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The Effect of START-Play Intervention on Reaching-Related Exploratory Behaviors in Children with Neuromotor Delays: A Secondary Analysis of a Randomized Controlled Trial

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Abstract

Aims: Children with neuromotor delays are at risk for reaching and object exploration impairments, which may negatively affect their cognitive development and daily activity performance. This study evaluated the effectiveness of the Sitting Together And Reaching To Play (START-Play) intervention on reaching-related exploratory behaviors in children with neuromotor delays.

Methods: In this randomized controlled clinical trial, 112 children (*Mean*=10.80, *SD*=2.59 months old at baseline) with motor delays were randomly assigned to receive START-Play intervention or usual care-early intervention. Performance for ten reaching-related exploratory behaviors was assessed at baseline and 1.5, 3, 6, 12 months post-baseline. Piecewise linear mixed-effects modeling was used to evaluate short- and long-term effects of the intervention.

Results: Benefits of START-Play were observed for children with significant motor delays, but not for those with mild delays. START-Play was especially beneficial for children with significant motor delays who demonstrated early mastery in the reaching assessment (i.e., object contact ≥65% of the time within 3 months after baseline); these children showed greater improvements in manual, visual, and multimodal exploration, as well as intensity of exploration across time.

Conclusions: START-Play advanced the performance of reaching-related exploratory behaviors in children with significant motor delays.

Keywords: children; reaching; motor delay; START-Play intervention; early intervention

Disclosure Statement: The authors declare no conflict of interest.

Data Availability Statement: Data from this study are available on request.

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Reaching is the ability to visually locate an object in space and move the hand(s) to contact it (Berthier & Keen, 2006; Thelen et al., 1993). Reaching develops gradually from early swiping movements just after birth (von Hofsten, 1982) through accidental object contacts by 10-12 weeks (Michel & Harkins, 1986; Thelen et al., 1993) to successful goal-directed reaching by 15-17 weeks of age (Lee et al., 2006; Michel & Harkins, 1986).

Reaching provides the foundation for grasping and object exploration (Corbetta & Snapp-Childs, 2009; Gibson, 1988; Lobo & Galloway, 2013; Needham et al., 2002; Wilcox et al., 2007). In turn, object exploration allows children to gather information about objects' properties and affordances, means-end relationships, and the construct of causality; this learning advances children's cognitive development (Bahrick et al., 2004; Corbetta & Snapp-Childs, 2009; Gibson, 1988; Jouen & Molina, 2005; Lobo & Galloway, 2008; Ruff et al., 1984; Zuccarini et al., 2017). Indeed, there is a significant positive relation between object exploration at 6-7 months and cognitive outcomes at 24 months of age (Ruff et al., 1984). In addition, delays in reaching and object exploration negatively impact children's cognitive outcomes and future academic achievement (Bornstein et al., 2013; Jouen & Molina, 2005; Lobo, Kokkoni, et al., 2015; Zuccarini et al., 2017).

Importantly, the *quality* of reaching behavior can impact opportunities to advance cognition; the ability to hold the hands open and contact objects with the palm of the hand provides richer opportunities to collect haptic information and facilitate learning (Babik et al., 2022; Lasky, 1977). Bimanual reaching, in contrast to unimanual, promotes the development of sophisticated role-differentiated bimanual manipulation (Babik & Michel, 2016). Visual attention to objects facilitates the development of visuomanual coordination, further advancing reaching and object exploration skills (Atkinson & Braddick, 2007; Lasky, 1977; McCarty & Ashmead, 1999). Multimodal exploration (i.e., visual-manual activity) strengthens learning and facilitates cognitive development (Bahrick et al., 2004; Wilcox et al., 2007).

Infants with a variety of risk factors or diagnoses have been shown to have delays and qualitative differences in reaching development during the first year of life (Campos et al., 2009). For example, infants at very high risk (VHR) of being diagnosed with cerebral palsy (CP) showed less smooth, fluent, and straight reaches and greater head instability compared to VHR-infants without CP from 4.7 to 22.6 months of corrected age (Boxum et al., 2017). Moreover, infants born preterm and/or with a brain injury exhibited not only reaching delays at six months corrected age, but also lower variability and intensity of object exploration behaviors throughout the first two years of life compared to their full-term peers (Lobo et al., 2014; Lobo, Kokkoni, et al., 2015).

Early intervention may improve reaching abilities of children (Heathcock et al., 2008; Lobo & Galloway, 2008; Lobo, Galloway, & Heathcock, 2015; Lobo et al., 2004). Daily, parent-led intervention starting at 2 months corrected age and lasting for 3-8 weeks had significant short- and long-term benefits in promoting spontaneous arm movements, postural control, and hand-eye coordination to advance reaching, object exploration, and problem-solving abilities in children with or without neuromotor delays (Heathcock et al., 2008; Lobo & Galloway, 2008). These successful interventions have focused on parent-infant handling, positioning, and play practices. The Sitting Together And Reaching to Play (START-Play; Harbourne et al., 2018, 2021) intervention, that targets motor skills within the context of problem-solving and play, effectively advanced the ability to contact objects for children who were 7-16-months old at baseline (Harbourne et al., 2021). START-Play specifically focused on providing opportunities to engage in problem-solving activities with objects and people to advance children's postural control, sitting, and object exploration; this successfully advanced reaching and fine motor skills in children with significant motor delays (Harbourne et al., 2021). It has not yet been shown whether START-Play might be effective for advancing the development of other reaching-related exploratory behaviors beyond contact frequency, such as bimanual or visual-manual exploration.

The purpose of the current analyses was to evaluate the effectiveness of START-Play intervention for improving reaching-related exploratory behaviors in children with neuromotor delays. The primary outcome paper demonstrated short-term improvements in problem-solving and fine motor skills and long-term advances in fine motor and reaching skills following the START-Play intervention for children with significant motor deficits (Harbourne et al., 2021). The presence of long-term improvements in reaching skills without short-term gains in this area warranted further investigation. The current analyses represent planned secondary analyses from the START-Play trial. The primary analyses reported only one reaching variable (frequency of total contacts), and did not analyze it in relation to children's mastery level (Harbourne et al., 2021). We hypothesized that children who received START-Play intervention in addition to usual care-early intervention (UC-EI) would show greater improvements compared to children who had UC-EI intervention alone. The primary outcome paper for the START-Play clinical trial demonstrated greater effects of the intervention for children with more significant motor delays and, therefore, greater potential for improvement (Harbourne et al., 2021); we expected to find similar effects in these secondary analyses of the START-Play data. Furthermore, we considered the timing of each child's reaching mastery (the visit when the child first contacted the object for ≥65% of the assessment time[1]) in our analyses, because we hypothesized that performance would shift at this level of skill: children might improve their reaching performance until they master the reaching task, subsequently decreasing their performance thereafter due to declining interest. To our knowledge, this is the first study to evaluate the way that reaching mastery achievement might impact the effects of an early intervention program targeting reaching in children with motor delays.

Methods

Study Design and Setting

This multi-site randomized controlled clinical trial represents a single-blind, parallel group design. The trial was registered at ClinicalTrials.gov (identifier: NCT02593825). Intervention and testing of the participants were performed across five sites: 1) University of Delaware, Newark, DE; 2) Virginia Commonwealth University, Richmond, VA; 3) Duquesne University, Pittsburgh, PA, 4) University of Nebraska Medical Center, Omaha, NE, and 5) University of Washington, Seattle, WA. Data were analyzed at the University of Nebraska-Lincoln, Lincoln, NE. The study was conducted with approval and oversight of the internal review boards (IRB) at Duquesne University (single IRB of record for all other sites), Virginia Commonwealth University, and University of Nebraska-Lincoln. The funders played no role in the design, conduct, or reporting of this study.

Participants

Recruitment for this study was done by advertising through physical and occupational therapy clinics, early intervention providers, and community organizations at each site. An a priori power analysis (Harbourne et al., 2018) suggested a sample size of 152 children to detect intervention effects (two-tailed α=.05, *power*≥.80, 8% attrition rate); 155 children were assessed for eligibility, and 112 children were enrolled at 7-16 (*Mean*=10.80, *SD*=2.59) months of corrected age (see the CONSORT flow chart in supplementary materials; Harbourne et al., 2021). The eligibility criteria were: 1) gross motor score on the Bayley Scales of Infant and Toddler Development, 3rd Edition (Bayley-III) more than 1 SD below the mean; 2) ability to sit with or without arm support for at least 3 seconds; 3) presence of spontaneous arm movements; 4) inability to transition to/from sitting; 5) no significant visual, progressive, neurologic, or genetic disorders/diagnoses as reported by the caregivers (e.g., retinopathy of prematurity, muscular dystrophy, spinal muscular atrophy, spinal cord injury, or Down syndrome).

[1] Previous research showed that contact 65-100% of the time is the ceiling range of performance for children experienced in reaching (Babik et al., 2022).

After the baseline visit, block randomization (based on children's movement ability[2], to achieve equivalent groups) was used to assign each participant to the UC-EI only or START-Play plus UC-EI treatment group (55 in UC-EI; 57 in START-Play; Harbourne et al., 2018). The random assignment was implemented by an investigator not involved in data collection, and was concealed by using sequentially numbered, opaque, sealed envelopes. Twenty-three (20.5%) of the enrolled children dropped out before the end of the study, without a significant differential attrition between the treatment groups, for reasons including changed family circumstances and scheduling conflicts. See Table 1 for participants' demographic and health-related information.

Intervention

The START-Play intervention was developed by our team of experts in child development and rehabilitation based on evidence from previous research and the grounded cognition theory of child development (Harbourne & Berger, 2019; Lobo et al., 2013). The intervention aims to advance motor (specifically, sitting and reaching) and cognitive skills in children with neuromotor delays by focusing on the development of four key cognitive constructs (body and object affordances, object permanence, means-end relationships, and joint attention) within the context of diverse, meaningful motor activities and social engagement (An et al., 2021; Harbourne et al., 2018, 2021).

The START-Play program consisted of twice-weekly, 40-60-minute intervention sessions (*Mean*=51.5, *SD*=4.4 minutes, range 40.8-60.0 minutes) provided by a trained, licensed physical therapist throughout the first 12 weeks of the study. There were one or two physical therapists at each site, each trained in the START-Play intervention via a multi-day training conducted by the study principal investigator; each interventionist was required to meet the study's fidelity criterion before providing intervention within the study as well as throughout the study period (An et al., 2021).

The study had two phases: *intervention* (baseline to 3-month visit) and *post-intervention* (3- to 12-month visit). Program differentiation between the START-Play and UC-EI showed that UC-EI therapists had much more "rigid adherence to correct [children's] way of moving", provided children with "greater motor assistance than needed", and were less effective in encouraging parental involvement in the intervention compared to START-Play therapists (An et al., 2021, pp. 100-101).

Testing Procedure

Children were assessed longitudinally at the baseline visit, and 1.5, 3, 6, 12 months post-baseline in their home environment by a trained researcher blind to the child's treatment group assignment. At each visit, children were assessed with an established reaching assessment (Babik et al., 2019); at each visit, except at 1.5 months, children were also tested on the Bayley-III fine and gross motor subscales. For the reaching assessment, children were tested while sitting in a booster seat that provided trunk support and interacting with a target object (easily graspable toy about 6 x 2") presented across five, 20-sec trials at the following locations within the child's reach (Figure 1): 1) midline at the child's hip level; 2) midline at the child's chest level; 3) midline at the child's eye level; 4) chest level on the child's right side; and 5) chest level on the child's left side. For the purpose of the current analyses, data were aggregated among locations to provide a global picture of reaching across space. The child's attention was brought to the toy at the beginning of each trial. All assessments were video recorded with one camera providing the frontal view of the child and testing materials. All testing was conducted while children were in a positive or neutral behavioral state.

Outcome Measures

Videos of the reaching assessment were coded by blinded experimenters using Datavyu software to identify: 1) *Total contact* – instances when the child contacted the target object with any hand(s); 2) *Unimanual contact* – instances when the child contacted the target object with only one hand; 3) *Bimanual contact* – instances when the child contacted the target object with both hands; 4) *Ventral contact* – instances when the child contacted the target object with the ventral/palmar side of the hand; 5) *Open-handed contact* – instances when the child contacted the target

[2] Considering the Gross Motor Function Classification System level, Manual Ability Classification System level, the distribution of motor impairment, and the level of active movement assessed by experienced therapists (Harbourne et al., 2018).

object with at least two fingers and the thumb extended more than 50%; and 6) *Looking* – instances when the child's eyes were directed towards the target object. Datavyu software enables frame-by-frame behavioral coding of testing videos, with a researcher assigning appropriate codes (with the corresponding timestamps) to each behavioral occurrence.

Occurrences of overlapping behaviors were identified using Filemaker Pro software (Filemaker, Inc., Santa Clara, CA), which resulted in the following additional variables: 1) *Looking during total contact* – instances of the child looking at the target object while contacting it with any hand(s); 2) *Looking during unimanual contact* – instances of the child looking at the target object while contacting it with only one hand; 3) *Looking during bimanual contact* – instances of the child looking at the target object while contacting it with two hands; and 4) *Bouts of behavior* – number of times per minute that the child switched among behaviors. The first three variables measured children's multimodal exploration, whereas the fourth measured the intensity of children's behavioral performance.

For the statistical analyses, data on each of these ten behavioral outcomes were normalized to frequencies of occurrence per minute (i.e., dividing total frequency of behavior by total assessment duration in minutes).

To establish reliable coding of the data, 20% of the Bayley-III and reaching videos were re-coded for intra-rater agreement and an additional 20% of the videos were re-coded for inter-rater agreement. For the reaching data, intra- and inter-agreement were calculated as [Agreed/(Agreed+Disagreed)]*100 and resulted in 95.8±5.5% and 93.0±6.9%, respectively. For Bayley-III, those were calculated as ICC and resulted in ICC(3,1)=100% and ICC(2,1)=100%, respectively.

Statistical Analyses

Based on the baseline visit, each participant's level of motor delay was categorized according to their Bayley-III motor composite score: mild motor delay (<2.5 but >1 SDs below the mean, n=62) or significant motor delay (≥2.5 SDs below the mean, n=50). Reaching mastery (the visit when the participant first contacted the object for at least 65% of the assessment time) was categorized as being early (baseline through 3 months post-baseline, n=65) or late (6-12 months post-baseline or never during the study period, n=47). To establish the equivalence between the treatment groups, chi-square analyses were performed to evaluate the distribution of children with different motor severity and mastery timing between the START-Play and UC-EI groups. Also, a chi-square analysis was conducted to evaluate the distribution of delay severity across reaching mastery status. Furthermore, baseline differences in sensorimotor performance (Bayley-III fine motor scores) were evaluated in children with mild versus significant delays (independent-samples t-test) and in children with different motor delay and reaching mastery status composition (ANOVA; i.e., children with mild delays and early reaching mastery, mild delays and late reaching mastery, significant delays and early reaching mastery, or significant delays and late reaching mastery).

Piecewise linear mixed-effects modeling was implemented to account for repeated observations within children and to investigate developmental trajectories of reaching outcomes for the intervention (baseline to 3-month visits) and post-intervention pieces of the trajectory (3- to 12-month visits). The intervention piece highlighted the effects of the ongoing intervention, whereas the post-intervention piece allowed identification of possible intervention carry-over effects. The intercept and slope were evaluated for each piece of the trajectory.

Two individually-varying timepoint variables (*TIME1* and *TIME2*) were used to enable estimation of developmental slopes for: 1) the baseline to 3-months piece of the trajectory, and 2) 3-months to 12-months piece of the trajectory. The *TRT* variable specified the intervention assignment of each child (0=UC-EI; 1=START-Play). The SEV variable recorded severity of the child's motor delay (0=mild; 1=significant). Finally, the *MST* variable represented timing of reaching mastery (0=late; 1=early). TIME, TRT, SEV, and MST variables were included in all statistical models. In all the analyses, we controlled for age at baseline (corrected for prematurity when applicable) and recruitment site.

Two statistical models were tested to comprehensively study the main effects and possible interactions. *Model 1* evaluated the effect of treatment (TRT) on each of the dependent variables while controlling for SEV and MST. *Model 2* evaluated TRTxSEVxMST interaction to evaluate whether SEV and MST moderated the effect of TRT on dependent variables. All statistical analyses were performed using Mplus software, version 8.5 (Muthén & Muthén, Los Angeles, CA). Baseline treatment group differences, as well as short- and long-term intervention effects were estimated using the Mplus MODEL CONSTRAINT command.

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Results

Preliminary Analyses

A chi-square analysis determined that the two treatment groups were equivalent in their baseline distributions of delay severity ($\chi^2(1)=0.03$, $p=.865$) and reaching mastery ($\chi^2(1)=0.05$, $p=.826$). Note that children with significant motor delays were more likely to achieve reaching mastery later than those with mild motor delays ($\chi^2(1)=16.01$, $p<.0001$), with 63.04% of children with significant and 23.64% of children with mild delays being classified with late reaching mastery onset. An independent-samples t-test showed significant differences in Bayley-III fine motor scores between children with mild versus significant gross motor delays ($t(76)=7.99$, $p\leq.0001$): children with mild delays (23.77±3.16) had better scores than those with significant delays (16.94±5.34).

One-way ANOVA found significant differences in fine motor scores ($F(3,97)=33.27$, $p\leq.0001$) among the four groups representing the delay severity and reaching mastery combinations; Tukey post hoc test revealed that children with mild delays and early (23.70±3.13) or late reaching mastery (23.50±3.52) had better scores than those with significant delays and early (20.42±3.17; $p=.006$ and $p=.045$) or late reaching mastery (13.53±6.88; $p\leq.0001$ and $p\leq.0001$). Children with significant delays and early reaching mastery also had better fine motor scores than those with significant delays and late reaching mastery ($p=.006$). No fine motor differences were found between children with mild delays and early versus late reaching mastery ($p=1.000$).

Statistical parameters from Models 1 and 2 are presented in the supplementary materials Table S1. For statistically significant effects ($p\leq.05$), we report Hedges' g effect sizes, with 0.20, 0.50, and 0.80 representing small, medium, and large effects, respectively.

Model 1: The Main Effect of Intervention

Model 1 evaluated intervention effects while aggregating the data across severity levels and reaching mastery timing (Table 2). At *baseline*, no difference was detected between the UC-EI and START-Play groups for any reaching outcomes. During the *intervention phase*, no differences between the two treatment groups were observed between the slopes of the trajectories for any reaching outcomes. During the *post-intervention phase*, the START-Play group had a steeper slope of change than the UC-EI group for looking ($p=.043$, $g=0.54$), but not for other reaching-related exploratory behaviors.

Model 2: Intervention Effects Related to Severity of Motor Delay and Reaching Mastery Timing

Model 2 evaluated intervention effects while considering severity of motor delay and reaching mastery timing (Table 3, Figures 2-3). At *baseline*, among children with significant delays and early reaching mastery, frequency of total contact ($p=.011$, $g=0.91$), bimanual contact ($p=.005$, $g=1.01$), looking during total contact ($p=.003$, $g=1.05$), looking during unimanual contact ($p=.013$, $g=0.87$), looking during bimanual contact ($p=.004$, $g=1.00$), and bouts of behavior ($p=.021$, $g=0.84$) were significantly higher in those in UC-EI compared to those in START-Play. No other differences were found at baseline.

During the *intervention phase*, among children with significant delays and early reaching mastery, those in START-Play had steeper slopes than those in UC-EI for looking during total contact ($p=.014$, $g=1.76$), looking during unimanual contact ($p=.043$, $g=2.00$), and looking during bimanual contact ($p=.011$, $g=0.91$). A higher rate of change in these outcomes allowed children with significant motor delays, early reaching mastery, and in START-Play to catch up with their peers in UC-EI by the end of the intervention phase and to even outperform them in these metrics by the end of the study (Figure 2B). No differences between the treatment groups were found for children with mild delays.

During the *post-intervention phase*, significant differences in the slopes of the trajectories between the treatment groups, benefitting the START-Play group, were observed in all reaching outcomes for children with significant delays and early reaching mastery: frequency of total contact ($p<.0001$, $g=2.78$), unimanual contact ($p<.0001$, $g=2.65$), bimanual contact ($p<.0001$, $g=1.93$), ventral contact ($p=.009$, $g=1.83$), open-handed contact ($p=.032$, $g=1.14$), looking ($p<.0001$, $g=2.94$), looking during total contact ($p<.0001$, $g=2.34$), looking during unimanual contact ($p=.005$, $g=1.93$), looking during bimanual contact ($p<.0001$, $g=1.81$), and bouts of behavior ($p<.0001$, $g=2.75$). Additionally, among children with significant delays and late reaching mastery, those in START-Play had a higher rate of change in looking behavior than those in UC-EI (p=.021, g=0.95). The steeper slopes of change during post-intervention allowed children in START-Play to further improve their reaching performance compared to those in UC-EI. No differences between the treatment groups were found for children with mild delays.

Discussion

The purpose of the current study was to evaluate the effect of the START-Play intervention on reaching-related exploratory behaviors in children with neuromotor delays. The results suggested that accounting for severity of motor delay and timing of reaching mastery onset provides the most comprehensive picture of the developmental effects of the START-Play intervention on reaching-related behaviors.

START-Play intervention was most effective for *children with significant delays and early reaching mastery*. Interestingly, improvements noted during the three-month intervention period related to visual attention and visual-manual coordination. Specifically, children with significant delays and early reaching mastery showed greater improvements in their ability to look at objects while contacting them with their hand(s). Significant carry-over effects of the START-Play intervention relative to UC-EI were then observed during the post-intervention phase for all reaching-related exploratory behaviors. Thus, participation in the START-Play intervention was associated with greater improvements during the post-intervention period in visual attention (i.e., looking at the object), reaching (i.e., contacting the object with one or both hands), grasping (i.e., contacting the object with the palm of the hand and/or with the hand open for exploration), visual-manual coordination (i.e., looking at the object while contacting it), and the overall intensity (i.e., bouts of behavior) of reaching-related exploratory behaviors for children with significant delays and early reaching mastery.

In *children with significant delays and late reaching mastery*, the START-Play intervention resulted in greater improvements in children's visual attention to objects during the post-intervention phase, without significantly affecting manual performance with objects throughout the study period. It is interesting that in both subsets of children with significant motor delays (i.e., those with early or late reaching mastery) improvements in visual attention to objects or visual-manual behavior were observed before improvements in reaching or grasping. Visual attention to objects plays an important role in the development of reaching: it guides the hand approaching an object, allows correct pre-shaping of the hand, and enables hand-eye coordination, thus increasing the probability of object contact, grasping, and exploration (Atkinson & Braddick, 2007; McCarty & Ashmead, 1999; Petkovic et al., 2016). Therefore, improved visual attention and visual-manual coordination may create a foundation to support future advancements in children's reaching and grasping performance. In this case, if children with late reaching mastery had fewer opportunities to reach for objects and coordinate their visual attention skills with manual activity, their visual attention and visuomotor skills would be delayed compared to those with early reaching mastery. As a result, children with significant delays and late reaching mastery may follow the same trajectory as those with significant delays and early reaching mastery, but with a lag: the benefits in visual attention as a result of START-Play would become apparent later, during the post-intervention phase, rather than during the intervention phase. Improvements in reaching and grasping performance might potentially follow, after the end of the study, yet this hypothesis could not be confirmed with the existing data.

It is likely that children with late reaching mastery exhibited significant delays in their visual attention and tracking, spontaneous arm movement, and hand-eye coordination, as evidenced by their lower Bayley-III fine motor scores. The compilation of such fine motor delays with gross motor delays (i.e., postural control and locomotion) may further hinder the development of children's reaching and grasping skills. Previous research has, indeed, reported that impairments in muscle tone, postural control, motor coordination, as well as visual tracking and hand-eye coordination negatively affect reaching performance in children born prematurely (Atkinson & Braddick, 2007; de Groot, 2000; McCarty & Ashmead, 1999; Plantinga et al., 1997; Lobo et al., 2014; Lobo, Kokkoni, et al., 2015). Importantly, according to previous research, sensorimotor improvements, like the ones reported in this study, for children with significant motor delays (early or late reaching mastery) may facilitate children's observational learning and information gathering, which would be expected to further facilitate positive changes in problem-solving skills and cognition (Corbetta & Snapp-Childs, 2009; Cunha et al., 2018; Gibson, 1988; Jouen & Molina, 2005; Libertus et al., 2016; Lobo & Galloway, 2008, 2013; Ruff et al., 1984; Schwarzer et al., 2013; Zuccarini et al., 2017).

No significant effects of START-Play for any of the reaching outcomes were observed in *children with mild delays*. To explain these results, children's sensorimotor skills at baseline must be considered: irrespective of reaching mastery timing, children with mild delays exhibited better fine motor skills than those with significant delays. Whereas children with significant delays likely found the reaching task challenging and interesting and continued active learning in the task throughout the study, children with mild delays, based on our observations, showed much less engagement during the reaching assessments across time. We can infer that ceiling effects were likely observed in the reaching task during the latter part of the study for children who solidified mastery of the task earlier in the study.

Note that in this study, severity of motor delay and reaching mastery timing were treated as separate constructs. However, the analyses identified a significant overlap between the two concepts in our sample: children with mild motor delays were more likely to exhibit early reaching mastery compared to those with significant delays (77.05 vs. 30.64%, respectively). Importantly, fine motor abilities were better for children with mild versus significant delays; they were also better for children with significant delays and early versus later reaching mastery; differences were not observed for children with mild delays and early versus late reaching mastery. Thus, children with motor delays likely represent a continuum of gross and fine motor skills affecting their performance of reaching-related exploratory behaviors.

Limitations and Future Directions

We acknowledge that current analyses resulted in multiple dependent comparisons which could lead to spurious inferences. Reaching was one of the a priori defined secondary outcomes, but these analyses focused on specific facets of reaching and were, thus, exploratory in nature. Future confirmatory research is needed to test the efficacy of START-Play on the reaching outcomes that showed promise in this study. Also, there were significant baseline differences among children with significant delays and early reaching mastery assigned to UC-EI vs. START-Play for some of the reaching-related exploratory behaviors evaluated. It could be argued that the greater improvements in performance for those in START-Play might reflect a regression to the mean rather than true intervention effects. However, this argument is not fully supported; specifically, for children with significant motor delays and early reaching mastery, differences were observed at baseline for 60% of the reaching variables, while positive intervention effects were observed for 30% of the variables, and positive post-intervention effects were observed for 100% of the variables (see Model 2 results in Table 3). Furthermore, the visual attention improvements noted in the subset of children with significant motor delays and late reaching mastery receiving START-Play relative to those receiving UC-EI were not accompanied by differences at baseline. It is also important to note that although the number of participants was less than the number suggested by an a priori power analysis, the large sample size was sufficient to detect significant group differences in statistical analyses presented here.

Conclusions

In summary, interventions focused on early advancement of reaching skills within the context of problem-solving, such as the START-Play intervention, should be considered by clinicians working with children having significant motor delays. Such interventions may optimize children's developmental outcomes for reaching and object exploration, thus advancing skills that promote cognitive development and future academic achievement (Bornstein et al., 2013; Jouen & Molina, 2005; Lobo, Kokkoni, et al., 2015; Zuccarini et al., 2017).

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Supplementary Materials

Appendix A: CONSORT Flow Chart

CONSORT
TRANSPARENT REPORTING of TRIALS

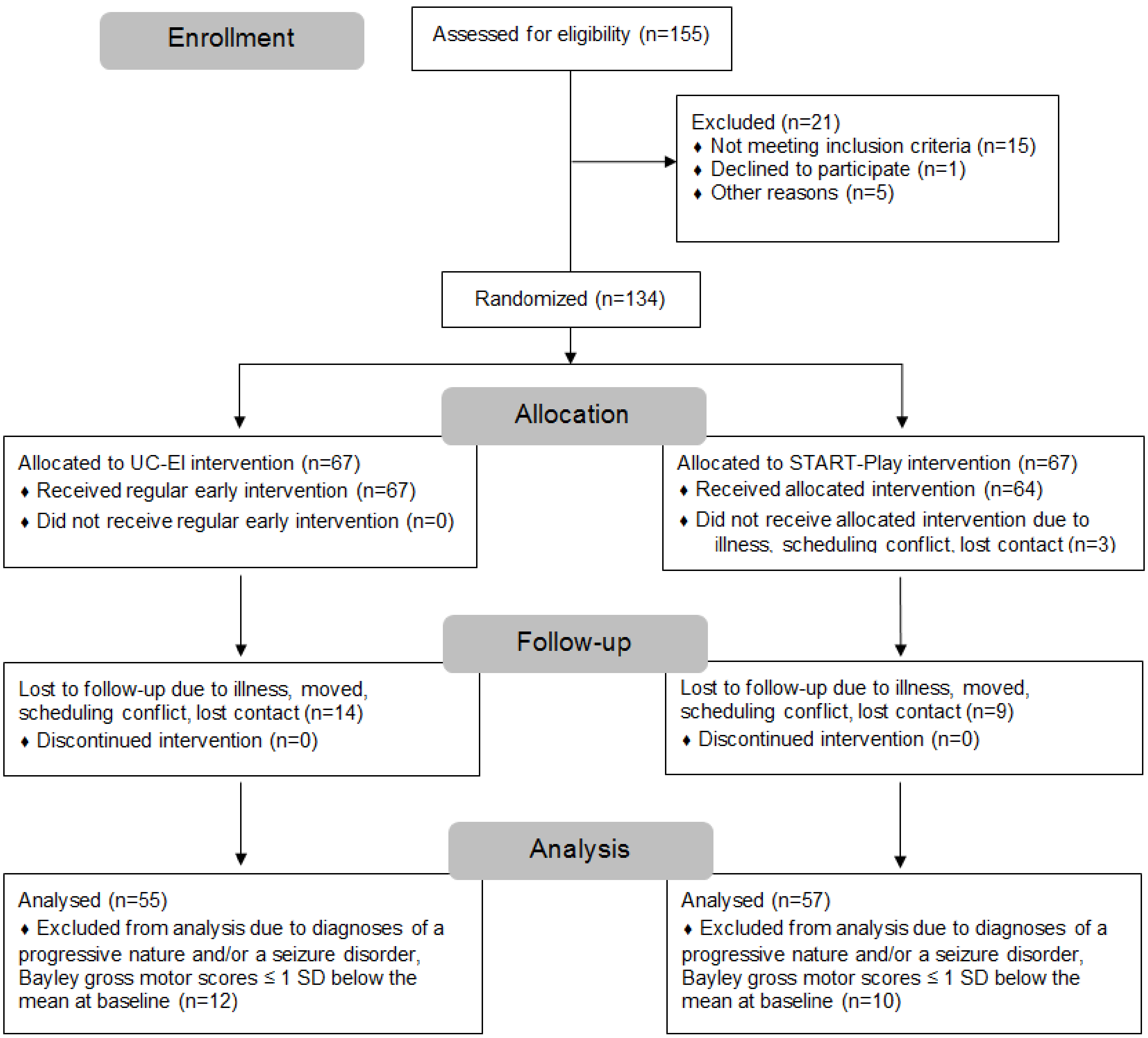

Table S1

Estimated statistical parameters for the intervention effects in Models 1 and 2; significant effects are marked in bold; *Est.* = estimated intervention effect; *z* = z-score; *SE* = standard error, *p* = p-value; TC = total contact, UC = unimanual contact, BC = bimanual contact, VC = ventral contact, OC = open-handed contact, LK = looking, LTC = looking during total contact, LUC = looking during unimanual contact, LBC = looking during bimanual contact, BB = bouts of behavior.

	Baseline (B)	Intervention Phase (B-3)	Post-Intervention Phase (3-12)
		Model 1	
TC	*Est.* = -0.81, *z* = -0.74, *SE* = 1.10, *p* = .462	*Est.* = 0.36, *z* = 0.30, *SE* = 1.21, *p* = .764	*Est.* = 1.73, *z* = 0.84, *SE* = 2.05, *p* = .400
UC	*Est.* = -0.59, *z* = -0.81, *SE* = 0.73, *p* = .418	*Est.* = 0.21, *z* = 0.24, *SE* = 0.88, *p* = .812	*Est.* = 0.97, *z* = 0.74, *SE* = 1.31, *p* = .460
BC	*Est.* = -0.18, *z* = -0.33, *SE* = 0.56, *p* = .744	*Est.* = 0.05, *z* = 0.09, *SE* = 0.56, *p* = .929	*Est.* = 0.96, *z* = 0.97, *SE* = 0.98, *p* = .331
VC	*Est.* = -0.52, *z* = -0.85, *SE* = 0.61, *p* = .393	*Est.* = 0.04, *z* = 0.05, *SE* = 0.73, *p* = .958	*Est.* = 0.62, *z* = 0.49, *SE* = 1.25, *p* = .622
OC	*Est.* = -0.34, *z* = -0.52, *SE* = 0.65, *p* = .605	*Est.* = -0.10, *z* = -0.13, *SE* = 0.77, *p* = .898	*Est.* = 0.12, *z* = 0.10, *SE* = 1.23, *p* = .920
LK	*Est.* = -0.10, *z* = -0.29, *SE* = 0.36, *p* = .773	*Est.* = -0.38, *z* = -0.85, *SE* = 0.45, *p* = .393	*Est.* = 1.11, *z* = 2.02, *SE* = 0.55, ***p* = .043**
LTC	*Est.* = -0.93, *z* = -1.12, *SE* = 0.83, *p* = .264	*Est.* = 0.29, *z* = 0.29, *SE* = 1.00, *p* = .771	*Est.* = 1.12, *z* = 0.73, *SE* = 1.53, *p* = .466
LUC	*Est.* = -0.66, *z* = -1.21, *SE* = 0.54, *p* = .225	*Est.* = 0.15, *z* = 0.23, *SE* = 0.67, *p* = .821	*Est.* = 0.60, *z* = 0.60, *SE* = 1.00, *p* = .549
LBC	*Est.* = -0.24, *z* = -0.64, *SE* = 0.38, *p* = .521	*Est.* = 0.10, *z* = 0.23, *SE* = 0.43, *p* = .821	*Est.* = 0.52, *z* = 0.77, *SE* = 0.67, *p* = .441
BB	*Est.* = -1.39, *z* = -1.07, *SE* = 1.30, *p* = .286	*Est.* = 0.23, *z* = 0.17, *SE* = 1.39, *p* = .868	*Est.* = 1.60, *z* = 0.67, *SE* = 2.38, *p* = .500
		Model 2 – Children with Mild Delays and Early Reaching Mastery	
TC	*Est.* = 0.26, *z* = 0.15, *SE* = 1.70, *p* = .881	*Est.* = 1.66, *z* = 0.81, *SE* = 2.05, *p* = .419	*Est.* = -2.77, *z* = -0.94, *SE* = 2.96, *p* = .349
UC	*Est.* = -0.63, *z* = -0.57, *SE* = 1.09, *p* = .567	*Est.* = 1.87, *z* = 1.35, *SE* = 1.38, *p* = .177	*Est.* = -2.12, *z* = -1.10, *SE* = 1.93, *p* = .273
BC	*Est.* = 0.89, *z* = 0.98, *SE* = 0.91, *p* = .327	*Est.* = -0.27, *z* = -0.25, *SE* = 1.08, *p* = .800	*Est.* = -0.65, *z* = -0.42, *SE* = 1.56, *p* = .677
VC	*Est.* = -0.36, *z* = -0.38, *SE* = 0.95, *p* = .707	*Est.* = 0.38, *z* = 0.35, *SE* = 1.10, *p* = .727	*Est.* = -1.66, *z* = -0.84, *SE* = 1.98, *p* = .401
OC	*Est.* = 0.09, *z* = 0.08, *SE* = 1.04, *p* = .935	*Est.* = 0.02, *z* = 0.02, *SE* = 1.18, *p* = .984	*Est.* = -2.06, *z* = -1.02, *SE* = 2.02, *p* = .306
LK	*Est.* = 0.07, *z* = 0.16, *SE* = 0.46, *p* = .875	*Est.* = 0.39, *z* = 0.57, *SE* = 0.68, *p* = .572	*Est.* = -0.73, *z* = -0.81, *SE* = 0.90, *p* = .416
LTC	*Est.* = -0.56, *z* = -0.42, *SE* = 1.32, *p* = .674	*Est.* = 0.86, *z* = 0.53, *SE* = 1.64, *p* = .599	*Est.* = -1.22, *z* = -0.57, *SE* = 2.16, *p* = .572
LUC	*Est.* = -0.88, *z* = -1.02, *SE* = 0.87, *p* = .307	*Est.* = 0.95, *z* = 0.92, *SE* = 1.04, *p* = .359	*Est.* = -0.74, *z* = -0.53, *SE* = 1.40, *p* = .599
LBC	*Est.* = 0.33, *z* = 0.55, *SE* = 0.60, *p* = .585	*Est.* = -0.10, *z* = -0.13, *SE* = 0.79, *p* = .900	*Est.* = -0.47, *z* = -0.45, *SE* = 1.05, *p* = .651
BB	*Est.* = -1.04, *z* = -0.52, *SE* = 1.98, *p* = .601	*Est.* = 2.19, *z* = 1.02, *SE* = 2.14, *p* = .306	*Est.* = -4.44, *z* = -1.33, *SE* = 3.34, *p* = .184

Model 2 – Children with Mild Delays and Late Reaching Mastery			
TC	*Est.* = 1.53, *z* = 0.54, *SE* = 2.82, *p* = .587	*Est.* = -5.36, *z* = -1.90, *SE* = 2.82, *p* = .058	*Est.* = 2.46, *z* = 0.50, *SE* = 4.95, *p* = .619
UC	*Est.* = 1.54, *z* = 0.86, *SE* = 1.79, *p* = .391	*Est.* = -3.41, *z* = -1.76, *SE* = 1.94, *p* = .078	*Est.* = 2.19, *z* = 0.63, *SE* = 3.49, *p* = .531
BC	*Est.* = 0.18, *z* = 0.13, *SE* = 1.39, *p* = .899	*Est.* = -2.18, *z* = -1.68, *SE* = 1.30, *p* = .093	*Est.* = 0.81, *z* = 0.42, *SE* = 1.90, *p* = .672
VC	*Est.* = -0.14, *z* = -0.08, *SE* = 1.75, *p* = .937	*Est.* = -2.24, *z* = -1.24, *SE* = 1.80, *p* = .213	*Est.* = 1.33, *z* = 0.38, *SE* = 3.51, *p* = .705
OC	*Est.* = -0.05, *z* = -0.03, *SE* = 1.80, *p* = .977	*Est.* = -2.39, *z* = -1.33, *SE* = 1.80, *p* = .184	*Est.* = 1.49, *z* = 0.43, *SE* = 3.44, *p* = .665
LK	*Est.* = 1.01, *z* = 1.14, *SE* = 0.89, *p* = .254	*Est.* = -1.99, *z* = -1.90, *SE* = 1.05, *p* = .058	*Est.* = 0.69, *z* = 0.50, *SE* = 1.37, *p* = .615
LTC	*Est.* = 1.71, *z* = 0.77, *SE* = 2.23, *p* = .444	*Est.* = -5.03, *z* = -1.78, *SE* = 2.83, *p* = .075	*Est.* = 2.01, *z* = 0.47, *SE* = 4.30, *p* = .640
LUC	*Est.* = 1.54, *z* = 1.09, *SE* = 1.41, *p* = .276	*Est.* = -3.15, *z* = -1.70, *SE* = 1.86, *p* = .090	*Est.* = 1.58, *z* = 0.52, *SE* = 3.02, *p* = .602
LBC	*Est.* = 0.20, *z* = 0.20, *SE* = 0.99, *p* = .840	*Est.* = -1.92, *z* = -1.79, *SE* = 1.08, *p* = .074	*Est.* = 0.65, *z* = 0.43, *SE* = 1.52, *p* = .671
BB	*Est.* = 2.54, *z* = 0.71, *SE* = 3.60, *p* = .480	*Est.* = -6.90, *z* = -1.77, *SE* = 3.89, *p* = .076	*Est.* = 1.67, *z* = 0.26, *SE* = 6.51, *p* = .797
Model 2 – Children with Significant Delays and Early Reaching Mastery			
TC	*Est.* = -6.71, *z* = -2.56, *SE* = 2.63, ***p* = .011**	*Est.* = 5.18, *z* = 1.85, *SE* = 2.80, *p* = .064	*Est.* = 16.51, *z* = 4.6, *SE* = 3.59, ***p* < .0001**
UC	*Est.* = -3.36, *z* = -1.78, *SE* = 1.89, *p* = .075	*Est.* = 2.81, *z* = 1.35, *SE* = 2.07, *p* = .176	*Est.* = 9.44, *z* = 3.80, *SE* = 2.48, ***p* < .0001**
BC	*Est.* = -3.24, *z* = -2.80, *SE* = 1.16, ***p* = .005**	*Est.* = 2.22, *z* = 1.90, *SE* = 1.17, *p* = .058	*Est.* = 6.88, *z* = 3.94, *SE* = 1.75, ***p* < .0001**
VC	*Est.* = -1.66, *z* = -1.24, *SE* = 1.34, *p* = .214	*Est.* = 2.06, *z* = 1.19, *SE* = 1.73, *p* = .234	*Est.* = 5.62, *z* = 2.61, *SE* = 2.16, ***p* = .009**
OC	*Est.* = -1.65, *z* = -1.26, *SE* = 1.31, *p* = .208	*Est.* = 2.06, *z* = 1.10, *SE* = 1.88, *p* = .273	*Est.* = 3.95, *z* = 2.14, *SE* = 1.85, ***p* = .032**
LK	*Est.* = -0.99, *z* = -0.97, *SE* = 1.03, *p* = .334	*Est.* = -0.02, *z* = -0.03, *SE* = 0.93, *p* = .980	*Est.* = 4.59, *z* = 4.85, *SE* = 0.95, ***p* < .0001**
LTC	*Est.* = -5.75, *z* = -2.95, *SE* = 1.95, ***p* = .003**	*Est.* = 5.77, *z* = 2.46, *SE* = 2.35, ***p* = .014**	*Est.* = 10.41, *z* = 3.55, *SE* = 2.93, ***p* < .0001**
LUC	*Est.* = -3.30, *z* = -2.47, *SE* = 1.33, ***p* = .013**	*Est.* = 3.45, *z* = 2.03, *SE* = 1.70, ***p* = .043**	*Est.* = 5.92, *z* = 2.80, *SE* = 2.11, ***p* = .005**
LBC	*Est.* = -2.41, *z* = -2.88, *SE* = 0.84, ***p* = .004**	*Est.* = 2.25, *z* = 2.54, *SE* = 0.88, ***p* = .011**	*Est.* = 4.25, *z* = 3.53, *SE* = 1.20, ***p* < .0001**
BB	*Est.* = -7.19, *z* = -2.31, *SE* = 3.11, ***p* = .021**	*Est.* = 5.76, *z* = 1.72, *SE* = 3.35, *p* = .085	*Est.* = 17.70, *z* = 3.90, *SE* = 4.54, ***p* < .0001**

	Model 2 – Children with Significant Delays and Late Reaching Mastery		
TC	*Est.* = -0.66, *z* = -0.41, *SE* = 1.61, *p* = .683	*Est.* = -0.92, *z* = -0.59, *SE* = 1.58, *p* = .559	*Est.* = 0.45, *z* = 0.19, *SE* = 2.42, *p* = .851
UC	*Est.* = -0.21, *z* = -0.18, *SE* = 1.17, *p* = .860	*Est.* = -1.45, *z* = -1.08, *SE* = 1.34, *p* = .281	*Est.* = 0.39, *z* = 0.25, *SE* = 1.57, *p* = .803
BC	*Est.* = -0.43, *z* = -0.61, *SE* = 0.70, *p* = .544	*Est.* = 0.41, *z* = 0.68, *SE* = 0.61, *p* = .496	*Est.* = 0.27, *z* = 0.23, *SE* = 1.16, *p* = .815
VC	*Est.* = -0.43, *z* = -0.43, *SE* = 1.00, *p* = .670	*Est.* = -0.31, *z* = -0.29, *SE* = 1.04, *p* = .769	*Est.* = 0.57, *z* = 0.36, *SE* = 1.59, *p* = .719
OC	*Est.* = -0.52, *z* = -0.50, *SE* = 1.05, *p* = .621	*Est.* = -0.14, *z* = -0.14, *SE* = 1.06, *p* = .893	*Est.* = 0.36, *z* = 0.23, *SE* = 1.57, *p* = .819
LK	*Est.* = -0.56, *z* = -0.94, *SE* = 0.60, *p* = .345	*Est.* = -0.58, *z* = -0.92, *SE* = 0.63, *p* = .357	*Est.* = 1.71, *z* = 2.30, *SE* = 0.74, ***p* = .021**
LTC	*Est.* = -0.29, *z* = -0.24, *SE* = 1.19, *p* = .810	*Est.* = -0.73, *z* = -0.54, *SE* = 1.36, *p* = .592	*Est.* = -0.60, *z* = -0.30, *SE* = 2.04, *p* = .768
LUC	*Est.* = -0.05, *z* = -0.06, *SE* = 0.83, *p* = .954	*Est.* = -0.94, *z* = -0.90, *SE* = 1.05, *p* = .368	*Est.* = -0.55, *z* = -0.42, *SE* = 1.31, *p* = .677
LBC	*Est.* = -0.21, *z* = -0.41, *SE* = 0.51, *p* = .681	*Est.* = 0.19, *z* = 0.39, *SE* = 0.48, *p* = .695	*Est.* = -0.08, *z* = -0.09, *SE* = 0.87, *p* = .930
BB	*Est.* = -0.87, *z* = -0.42, *SE* = 2.08, *p* = .674	*Est.* = -1.64, *z* = -0.80, *SE* = 2.05, *p* = .423	*Est.* = 1.53, *z* = 0.55, *SE* = 2.77, *p* = .580