Study Title: The Effect of Play on Social and Motor Skills of Children With ASD

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Study Protocol

Participants

45 children with ASD aged between 5 and 15 years were recruited through fliers distributed to local schools, ASD services, advocacy groups, as well as Simons Powering Autism Research (SPARK) participant-research matching service (https://www.sfari.org/resource/spark/). We interviewed the potential participants to gather their demographic information (i.e., age, sex, ethnicity), and to confirm their eligibility for participation. Children were included in the study if they had formal ASD diagnoses that were confirmed through a school record (e.g., school psychologist record confirming an ASD diagnosis) and/or an Individualized Education Plan for ASD-related services or a medical or neuropsychological record from a psychiatrist or clinical psychologist using the Autism Diagnostic Observation Schedule (ADOS) and/or Autism Diagnostic Interview-Revised (ADI-R) measures. We additionally used the Social Communication Questionnaire (SCQ) as a screener for ASD symptoms (Rutter et al., 2003). Children were excluded if they have limited comprehension of one-step simple instruction and/or could not complete the pretests due to behavioral issues. Parents of the children completed the Vineland Adaptive Behavioral Scales-2nd edition (VABS; Sparrow et al., 2005), and the Social Responsive Scale questionnaire (SRS; Constantino et al., 2000) to assess the child's adaptive functions and social responsiveness. Following enrollment, children were matched on age, sex, and level of functioning then randomly allocated to the 3 intervention arms.

The study procedures were carried out according to the Declaration of Helsinki and were approved by the University of Delaware Institutional Review Board (UD IRB, Study Approval #: 1539736-5). Written informed consent of study participation was obtained from the parent, and a written/verbal assent was obtained from the participating children.

Experimental Procedures

This study includes 3 pretests, 3 posttests, and 16 training sessions conducted over 10 weeks. Eight weeks later a follow-up test was also completed. Specifically, the pretests and posttests were conducted during the first and the last week of the study, while the training sessions were provided during the intermediate 8

weeks (2 sessions per week). After pretests, the children were matched age, sex, and level of functioning and then randomized into the 3 groups. A parent orientation was conducted in-person/ through zoom before the training period to introduce the training activities and intervention strategies. Each training session lasted about one hour. All sessions were video recorded for further behavioral coding. The current study was conducted in the midst of the COVID-19 pandemic (between 2019 and 2022). Due to the initial close down and the later restriction of face-to-face (F2F) interaction, we decided to be more pragmatic and used a hybrid clinical trial delivery model (Bhat et al., 2021; Cleffi et al., 2022; Srinivasan et al., 2021; Su et al., 2021). The participating families chose between an F2F or a Telehealth (TH) training delivery method based on their convenience and comfort level of social interactions during the pandemic.

Training Protocols

For each intervention arm, Applied Behavior Analysis (ABA), Picture Exchange Communication System (PECS), TEACCH, and motor learning principles were used to provide structure, reinforcement, and free time for exploration. Specifically, visual, verbal, manual prompts/assistance, positive reinforcements were given throughout the intervention, and the child was encouraged to choose from a set of actions or improvise their own movement patterns. We also used a picture schedule to explain the order of tasks and to provide more structure to the session. During the training session, people sat/stood in a triad involving the child, expert trainer, and an adult model/parent was used. The expert trainer guided the child through the training-specific activities, while the model/parent assisted and acted as a buddy to provide visual model/assistance for the children. For the F2F intervention delivery format, a trained undergraduate student acted as the model, while for the TH format, the parents were trained to aid during the intervention. Both, undergraduate students and parents were provided in-person/Zoom trainings to explain the training goals, intervention principles, and the main activities according to the intervention types. The key ingredients for the multimodal group included engaging in interpersonal synchrony and multi-limb, whole-body movements performed to music, while the general movement group received multi-limb, whole-body movements based in exercise and games; whereas the seated play, control group focused on reading and fine motor activities.

To ensure training fidelity, a student coder randomly chose and coded one early (session 1-5) and one late session (session 12-16) for each child using a behavior checklist assessing trainer's and the model's behaviors. Specifically, the coder evaluated: A) the accuracy of completing the critical components of the training activities B) Trainer and model's behaviors including instructions, prompts, positive reinforcement/praise, body movements (clarity, energy), voice, affect (smile and expressivity), scored on a 5-point Likert score (1 indicates poor quality and 5 indicates high quality), and C) child's compliance with the training activities, also scored on a 5-point Likert score.

Testing Protocol

Trained testers assessed the training-related changes in motor performance using standardized during each test visit. For the standardized tests, we used the Bruininks-Oseretsky Test of Motor Proficiency (BOT-2) to assess children's gross and fine motor proficiency (Bruininks et al., 2005), a 2-Minute Walk Test (2MWT) to assess their endurance (Bohannon et al., 2018), and the bilateral motor coordination subtests of the Sensory Integration and Praxis Tests (SIPT) to access their praxis performance (Ayres, 1988). Parents also completed the Developmental Coordination Disorder Questionnaire (DCD-Q; Schoemaker et al., 2006) at each test visit, and both parents and the children filled out exit questionnaires to provide feedback on the feasibility, acceptability, and benefits of the interventions

Standardized Tests

Bruininks-Oseretsky Test of Motor Proficiency (BOT-2): BOT-2 is a valid and reliable assessment that targets 4 motor area composites with 8 subscales, including a) Fine Manual Control area, consisting of Fine Motor Precision, Fine Motor Integration subscales; b) Manual Coordination, consisting of Manual Dexterity and Upper-limb Coordination subscales; c) Body Coordination, consisting of Bilateral Coordination and Balance Subscales; and d) Strength and Agility, consisting of Running Speed and Agility and Strength subscales. The standard scores of the four motor areas were used to assess the training-related changes in motor performance.

Two Minute Walk Test (2MWT)

2MWT is a standardized measure of endurance. The child was asked to walk as fast as they can (without running) around 2 cones placed 50-feet apart for 2 minutes. The total distance the child walked in the 2-minute period was used to assess the training-related changes in endurance.

Sensory Integration and Praxis Tests (SIPT): We used the postural praxis and bilateral motor coordination subtests of the Sensory Integration and Praxis Tests (SIPT-PP and SIPT-BMC) to evaluate the praxis and sensory integration performance in children with ASD (Ayres, 1988). During the SIPT-PP, the tester sat across the children and performed 17 novel postures that involved fingers and upper/lower limb movements. An error was counted if the children posed with insufficient/exaggerated joint angles, incorrect joint and hand orientation, or using the wrong side of the body. Similarly, during the SIPT-BMC test, the tester sat across the children and performed 22 rhythmic action sequences involving hand-tapping, foot-stomping, and foot-tapping. The children were asked to repeat the movement sequences back to the tester. An error was counted if the child paused in between the movement sequence, couldn't pick up the rhythm, moved too fast or too slow, or failed to perform the right movement sequences. The number of errors the children made during the SIPT-PP and SIPT-BMC tests were used to monitor the training-related changes in praxis performance.

Executive functioning (EF) Task

During the EF task, we will use e-versions of variations of the Flanker test to assess the inhibition control and cognitive shifting elements of EF. There will be 2 conditions in the Flanker task, including: a) Congruent: Five fishes facing in the same direction (left or right) will be presented, and the child will be asked to raise the left or right index finger depending on the direction in which all the fishes are facing, b) Incongruent: the child will be presented with 4 fishes facing the same direction while the center fish will be facing in the opposite direction. Children will be asked to point to the left or right index finger depending on the direction of the center fish.

Drumming Synchrony Task

During the drumming synchrony task, children will be seated with a drum placed on the table in front of them. There will be 3 conditions: a) Music: the child will be asked to drum in order to match up to rhythmic beats played aloud in the background, b) Social: the child will sit face to face with an adult and be asked to match up to the movements of the adult. C) Virtual Social: the child will be seated facing a laptop screen and drum with a virtual partner through zoom conferencing. Both the child and the virtual partner will drum to rhythmic beats played aloud in the background.

Parent reported motor outcome using the Developmental Coordination Disorder Questionnaire (DCD-Q)

DCD-Q is a parent questionnaire to screen for developmental coordination disorder in children. Specifically, it screens for the child's performance in three components, Control during movement (motor control while the child is moving or the target object is in motion, ex: catching, throwing), Fine motor/Handwriting (fine motor skills, ex: writing fast and legibly), and General coordination (motor planning/learning, ex: like sports and learn new skills).

Children's survey feedback

Upon finishing all training sessions, each child answered 3 questions to provide feedback on their training experience. The questions include: A) Did you enjoy the activities we did? B) Did you find the activities easy or hard, C) Will you practice similar activities on your own or with mom/dad? Each question was answered with a picture-assisted 5-point Likert score (5- definitely yes/ very easy; 4- yes/easy; 3- maybe, neither too easy nor too hard; 2- not so much/hard; 1- not at all/very hard).