Sitting Together And Reaching To Play (START-Play): Protocol for a Multisite Randomized Controlled Efficacy Trial on Intervention for Infants With Neuromotor Disorders

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Background. There is limited research examining the efficacy of early physical therapy on infants with neuromotor dysfunction. In addition, most early motor interventions have not been directly linked to learning, despite the clear association between motor activity and cognition during infancy.

Objective. The aim of this project is to evaluate the efficacy of Sitting Together And Reaching To Play (START-Play), an intervention designed to target sitting, reaching, and motor-based problem solving to advance global development in infants with motor delays or neuromotor dysfunction.

Design. This study is a longitudinal multisite randomized controlled trial. Infants in the START-Play group are compared to infants receiving usual care in early intervention (EI).

Setting. The research takes place in homes in Pennsylvania, Delaware, Washington, and Virginia.

Participants. There will be 140 infants with neuromotor dysfunction participating, beginning between 7 to 16 months of age. Infants will have motor delays and emerging sitting skill.

Intervention. START-Play provides individualized twice-weekly home intervention for 12 weeks with families to enhance cognition through sitting, reaching, and problem-solving activities for infants. Ten interventionists provide the intervention, with each child assigned 1 therapist.

Measurements. The primary outcome measure is the Bayley III Scales of Infant Development. Secondary measures include change in the Early Problem Solving Indicator, change in the Gross Motor Function Measure, and change in the type and duration of toy contacts during reaching. Additional measures include sitting posture control and parent-child interaction.

Limitations. Limitations include variability in usual EI care and the lack of blinding for interventionists and families.

Conclusions. This study describes usual care in EI across 4 US regions and compares outcomes of the START-Play intervention to usual care.

Early intervention (EI) services are established throughout the United States due to the Individuals With Disabilities Education Act (IDEA), Part C, the law passed in 1989 that mandates that infants with significant delays receive early intervention.[1] The evidence that these services affect developmental or educational outcomes for infants with neuromotor dysfunction, however, is limited. A Cochrane review of randomized trials of early intervention for preterm infants found a positive influence on cognitive and motor outcomes during infancy, with only cognitive effects persisting to preschool age.[2] Problems with evaluating EI included varying intensity of programs, lack of a standardized approach, and outcome measures insensitive to changes in infant skills. Morgan et al[3] performed a systematic review of the literature on early motor intervention for infants at high risk for cerebral palsy (CP) and found limited evidence of effectiveness. However, the review found promising evidence for effective motor intervention, which included programs that incorporated child-initiated movement, parent education, and environmental modification.

Although physical therapy EI providers generally value the importance of early motor skills, their focus is often on motor milestone achievement in isolation[4] without emphasis on the cognitive implications of these behaviors,[5] despite the fact that developmental research demonstrates strong associations between motor activity and cognitive ability.[6] Early motor intervention historically has been passive, and has not been linked to broader learning.[7,8] Thus, motor interventions previously studied may have had limited longer-term effectiveness because they target specific motor milestone achievement. EI may be more effective if the focus is on learning to utilize motor behaviors for the purpose of exploring, interacting with, and learning about the world. Although there is currently no clear description of usual care in EI, evidence points to the assumption that EI providers do not traditionally provide sufficient motor-based active problem-solving opportunities.[9–12]

The Sitting Together And Reaching To Play (START-Play) intervention aims to advance cognition by targeting the early motor skills of sitting and reaching through motor-based problem-solving strategies. Sitting and reaching are measurable skills that are critical to facilitate early exploration, interacting, and learning.[13,14] Very early in development, sitting allows orienting to important features in the world, and also frees the arms and hands for active exploration.[15–18] These motor skills then scaffold the child's interaction with people and objects, which can be used in countless problem-solving play scenarios to build critical cognitive constructs.[19–25] The connection of fundamental motor skills of sitting and reaching to early learning is the basis of our conceptual model for the improvement of educationally relevant outcomes (Fig. 1). We maintain that early learning emerges from motor-based active problem solving, as a child acts on objects and perceives the effect of those actions.[6,26–28]

The primary purpose of this project is to evaluate the efficacy of the START-Play intervention in addition to usual care, in comparison to usual care alone, which typically is provided through EI providers complying with federal standards through IDEA.[1] Because usual care in EI is not well defined, this project will also enable a description of those services across 4 regions in the United States.

The primary hypotheses for the START-Play project are:

1. Compared to the usual care-only EI group, the START-Play+ usual care group will show greater improvements from preintervention to postintervention (short-term) and in the long term (1-year follow-up) in sitting, reaching, problem-solving, and global development outcome measures.

2. Improvements in global development will be (at least) partially mediated by improvements in problem solving as a function of the START-Play+ usual care intervention at the end of the project (long-term proximal effect).

Secondary hypotheses will be explored to analyze the effects of severity of motor impairment on the primary outcome. Factors external to the child including parent-child interaction, home environment, and socioeconomic status will be examined to determine effects on changes in gross motor skill, reaching, problem solving, and global development. Additionally, changes in sitting kinematic variables and reaching variables (duration, type of grasp) will be examined over time and compared between groups.

This longitudinal single-blinded randomized controlled trial of START-Play is being conducted across 4 regions (Pennsylvania, Delaware, Virginia, and Washington). These sites are based on representation of different regions of the United States, and the expertise of the researchers participating in the design and development of the START-Play trial. The study is conducted in the family's choice of setting, primarily the home or daycare.

Methods

Participants

We aim to recruit 152 infants with neuromotor disorders for participation in this study, beginning at the age of 7 to 16 months, with a possible dropout rate of 10%, leaving a total of 140 infants. Inclusion criteria were:

- Score on the Bayley III gross motor subtest[29] >1.0 SD below the mean.
- Neuromotor disorder such as cerebral palsy (CP), or at risk for CP because of extreme prematurity or brain damage occurring at or around birth, or infants with motor delay of an unspecified origin.
- The infant sits with support of their arms for 3 seconds after being placed, and exhibits at least some spontaneous movement of arms. Infant should not be able to transition in or out of the sitting position independently.

Exclusion criteria were:

- Medical complications limiting participation in assessments and intervention

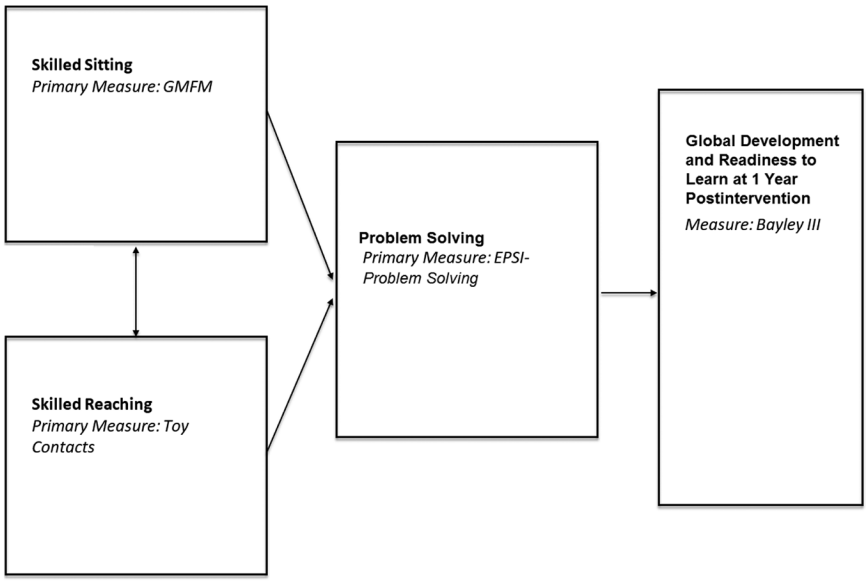

Figure 1.
Theoretical model of change due to START-Play intervention. Bayley III = Bayley Scales of Infant and Toddler Development-III (ed 3), EPSI = early problem-solving indicator; GMFM = Gross Motor Function Measure.

such as a severe visual disorder or uncontrolled seizure disorder.

- Primary diagnosis other than a general neuromotor disorder (eg, autism, Down syndrome, spinal cord injury, progressive disorder such as muscular dystrophy).
- Plans to move out of the local area within 1 year from the start of the study or plans for major surgery that might affect physical performance.

Recruitment

Prior published research by Harbourne et al[30] and Heathcock et al[31] were used to derive effect size estimates for sitting (Gross Motor Function Measure,[32] d = 1.21) and reaching (toy contacts, d = 1.32), respectively.[33] Pilot data from Lobo and Galloway[34] and Harbourne et al[35] were used to derive effect size estimates for global development (Bayley III, d = 0.43) and problem solving (Early Problem Solving Indicator,[36] d = 1.11), respectively. Power analyses suggest that the targeted sample size (N = 152, initial participants) is sufficient to detect the reported effects.[37,38] The power to detect mean group differences in slopes during the intervention period is >99% for sitting, 93% for reaching, and >99% for problem solving.[39,40]

Recruitment of study participants is continuous throughout the project's recruitment period, and assignment to group occurs at the individual child level (Fig. 2). Recruitment is done through local agencies and health care professionals serving infants requiring early intervention. Each of the 4 sites will recruit 38 infants to retain 35 infants for a total of 140 infants in the study.

Randomization to group is completed after the baseline assessment with infants stratified by the severity of neuromotor disorder (mild, moderate, and severe) based on a scale incorporating Gross Motor Functional Classification System levels, distribution of motor deficit (eg, quadriplegia, hemiplegia), and active movement.[30] This stratification ensures that the intervention groups are balanced. Random assignment is predetermined by a computer simulation, and individual assignments for participants across the severity levels are secured in sealed envelopes and opened after baseline for each participant.

Randomization is to either the START-Play intervention plus usual EI, or only usual EI services, for the first 3 months of the study. Assessments occur at the start of the study and then at 1.5, 3, 6, and 12 months post entry into the study to examine short- (3 months) and long- (12 months) term outcomes (Fig. 2). Multiple assessments allow examination of the trajectory of change over time in multiple variables.[41]

All children enrolled in the study continue to receive their usual care, as it is considered unethical to require families to stop services to enroll in the current study. Enrolled children are delayed enough to be eligible for EI services based on the federal mandates.[1] Thus, each child who is enrolled in usual EI services will have a unique individual family service plan, with providers from the local community. We will collect data about the amount and type of EI service but will not interfere with that plan. Usual EI services are also provided in the home or daycare of the child. Retention is promoted by stipends to families at each assessment and toys to infants at the first 3 assessment visits.

Description of Intervention

Infants randomized to the START-Play intervention group receive home visits by a physical therapist twice weekly for 3 months, for a total of 24 one-hour sessions. The interventionists are trained by the principal investigator in the intervention via information provided online and in person with infants and parents not involved in the study. The therapists also receive rechecks on the delivery of the START-Play program via fidelity videotaping with each participant, and via interventionist meetings twice yearly with the principal investigator. Daily intervention is provided by caregivers, based on suggestions from the home visits of the START-Play therapist.

During the START-Play visits, therapists and families work together to provide intensive, individualized, daily activities to advance reaching and sitting through small increments of challenge and support for these skills, which then become the building blocks for motor-based problem solving. More specifically, the intervention focuses on

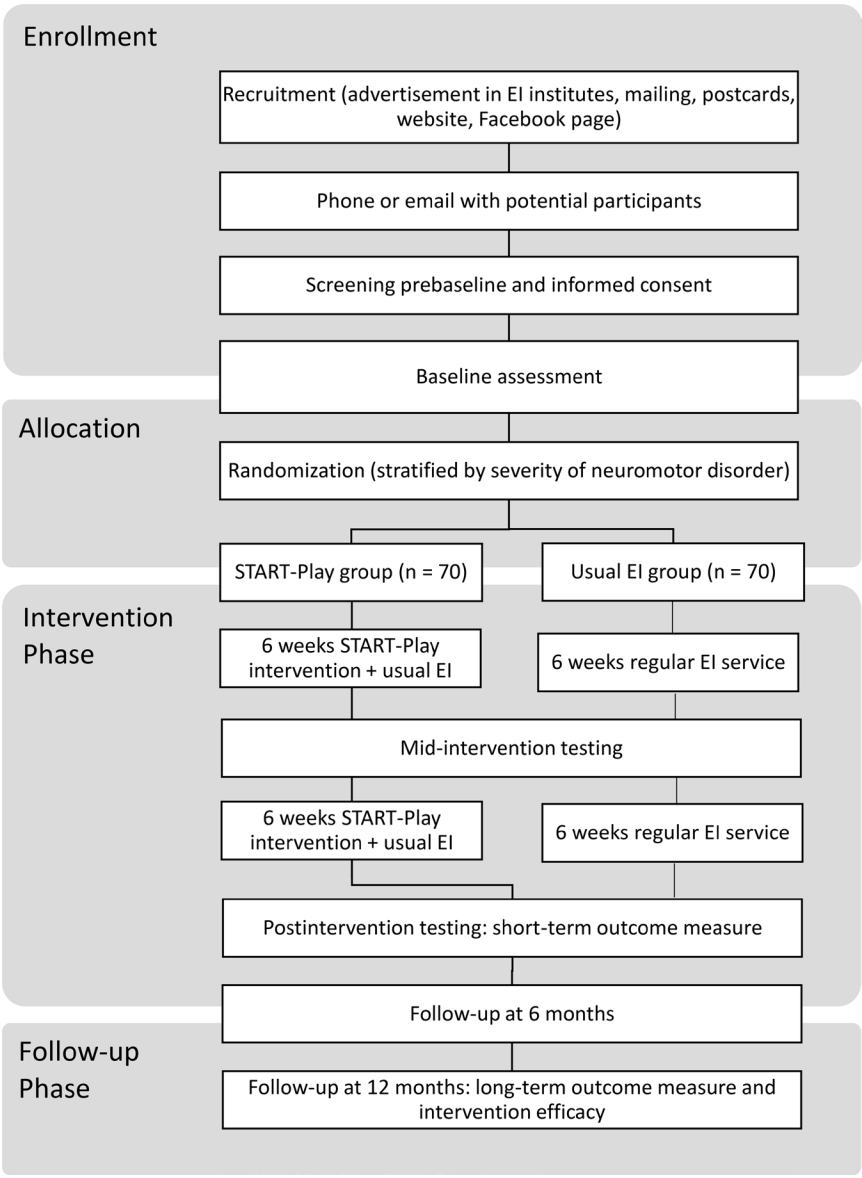

Figure 2.
Flow diagram of enrollment, assessment, and intervention. EI = early intervention.

self-initiated, goal-directed movements to build orientation and attention to objects, while learning basic relationships of cause and effect.

The START-Play intervention utilizes physical therapists to deliver a perceptual-motor program centered on early cognitive constructs. Intervention occurs in infants' natural environment, with caregiver social support to scaffold infant skills. The key ingredients of the START-Play intervention are:

- Cognitive constructs blended with motor challenges.
- Opportunities for 4 critical concepts blended with social support—these concepts are object permanence, means-end understanding, body/object affordances, and joint attention.
- Parents brainstorming and assisting directly with the "just right" challenge of blended motor/cognitive skills.

Therapists aim to engage infants and parents in play and problem solving utilizing variable sitting and reaching abilities while learning about the 4 key cognitive constructs. The specific intervention activities match the skill level of each child from early to more mature skill (Tab. 1). Unlike passive positioning or motor-only physical therapy in usual EI, the START-Play approach encourages active, variable, child-initiated movement to exploit environmental opportunities,[42,43] while learning to solve problems of object and body manipulation, which then scaffold cognitive skill.[16] Parents learn to discover and problem-solve motor/cognitive challenges as a unit, and link small motor changes to cognitive advancement for overall developmental progression (Tab. 2). In contrast, Table 3 shows an example of differences between a START-Play session and a usual EI visit. A usual care visit might consist of the therapist trying and then coaching the parent on routine motor milestone activities, which are end-points and not specifically linked to cognitive tasks.[44] However, EI visits vary widely; therefore, EI therapists will fill out a questionnaire on content of the individual child visits, the therapist's background, as well as videotaping the EI therapist as part of our fidelity process.

The START-Play therapists provide only the START-Play intervention, and are specially trained for 3 days prior to initiating therapy, and reviewed for each child via video. The usual EI services for each child are not interrupted, and are provided by the same team and therapist that the child usually sees (not START-Play interventionists). The START-Play therapists do not interact with the usual care team of the child. We have created an extensive procedure for fidelity of intervention, to assure that the START-Play group has adherence to the protocol, and to describe and quantify the differing features of START-Play from usual EI.

Fidelity of the intervention will be determined by videotaping 3 intervention sessions for each child.[45] Both the START-Play therapist and the usual care EI therapists will be videotaped. These videos will then be coded minute-by-minute for adherence to the protocol and inclusion of the key

Table 1.
Intervention Elements for Early and Advanced Skill Levels

Behavior/Item Coded	Example Early Skill	Example Higher-Level Skill
Cognitive opportunities	Tracks object, follows it when disappears	Finds object when hidden behind barrier and must change posture to get it
Social opportunities	Looks at parent when parent voices approval/ smiles	Looks at parent when engaged with new task/ object or when successfully manipulating; looks back and forth between parent and object, may vocalize
Flexible and not rigid	Parent/therapist allows child to lean/get postural support frequently during task	Parent/therapist allows child to move in many ways (not prescriptive "normal" during task)
Brainstorm with parents	What might child enjoy in what position?	Determines that child needs slightly more motor support in order to accomplish advanced cognitive task
Encourages parent to lead	Therapist asks parent to try what the therapist models	Parent continues therapist-initiated activity, but expands it
"Just right": motor challenge with cognitive challenge	Early sitting with prop support of arms, tracking object from center to side Early batting or sliding of toy on table in visual field and tracking	Turns in sitting to reach and obtain toy that disappeared behind them and out of view Places toy in tilted tunnel and looks for it on the other side, retrieves it
Parent and child engaged with therapist in activity	Parent with therapist and child periodically during session, attending, when necessary, to get specific messages	Parent adapts family activities to stay engaged with child and therapist entire time

Table 2.
Steps in START-Play Intervention Session (Generic Guideline)

Step	Activity
1	Establish cognitive task(s) and level of that task for the session—what is the challenge point for the child?
2	Establish sitting and reaching strategy available for that child—what is the current challenge point?
3	Weave the cognitive/motor challenge together in multiple ways; if motor challenge is difficult, simplify cognitive challenge. If cognitive challenge is difficult, support or simplify motor challenge.
4	Progression of physical assistance: set up environment; add environmental support (parent's body, therapist's body, furniture, pillows—anything not rigid and not "positioning in a static way"); place object in "reachable" place, or provide adaptation to object; touch cues; allow any movement option for several tries, and, if unsuccessful, provide "boundaries" to direct movement; light and slow assist as last resort, allowing child to initiate and direct movement. Child must be allowed to problem-solve about movement and to experience errors. Parent must help at each point to brainstorm options.
5	Engage parent in all of the above, and trade places with parent as person assisting child. As one cognitive/motor task is done, move to another construct while discussing the cognitive and motor components of the task and the next options.

ingredients of the intervention.[46] Differentiation of the START-Play intervention from usual care EI will be determined by comparison to the usual care therapist visits. Dosage and overall quality of the intervention will also be determined through these videos. Dosage of the START-Play features will be embedded in the analysis of the outcomes as a moderator variable.

Participation in the START-Play intervention requires consistent visits; therefore, participation in the study will be discontinued if the family misses more than 2 weeks of intervention. Participation in either arm of the study will be stopped at the family's request, or if assessments cannot be scheduled within a 2-week window of the required timeline.

Specific Outcome Measures

The primary outcome measure is change in the Bayley Scales of Infant Development III[29] cognitive scale from baseline to 12 months after baseline, which will indicate intervention efficacy. The Bayley III was selected because it is a common assessment used in the United States to determine eligibility and progression of development for EI services. Secondary outcome measures include change in Gross Motor Function Measure (GMFM)[32] score, change in type and duration of toy contacts during reaching,[13] and change in the Early Problem Solving Indicator (EPSI)[36,47] measure. Secondary measures were selected to measure targeted early motor behaviors that were expected to change in response to the START-Play intervention (see model of change, Fig. 1). All outcome measures will be compared between the START-Play Group and the usual care EI Group.

Table 3.
Examples of Differences Between START-Play and Usual Early Intervention

Example Content	Usual Early Intervention Session	START-Play Session	Difference
Sitting and object permanence	1. Child practices sitting balance reactions on a ball (isolated motor task). 2. Therapist provides supportive seat to constrain trunk and suggests presenting toys on tray in front of infant and modeling use of toy.	1. Select activity for motor-based problem solving— finding hidden toy. Child is encouraged to shift weight; re-orient to look behind/under/in containers, thus building sitting balance in the service of spatial understanding. 2. Dynamic low support sitting allows child to re-orient and gain spatial understanding; multiple options for variable sitting support depending on problem-solving task.	1. Cognitive construct is selected first and is primary; movements are built around the cognitive construct. 2. Parents are taught that chair is passive and not variable. Multiple options, with minimal support needed, allow exploration and link motor to problem solving.
Reaching and means-end	3. Therapist presents toys in different locations for child to reach. 4. Therapist presents toys of different shapes, colors, weights, and textures for child to reach.	3. Therapist sets up the environment so that reaching a proximal object (beads) will cause distal object to move (tied to other toy). 4. Therapist places desirable toy just out of reach, but on a cloth so child has to pull cloth to get toy.	3. Cognitive construct of means-end is overarching theme in motor activities. 4. Child must solve a problem: how to reach "unreachable" toy. Cognitive is end-point of motor problem.

Secondary motor measures will be further analyzed to quantify and describe change over time. Additional tertiary measures for sitting related to impairments in postural control are as follows: angle of forward bending during independent sitting; angular velocity from vertical to self-supported resting position; and angular displacement from vertical supported position; to self-supported sitting position.[48] Additional tertiary measures to describe changes in reaching and object exploration over time are as follows: age of reach onset, defined by the first session the child contacts the toy more than 5 times in 3 minutes of trial time; percent of time each hand is in contact with the toy; contact duration; number of toy contacts with both hands; and hand position at initial contact and during contact (open/closed hand, ventral/dorsal surface).[49]

Additional measures for child and family characteristics (severity, age, health) will be recorded, respectively, from previously described severity index and a demographic questionnaire and health questionnaire, which are both completed by parents. In addition, several environmental factors will be measured as possible moderators of the primary outcome: (1) parent/child interaction (PCI-DMC),[50,51] (2) home environment (AHEMD-SR scale,[52] (3) socioeconomic status (SES), (4) program attendance/participation (visit counts), and (5) overall amount of services (therapy services questionnaire). The Affordances in the Home Environment for Motor Development-Self Report (AHEMD-SR) assesses the quality and quantity of factors in the home that afford or enhance motor development. The socioeconomic status will be measured on a demographic questionnaire completed by parents. Program attendance will be recorded by the number of accomplished visits, documented by the therapist visiting the home. Amount of therapy will be recorded via a therapy service questionnaire completed by parents.

Data Collection

All data are collected by assessors blinded to group assignment of the child. Additionally, all coders of videotaped assessments are blinded to group assignment. Unblinding will occur at the point of statistical analysis. Assessment sessions are usually completed within 1 home visit, lasting 1 to 1.5 hours. Parents are present during all procedures.

Data Management

Data are collected in the home or daycare of the child, or a place chosen by the family. The assessment schedule is in Figure 2. All assessments are videotaped and de-identified, then stored in a password-protected database for later analysis by blinded coders. The data management site (University of Nebraska–Lincoln) provides coordination of data processing, cleaning, and filing of data to allow access to all sites. Each site is responsible for coding of several variables by researchers who have demonstrated intrarater and interrater reliability on the measurements, and assuring reliability of measurement by recoding of 20% of the data to assure at least 85% agreement on all scoring.

Data Analysis

The investigators will use linear mixed modeling to determine the efficacy of the intervention on primary child outcomes, comparing the START-Play group with the usual EI group.[53,54] Parallel process growth modeling within a structural equation modeling framework will be used to examine whether improvements in sitting and reaching are factors leading to improvements in problem solving, which is then a mediator leading to long-term global cognitive development.[55,56] Linear mixed modeling will also be used to examine relationships of moderating variables, including secondary and tertiary measures. All children entered into the study with baseline assessment date will be included using an intention-to-treat analysis plan. Fidelity of intervention measures for adherence to the START-Play protocol will be an additional moderating variable, and will also be examined to differentiate START-Play intervention from the usual care EI program.

Improvements in sitting, reaching, problem solving, and global development will be moderated by internal variables (including the severity of neuromotor disorder, health status, entry age, and cognitive status at entry) and by external variables (socioeconomic status, compliance/attendance to home visits, the home environment [HOME], and overall amount of service to the family and child). Evaluation of these variables as moderators of the effect of the START-Play intervention on change in primary outcomes (sitting, reaching, problem solving, and global development) will be done by modifying the linear mixed modeling model equation used in evaluation of primary hypothesis 2.

Relative to infants in the usual care EI only group, infants in the START-Play+ usual care intervention group will show greater improvements in the secondary variables both postintervention and at long-term follow-up. Evaluation of the secondary hypotheses will utilize the same linear mixed modeling framework presented for evaluating primary hypotheses 1 and 2, with the exception that the outcome measures will be sitting kinematic variables and reaching variables (duration, type of grasp).

Monitoring and Auditing

Data will undergo a partial analysis when 50% of the subjects have been recruited to assure there are no clear negative effects of receiving or not receiving the target intervention. Any adverse events during the assessments or intervention are reported to the principal investigator at each site as well as to the institutional review board (IRB) of the site.

Ethics

Approval and Consent

IRB approval is in place at each site, and informed parental consent will be obtained for participants in both groups, as well as from the EI therapists who are videotaped. Permission for the sharing of videos and data between sites is obtained. The funding agency mandated IRB approval prior to funding the project. IRB updates and annual reports are provided at each site, including our data management site at the University of Nebraska–Lincoln.

Videos of assessments and fidelity of intervention are uploaded to a secure central data management site without including identifying information. The identifying information is only available to the primary investigator at each site, and shared with the data management site at the time of statistical analysis.

Role of the Funding Source

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Discussion

This project is the first comprehensive research project to assess whether early perceptual-motor intervention can positively and longitudinally impact global development, including cognition, when added to usual care. The START-Play project is also the first attempt to document the types of intervention activities taking place in EI for infants with neuromotor disorders.

For the START-Play intervention, we propose, based on prior developmental and early intervention research, that infants' ongoing, daily use of early sitting and reaching skills within a problem-solving context boosts global development and readiness to learn.[20–26] The START-Play intervention adds to the current EI model by translating developmental research to guide intervention teams in best practice: what skills need a focused effort at what time, and in what way.[57]

Importantly, early reaching and object exploration skills in the first year of life relate to future cognition.[21–23,58] Research from our consortium revealed key differences in early exploration and learning abilities in high-risk infants, such as those in this proposed study. For instance, we now know that high-risk infants perform less exploration in the first years of life.[59] Their exploratory behaviors are less variable, with fewer combinations of behaviors and fewer multisensory behaviors relative to typically developing infants. Furthermore, high-risk infants tend to perform behaviors generically on objects rather than matching their behaviors to the properties of objects, thus missing information about the unique properties of objects.[24] This altered information gathering impairs early learning.[60] In fact, high-risk infants demonstrate learning disabilities as early as 3 months in a contingency task where their leg kicks are associated with movement of an overhead mobile.[61] These learning disabilities persist through toddlerhood in causal learning tasks, such as using switches to activate a distant toy.[62] Most importantly, performance in learning tasks requiring exploration and modification of ongoing perceptual-motor behaviors to control associated events is a better predictor of future cognition at 2 years of age on the Bayley Scales of Infant Development III than was the Bayley itself at the same age points.[34] These findings suggest infants with motor delays that limit exploration have impaired early information gathering, which will persist and affect global development if not addressed. Thus, adapting early motor behaviors to control related events that build cognitive constructs should be a focus of early intervention.

Although early intervention services are mandated for infants with neuromotor disorders, training of therapists and interventionists for this special group of children is not optimal,[10,57] and a comparison of usual care to specifically trained interventionists is timely. The limitation of this study is that families and interventionists are not blinded to the group assignment, due to the direct nature of the project.

Author Contributions

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Outcome measure assessment: S.C. Dusing, M.A. Lobo, S.W. McCoy
Statistician: J. Bovaird, N. Koziol
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Data management: J. Bovaird, N. Koziol

Ethics Approval

Institutional review board approval is in place at each site, and informed parental consent will be obtained for participants in both groups, as well as from the EI therapists who are videotaped. Permission for the sharing of videos and data between sites is obtained.

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Clinical Trial Registration

This trial is registered at ClinicalTrials.gov (identifier: NCT02593825).

Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest. They reported no conflicts of interest.

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