

ASSESSING THE MALLEABILITY OF SPATIAL ABILITIES IN INDIVIDUALS WITH DOWN SYNDROME

NCT05332912

Initial IRB Approval: 9.19.2019

Lastest IRB Approval: 8.08.2024

PROTOCOL AND DATA ANALYSIS PLAN

Project Title: Assessing the Malleability of Spatial Abilities in Individuals with Down Syndrome

Please read this informed consent carefully before you decide to participate in the study.

We are asking permission for your child to take part in a research study. This study is called "Assessing the Malleability of Spatial Abilities in Individuals with Down Syndrome". The study is being conducted by Drs. Ed Merrill, Fran Conners, and Bev Roskos, along with their research assistants at The University of Alabama. It is also being conducted by Dr. Yingying (Jennifer) Yang and her assistants at Montclair State University.

Consent Form Key Information:

- Participate in an intervention study to improve spatial abilities of persons with Down syndrome
- Study and intervention will require participating in three assessment sessions (15 - 45 minutes) and 32 intervention sessions of 30 minutes each
- All data will be confidential and identified by number rather than name.
- Participants will include adolescents and young adults with Down syndrome and young children without Down syndrome who may also benefit from the intervention
- Researchers will be at a remote location, with all interactions taking place using ZOOM meeting technology available on the tablet computer provided for the study by the researchers.

Purpose of the research study: The purpose of the study is to assess whether or not it is possible to improve spatial abilities of people with Down syndrome. In this study we use spatial activities and games to improve performance. We compare people with Down syndrome to children matched on nonverbal ability to evaluate the benefit of the experience. However, we expect both the people with Down syndrome and the young children to improve through the intervention.

What your child will do in the study: If you and your child are willing to participate in this study, your child will be asked to do the following. First, your child will be asked to complete measures of cognitive and spatial abilities. Then your child will take part in 32 spatial activity sessions over 16 weeks. These are described below. The large number of sessions is needed to get a positive change in spatial abilities. For half of the participants, the spatial activity sessions will begin immediately following the assessment. For the other half of the participants, the first activity sessions will begin after a two-month delay. The delayed start is necessary to determine whether any change we see is due to the activities that we provide rather than children getting older. Your child's assignment to the delay condition does not impact the amount of training they will receive.

The initial assessment will take about 45 minutes. Four measures are included.

1. The Peabody Picture Vocabulary Test - Each item on the test includes four pictures. The researchers say a word and your child selects the picture option best represents the word's meaning.
2. The Ravens 2 Matrices Test - Your child will be shown several pictures that follow a pattern, with one element missing. He or she is asked to point to one of several new pictures that will complete the pattern.
3. Mental Rotation - On several trials, your child will be shown a geometric shape (rotated at different angles) in the center of a computer screen. The shape fits a blank space one of two

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rectangles presented at the bottom of the same screen. Your child points to the rectangle that fits the shape.

4. Perspective Taking - Your child will be seated at a table with four chairs and four different objects (street lamp, mailbox, stop sign, traffic signal). A stuffed animal is placed behind each object. Your child will be asked to point to a picture representing what they would see from the other three chairs around the table.

Each Spatial Activity Session (approximately 30 minutes per session) will include one object manipulation experience and one large environment experience. We will try to schedule two activity sessions each week.

Object Manipulation Experience:

1. Lego Block Play- Your child and the experimenter will take turns designing and copying objects made with Lego blocks.
2. Puzzle Play-Your child will be asked to complete several puzzles using a computer tablet app. The puzzles will require selecting pieces and rotating them to fit the puzzle.

Large Environment Experience:

1. Hide and Seek - Your child will be asked to find a hiding person in a video game. During the game, your child will be shown what the hiding person can see. Then he or she will be asked to locate the person. We will repeat this until he finds the hiding person.
2. Wayfinding - Your child will be asked to learn a virtual environment presented as a computer app. Environments will be, for example, a small city, a shopping mall, and a farm. We will show them the environment. Then we ask them to locate other places in the environment to find different objects (e.g., cows on the farm, theater in the mall).

Re-evaluation of Spatial Abilities:

The Mental Rotation and Perspective Taking Tasks will be re-administered at the end of the 16th and 32nd activity sessions (approximately 15 minutes additional time).

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Time required: The study will require about 18 hours of your child's time over the course of several months. As indicated above, the initial assessment session will take approximately 45 minutes. Each of the 32 experience sessions will take about 30 minutes. At the end of two of the experience sessions, we will include a reassessment of spatial abilities (15 minutes each). We will attempt to schedule two experience sessions per week. We will schedule at times that are best for you and your child. All activities will take place in your home or another convenient location that you may choose (e.g., school, service provider). The researcher will be at a remote location with all interactions taking place using ZOOM meeting technology.

Risks: There are no foreseeable risks associated with participating in this study. Mild fatigue or frustration may result; however, the tasks are designed to be easily answered and there are short breaks provided if your child appears tired. If your child indicates a reluctance to complete a scheduled session, we will simply reschedule for another time.

Benefits: We cannot promise any direct benefits to your child for participating in this research study, although we anticipate some improvement in performing basic spatial activities. The study will help us understand whether or not experience with spatial activities can improve performance on spatial tasks. We hope this information can be used to design future interventions that can be used to improve spatial skills in children and people with Down syndrome.

Confidentiality: All data collected in this study will be confidential. We are interested in group results and not the results of any individual.

Data linked with identifying information:

The information that your child provides in the study will be handled confidentially. Your child's information will be assigned a code number. The list connecting your name to this code will be kept in a locked file. When the study is completed, and the data have been analyzed, this list will be destroyed. Your child's name will not be used in any report.

Voluntary participation: Participating in this study is completely voluntary for both you and your child. You may choose to not allow your child to take part at all. Before starting the study, your child will be asked if he or she would like to participate. He or she may also decide not to participate.

Right to withdraw from the study: You have the right to withdraw your child from the study at any time without penalty. In addition, your child can choose to stop participating without any consequence.

How to withdraw from the study: To withdraw from the study, you or your child simply need to tell the researcher that either of you have decided to end your child's participation. There is no penalty for withdrawing. Your child will still receive full compensation/reimbursement for the time he or she spent in the study. We are providing reimbursement at the rate of \$25 for each 4 weeks of spatial ability experience, for a total of \$100. If you would like to withdraw after your materials have been submitted, please contact Dr. Ed Merrill at The University of Alabama (205-200-2183 or emerrill@ua.edu).

Compensation/Reimbursement: For taking part in the study, your child will receive the Tablet computer used during the study (valued at approximately \$75) and \$100 in payment.

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If you have questions about the study or need to report a study related issue please contact:

Principal Investigator: Edward Merrill, PhD (The University of Alabama)

Professor of Psychology

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Principle Investigator: Yingying (Jennifer) Yang, PhD (Montclair State University)

Assistant Professor of Psychology

Telephone: (973) 655-7639

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If you have questions about your child's rights as a participant in a research study, your rights as a parent or guardian, or would like to make suggestions or file complaints and concerns about the research study, please contact:

The University of Alabama Office for Research Compliance (205)-348-8461 or toll-free at 1-877-820-3066. You may also ask questions, make suggestions, or file complaints and concerns through the IRB Outreach Website at <https://research.ua.edu/compliance/irb/>. You may email the Office for Research Compliance at rscompliance@ua.edu.

Agreement:

I agree to allow my child to participate in the research study described above.

I do not agree to allow my child to participate in the research study described above.

Signature of Parent or Guardian

Date

Print Name of Parent or Guardian

Signature of Second Parent or Guardian (optional)

Date

Print Name of Second Parent or Guardian (optional)

Print Name of Research Participant

Signature of Investigator or other Person Obtaining Consent

Date

Print Name of Investigator or other Person Obtaining Consent