cerebral Palsy

PRINCIPAL INVESTIGATOR
Areum K. Jensen, Ph.D.
Department of Kinesiology
(408) 924-8153
Areum.jensen@sjsu.edu

PURPOSE OF STUDY
The purpose of this study is to determine whether exercise training improves muscle and bone health leading to better functional mobility in individuals with cerebral palsy. We will also determine that such improvements in bone and muscular strength contribute to a reduced incidence of falls and fractures.

STUDY PROCEDURES
A detailed description of each experimental procedure is provided at the bottom of this section. You will be given a detailed explanation of the specific experimental measurement and procedures that you will be asked to perform during the study. These specific measurements and procedures will be circled as explained to you.

Visit 1

1. After signing the informed consent, you will complete a medical history questionnaire regarding basic information about your health status (e.g., age, height, weight, previous surgeries, current medications, etc.). You will also be familiarized with some of the experimental measurements that will be made and procedures to be performed.
2. After this, you will perform various experimental measurements and procedures described in detail below.
3. After completion of the measurements and procedures, you will be randomly assigned to be a control or exercise intervention group. If you are in exercise intervention group, you will undergo one year of progressive strength/resistance training regimen 3 times per week in facilities at Ability Now Bay Area supervised by a trained research team with an instructor-to-subject ratio of 1:2. The training program consists of various individualized exercises including upper and lower body, lower back, and abdominal exercises. Examples of exercises are rows, chest press, grip ball squeezes, etc. You will start your training at low intensity with minimum 2 sets of 10 repetitions each, then will increase the repetition by 12 and 14, and/or higher intensity progressively. The current research staff will continuously monitor total exercise load as well as your fatigue level.

Visit 2

1. After twelve weeks of exercise training session, you will revisit the laboratory to perform the exact same experimental measurements and procedures performed during visit 1.

Visit 3

1. After one year of exercise training session, you will revisit the laboratory to perform the exact same experimental measurements and procedures performed during visit 1 and 2.

Experimental Procedure for Each Visit

1. **General measurement:** Height, weight, waist and hip circumference will be measured.
2. **Body composition and bone mineral density:** Whole body X-ray scanning will be used to assess overall body composition for the mass and density of the bone, muscle, and fat in the whole body. In addition, bone mineral content and density using regional X-ray scan will be measured at regions of spines, forearm, and hip joints. In addition, four surface electrodes with no exposure of X-ray will be placed on one hand and one foot to quantify fat mass, fat free mass, and water content of the body.
3. **Muscular strength:** You will perform leg press, leg curl, and leg extension at submaximal level to estimate 1 repetition maximum. In addition, you will perform knee extension and flexion testing to measure muscular strength in thigh muscles.
4. **Functional mobility**: The timed up and go, and 6 min walk will be performed to assess functional mobility. For timed up and go, you will be asked to stand from a seated position and walk 10 feet, and return to their starting position. The completion time will be recorded to assess the functional mobility. In addition, 6 min walk will be performed to detect how far you walk within 6 minute period. The absolute and relative changes in the completion of time and distance will be used to assess functional mobility.
5. **Balance and related fall risks:** By completing 14 assessments with varying multiple tasks, such as standing with eyes closed, you will receive a point per task to have a final score which indicate the balance and risk of fall. In addition, you will stay still on the foam pad to stabilize and maintain the balance. These tests will provide a quantified value for fall risk screening and conditioning status.
6. **Detection of falls and physical activity**: Throughout the one year intervention period, you will inform any experience in fall and unusual level of physical activity to the research team.

RISKS

Individually, each procedure should not cause you much discomfort. However, it is possible that you may experience discomfort due to the sum of these procedures. The protocol is designed to reduce the likelihood of occurring by minimizing the duration of each procedure. Nevertheless, if you experience a degree of discomfort which is greater than your expectations, we will stop the procedure(s) at your request. All tests that are to be performed have safely been used in both healthy and diseased individuals. Throughout the tests you will be closely monitored. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

Muscular strength measurements: You may experience shortness of breath, muscle fatigue and/or soreness during and/or following the muscular strength tests.

X-ray scanning*:* You will be exposed to a small amount of X-ray to measure bone density and muscle and fat mass. However, the total amount of X-ray is comparable to the amount of all day UV exposure from the natural sun during a sunny day. This risk will be minimized by minimal total numbers of scanning throughout the study. For example, an experienced and certified individual will scan you to make sure that you are minimally exposed to X-ray during scanning. Also, the X-ray will be only exposed during pre-visit, twelve weeks and one year post-visit.

Balance test: One of the test requires a unipedal standing. You may have hard time performing this task. When you attempt, it may increase a chance to fall. However, two research assistants will stay aside to hold you when you perform this test.

Exercise intervention program: The one year exercise intervention consists of many different types of resistance training. Thus, you may experience shortness of breath, muscle fatigue and/or soreness during and/or following the training session.

BENEFITS
This study will help improve our understanding of how musculoskeletal health is altered with exercise in individuals with cerebral palsy. No direct medical benefit will be provided. However, you may feel the improvement of muscular function with exercise training. There will be no charge for any tests required for the study. The information we obtain will help us understand physiological mechanisms with exercise training in the population with cerebral palsy.

CONFIDENTIALITY
Every attempt will be made to see that your study results are kept confidential. A copy of this signed consent form and all data collected from this study will be stored in the investigator's lab (electronic data) and office (paper files) for at least three years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Additional research studies could evolve from the information you have provided, but your information will not be linked to you in anyway (i.e., it will be anonymous). Although your rights and privacy will be maintained, the Institutional Review Board (IRB) and personnel particular to this research have access to current legal requirements. They will not be revealed unless required by law, or as noted above. The IRB at SJSU has reviewed and approved this study and the information within this consent form. In case of an unlikely event it becomes necessary for the IRB to review your research records, the SJSU will protect the confidentiality of those records to the extent permitted by law.

During the course of the study, you may decide not to participate in a particular experimental measurement or procedure and therefore, this portion of the protocol will not be completed. However, all other measurements and procedures will be performed. This will not affect the scientific value of your participation as each experimental measurement and procedure provides important and in most cases independent information. In addition, the principal investigator and the research staff may decide to reenroll you in the study if previous testing was unsuccessful or certain experimental measurements and procedures were not initially performed. The re-enrollment has no additional safety risks other than those inherent to the protocol and this will assist in the scientific merit of the project by providing additional information.

COMPENSATION
There will be no compensation participating in this study.

CONTACT INFORMATION
Questions about this research study may be directed to Dr. Areum Jensen (408-924-8153, areum.jensen@sjsu.edu). Any questions you may have about your rights as a research subject or a research related injury may be presented to Dr. Pamela Stacks, Office of Research, who can be reached at (408) 924-2479. Any complaints about the research may be presented to Dr. Matthew Masucci, Chair of the Department of Kinesiology at (408) 924-3021.

VOLUNTARY PARTICIPATION
Participation in this research is voluntary. You have the right to decline participation in any or all study procedures or quit at any time at no consequence.

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

_____ _____
SIGNATURE AND PRINTED NAME OF PRINCIPAL INVESTIGATOR OR PERSON OBTAINING CONSENT **DATE**

CONSENT
By signing below, you confirm that you are 18 years of age or older and have read or had this document read to you. You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

_____ _____
SIGNATURE OF VOLUNTEER **DATE**