

# Columbia University Assent Form

## Protocol Information

**Attached to Protocol:** IRB-AAAS7804

**Principal Investigator:** Sunil Agrawal (sa3077)

**IRB Protocol Title:** Postural Control Intervention with the Robotic Trunk-Support-Trainer in Children with Cerebral Palsy: A Randomized Controlled Trial

## General Information

**Consent Number:** CF-AABU5285

**Participation Duration:** 16 days across 4 months

**Anticipated Number of Subjects:** 82

**Research Purpose:** We are trying to find out if our training program, which consists of playing different games that involve different activities while sitting can improve the way you sit and how you move your head, body, arms, and hands.

## Contacts

Contact	Title	Contact Information
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## Information on Research

### [What will we be doing?](#)

We have created two devices. One is an automated device that we call Trunk-Support-Triner or just TruST. The other device is a Rigid Trunk Support Trainer. TruST the Rigid Trunk Support Trainer are non-FDA-approved experimental

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systems. If you decide to participate, you may end up using TruST or the Rigid Trunk Support System. We will assign the use of one device or the other by chance. The goal of both devices is to help children learn how to move the head, body, arms, and hands while sitting. So, we want you to sit in our device while practicing many different activities that include board games, construction shapes, balls, and other toys. In this way, we can see how you move and how much you can improve.

We will test how fast you are able to move small blocks from one box to another and how well you are able to keep your balance while sitting. Also, we will ask you to do some movements like sit straight up with arms up, stand straight up and reach, and/or catch a ball and reach for objects. While you practice all these activities in a sitting or standing position, we will support your body with a support belt that will help you to sit straight. In this way, you can move without falling from the bench while practicing all the activities with your arms.

The participation in this study requires a total of 16 days spread across 4 months. Each session will be around 90-120 minutes, including breaks. We expect that you improve your posture and reaching during sitting with either TruST or the Rigid Trunk Support System. We will study if TruST may result in greater improvements; although, we do not know it for sure.

## Risks

### Is the study safe?

The chances of you falling or getting hurt with either TruST or the Rigid Trunk Support System are very small. You are protected with a belt, which will not let you fall or get hurt. The brace you wear might feel a little tight while you move, but that is it. You can always let us know if the belt is too tight or it hurts somewhere on your body, so we can adjust it. Also, your pelvis will be strapped on the bench where you sit until you learn how to sit by yourself without falling.

The games we will be playing are fun but these will be challenging how you move. This means that you may get frustrated some times. We need to tell you that is ok and you can always let us know if it is too hard, so we can make the game a bit easier for you.

It is important you always let us know if you feel too tired or you are feeling some kind of pain. You will have a 15minutes break, but remember that you can rest at any time during the study if you feel very tired. You will be surrounded by me, Victor, and other people who are assisting in this study.

## Benefits

### Are there any benefits of this study?

You should expect some benefits with your participation in our study such as sitting for longer, getting less tired when you sit and move your arms and hands, and maybe you may learn new movements.

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## Alternative Procedures

### Do I have to be in this study?

Remember that you do not have to be in this study and you can stop the study any time you want.

## Confidentiality

### What will happen with this collected information?

We want to tell you that all the information and data we are collecting in this study are for us. We will keep it safe with a password or by locking it up in cabinets. This information will be used to learn more about how other children sit and move. Also, if you allow us, we may use your data to publish it in our future scientific works.

As part of the research study, we seek your permission to take pictures and short clips of your child. The recording(s) will be used for analysis and as a possible dissemination tool to those who are not members of our research team. The videos will include you performing several upper limb tasks, but your face or anything that can identify you will never be used. Accordingly, your name or face pictures will not be used. If you agree, we will also use these pictures for scientific publications and conferences.

I consent to be video-recorded during the experiment

I consent that my videos/pictures are used for publication purposes

## Research Related Injuries

### Do I expect to feel any pain or feel uncomfortable?

You should not feel any pain or be uncomfortable at any moment during the study. However, you may feel tired during and after the study.

## Compensation

### Will I get anything for participating?

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You will get a personalized "training passport" to record the number of times you are participating with us. Also, we will pay transportation (subway, cab, or bus) for you and the people who come with you to the study.

**Voluntary Participation**

**Can I stop if I want to?**

We are very happy to have you here with us, but you can stop being a participant in this study if you do not want to be here.

**Statement of Consent**

**Signature block**

By signing this form, you agree to the study I have explained to you. Please, feel free to ask for any questions you may have at any time during the research.

**Signatures**

**Participant Signature Lines**

**Parent/Guardian**

Print Name \_\_\_\_\_ Signature \_\_\_\_\_  
Date & Time \_\_\_\_\_

**Research Signature Lines**

**Person Obtaining Assent**

Print Name \_\_\_\_\_ Signature \_\_\_\_\_  
Date & Time \_\_\_\_\_

**Witness Signature Lines**

**Witness**

Print Name \_\_\_\_\_ Signature \_\_\_\_\_  
Date & Time \_\_\_\_\_

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