Title	Novel Gait Training Paradigm to Promote Healthy Aging in Individuals with Cerebral Palsy
IRB Institution	University at Buffalo
IRB Approval period	3/7/22-3/6/23
Note	Version Date appears as 12. 21. 2020 because the initial approval date was 4/5/2021. There was no further modification after initial approval.

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

"Adult Consent to Participate in a Research Study"

Title of research study: Novel Gait Training Paradigm to Promote Healthy Aging in Individuals with Cerebral Palsy

Version Date: 12. 21. 2020

Investigator: Jiyeon Kang

Key Information: The following is a summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are an adult (18-65 years old) diagnosed with cerebral palsy. Also, you can walk independently with or without the continuous use of walking aids and you do not need physical assistance from a caregiver while walking.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

There are two goals in this study. Firstly, to investigate the benefits of strength training for adults with cerebral palsy using a robot that provides downward pull with the help of cables. This robot is called the cable-actuated robot. Secondly, Investigate the potential of prolonging the benefits of the cable-actuated training by using 3 different sounds acting as feedback in adults with cerebral palsy. These sounds are termed auditory feedback. The cable-actuated robot is a device that consists of a climbing belt, a sensor measuring tension in the cables, and electrical motors. Subjects will wear the climbing belt on their waist and the belt will be connected to the cables that are controlled by electric motors. We will collect movement data using a motion capture system to detect an improvement in waking patterns and surface electromyography (sEMG) sensors will be used to understand the muscle activation patterns. The force exerted on the ground by the foot during walking will also be evaluated using an insole and a treadmill fitted with sensors that measure this force. The measured force will be used to quantify the improvement in walking patterns from cable actuated robot and auditory feedback. Participants will undergo training, conducted on a treadmill using a cable actuated robot. After cable actuated robotic training, the cables will be removed and the participants will walk on the treadmill. Furthermore, one of the 3 types of auditory feedback will be provided to a few randomly selected participants as they walk on and off the treadmill. One type of auditory feedback is a rhythmic sound which will provide information about the

speed of walking to help synchronize the footsteps. Another type of auditory feedback consists of, an unpleasant sound that will be generated to provide cues to change your walking pattern. The last type of auditory feedback will comprise altering the characteristics of sound such as pitch and tempo to reflect the motion of the lower limbs. At the start of the sessions, the sound level will be adjusted based on the feedback received from the users. The researcher will ask the comfortable sound level to the participant before starting the experiment. The results of this experiment will enable us to validate our hypothesis that, improvement in walking through cable-actuated robotic training and auditory feedback is retained for a longer duration in adults with cerebral palsy.

How long will the research last and what will I need to do?

We expect that you will be in this research study for a maximum of 10 sessions, two or three sessions per week, and each session will take a maximum of 3 hours.

You will be asked to wear reflective markers, surface electromyography sensors, and an instrumented insole to measure your motion, muscle activation, and various other movement-related data. You will walk on a treadmill with and without a cable actuated robot. If you are assigned to an auditory feedback group you will receive auditory feedback belonging to one of the 3 different types of feedback during and after cable actuated robotic training.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

Risks are unknown, so if you have any shortness of breath or chest pain while walking, you should not participate in this study. Though highly unlikely, the participant may feel fatigued from the repeated walking tasks. Breaks will be provided between sessions and based on the need of the participant. More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Our previous studies involving the cable-actuated robot have shown improvement in the walking speed and posture of children with cerebral palsy. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include increased walking speed, improved walking posture, and symmetry similar to the studies involving children with cerebral palsy.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-645-6063 or jiyeonk@buffalo.edu You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about __20___ people here will be in this research study.

What happens if I say yes, I want to be in this research?

If you agree to take part in the study, our research team will contact you by email or phone to set up an appointment. You will visit AWEAR Laboratories in Furnas Hall Room 809 or Kimball 115 at the University at Buffalo. We will ask you to wear comfortable clothing which won't affect your natural movement. Once we start the experiment, reflective markers and Delsys Trigno surface electromyography sensors will be placed in various locations on the subject's skin, including the head, neck, shoulders, arms, torso, and a few on the lower body. These are non-invasive detectors, attached with double-sided tape to detect motion and muscle activity. Additionally, a smart insole will be worn by the subjects on their feet. Subjects will walk on the ground and on a treadmill with and without the cable actuated robot and auditory feedback. During each session, subjects will walk on the treadmill using a cable actuated robot for 20 minutes followed by 4 minutes of walking on the treadmill without the cable actuated robot. Furthermore, after a 10 minute break, subjects will practice walking on the floor with or without auditory feedback. Each subject will undergo a maximum of 10 such sessions and the length of visit won't be longer than 3 hours. Throughout the test, the subject will only be interacting with the test administrator. Once the test is complete, there only one follow-up session to assess the benefits of the training.

What happens if I say yes, but I change my mind later?

You can leave the research at any time if you would like. You will be compensated for the amount of time you invested in the research.

Is there any way being in this study could be bad for me? (Detailed Risks)

The sEMG sensors and reflective markers will be attached to the skin which can cause mild skin irritation. The cable-actuated robot can lead to fatigue while walking. Once you express discomfort, we will stop the experiment and remove sensors and markers. Furthermore, as additional resistance is involved, there is a slight possibility of falls or cardiac events. You will wear a safety harness for protection while walking. Lastly, even though care will be taken to maintain confidentiality, there is a potential risk of a breach of confidentiality.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the FDA, and other representatives of this organization.

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

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Your name will be assigned a code number. The file that links your name to the code number will be kept in a locked file cabinet and only the investigator/researchers will have access to the file. All collected sensor data, pictures, or videos will be identified by this code and will be stored on a secured endpoint. Access will only be available to those working on the project. If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Can I be removed from the research without my OK?

If the participant has difficulties walking with the force applied to the body, we will automatically withdraw the participant. Though highly unlikely, if the participant cannot follow simple instructions to walk and stop you may be withdrawn from the study. If you stop during the study, all your data will be removed. Furthermore, you will be compensated for the hours you participated in the study.

What else do I need to know?

Who is paying for this research?

SUNY seed grant (State U-Wide account is 240202-06) and start-up fund of Dr. Jiyeon Kang .

Will I get paid for my participation in this research

If you agree to take part in this research study, we will pay you $20/hour for your time and effort. You will be compensated via cash at the end of each session before the participants leave the lab.

Audio/video recording or photography

As part of the research study, we seek your permission to take pictures and short clips of you. The recording(s) will be used for analysis and as a possible dissemination tool to those who are not members of our research team. Before disclosing your recording for educational or academic purposes, your face or personal identifiers will be removed from recordings or pictures. Pictures or videos will be stored on a secured endpoint (computer/laptop) together with the other digital data for at least 3 years in a folder regarding this project, and will only be accessible to those working on the project. Your signature on this form grants the investigator permission to record you as described above during participation in this study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

Please select one of these options (Your initial):

___ Option 1: I consent to allow portions of the videotape and pictures of me to be shown to scientific and educational audiences for research and instructional purposes only. I understand that no identifying information beyond that contained in the tape will be provided in such sessions. I understand that these videos will be kept in a safe location.

___ Option 2: I do not consent to have portions of the videotape or pictures of me to be shown to scientific and educational audiences.

Signature Block for Capable Adult

Permission to Take Part in a Human Research Study

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	