

UCSF Pediatric Brain Body Training: Consent

Study Title: Characterizing Synergistic Effects of Physical and Cognitive Training in Children

Why is this study being done?

The purpose of this study is to find out whether a child's memory and attention can be improved through practice that integrates physical movement with thinking tasks.

How many people will be in this study?

Approximately 60 children will take part.

What happens if my child takes part in this study?

I. Pre and Post Training Assessment:

Your child will come to our Neuroscape laboratory at UCSF Mission Bay before and after the training program. The pre and post assessment evaluations will take about 6 hours each and can be done either in a morning and afternoon session or on different days, depending on your preference. These assessments are often done in the evening or weekend to accommodate your schedule.

Parent:

You will complete surveys/ questionnaires about your child's medical background and behavior history. The information from these questionnaires will be added to a secure, confidential database that only the UCSF research team may access.

Child:

Questionnaires (5 min): Your child will fill out a questionnaire on video game use.

Cognitive & Motor Testing (180 min): Your child will receive an IQ test as well as assessment for auditory processing, attention, motor abilities and fitness.

Cognitive Tasks with EEG (120 min with set up): Your child will get an electroencephalogram (EEG) both while resting and during a game of driving and attention. This allows us to evaluate brain activity. It involves placing a cap with sensors on your child's head.

MRI Assessment (60 min): We will assess brain structure and function, using magnetic resonance imaging (MRI), while your child is resting and during memory and attention tasks. Your child will lie on a platform that slides into the MRI magnet's center. Your child's comfort is important, so foam pads will provide head support and ear plugs/ headphones will reduce noise. Between pictures, your child can take a break and come out of the scanner.

II. Training:

Training sessions will be conducted at Neil Cummins by the UCSF study team in conjunction with Neil Cummins OT staff.

Brain and Body Training (BBT): Your child will complete 30 min sessions, 3 times a week for up to 8 weeks. He or she will be randomized to one BBT condition to help us understand the role of the brain and body in different aspects of cognitive performance.

During training, your child will wear non-invasive sensors to measure **heart rate** and **skin conductance**, which give us important physiological information.

III. Follow-Up Assessment:

We will ask your child to come to the laboratory at UCSF Mission Bay for a follow-up assessment approximately 6-12 months after completing the training program. This assessment is identical to the pre and post assessments.

Voice recording: We ask your permission to take audio (voice) recordings of your child's study sessions for training and supervision purposes. These recordings are completely voluntary and your child may still participate in the study whether you agree to the recordings or not. Your child's personal information will not be on the recordings. These recordings are kept on a secure server that requires password access and the recordings will be destroyed at the end of the study. **Circle one option:**

Yes	No
-----	----

Can my child stop being in the study?

Yes. Your child can stop at any time without any effect on school services or future clinical care.

What side effects or risks can I expect from being in the study?

Depending on the nature of the **cognitive tasks**, mental fatigue or boredom are minor risks. During the **EEG recording**, cap and gel may cause mild skin irritation/ discomfort. We remove as much gel as possible and it is easily removed by shampooing. There are also minimal risks during the **MRI scan**. You will complete a safety screener prior to your child entering the MRI room to ensure that your child is MRI-safe. Boredom, discomfort, or claustrophobia may occur in the scanner, but we will make every effort to ensure comfort (we can even play a movie). Your child can leave and re-enter the scanner as needed. The **physical assessments and training** may cause fatigue. Some of the assessments include moderate-high exertion, under researcher supervision, to gauge physical fitness.

Are there benefits to taking part in the study?

This is a research study. Thus, there is no known direct benefit to your child from participating. At the end of the experiments, we will explain what we learned from the study. We hope that this knowledge will be useful in the future diagnosis and treatment of children with attentional challenges.

Will information about my child be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your child's name and other personal information will not be used. The UCSF

Committee on Human Research may look at or copy your child's research records for research, quality assurance, and data analysis include.

What are the costs of taking part in this study?

Neither you nor your child will be charged for any of the study procedures.

Will my child be paid for taking part in this study?

You will be compensated \$20/lab session and \$5/session (\$15/week) for each training session. You will receive cash payment. Parking can be reimbursed.

Who can answer my questions about the study?

You can talk to the researchers about any questions or concerns you have about this study. Contact Molly Gerdes, the study coordinator, at 415-640-2680 or email molly.gerdes@ucsf.edu.

You may also contact the office of the Committee on Human Research, UCSF's Institutional Review Board at 415-476-1814, 8 am to 5 pm, Monday through Friday. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

CONSENT

The person being considered for this study is legally unable to consent for herself/himself because s/he is a child. By signing this form, you are giving permission for your child or ward to participate in the study. You will receive a copy of this consent form and your bill of rights.

PARTICIPATION IN RESEARCH IS VOLUNTARY. If you wish for your child to participate in this study, please sign below.

Name of child/participant

Date

Parent/Guardian's Signature for Consent

Date

Person Obtaining Consent