THESIS

PARENT-MEDIATED INTERVENTIONS FOR INFANTS WITH DOWN SYNDROME

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ABSTRACT

PARENT-MEDIATED INTERVENTIONS IN INFANTS WITH DOWN SYNDROME

Parent-mediated interventions (PMIs) are becoming increasingly popular but the parents’ role as the administrator of the intervention, specifically the parental fidelity to an intervention protocol (PF) has yet to be standardized. Early syndrome specific PMIs can influence many domains of development for infants with Down syndrome (DS); however, the impact of PMIs on object exploration for infants with DS has yet to be tested. The current study examined the impact of parental fidelity to a PMI protocol on object exploration skills in infants with DS. The sample for this study consisted of 37 infants ($M=7.04$, $SD=2.44$) infants from 4 to 18 months with a confirmed case of trisomy 21. Infants in the intervention group ($n=19$) received the Sticky Mittens intervention and infants in the alternative group ($n=18$) received the ‘object dance’ activity. Parents were asked to fill out a parent logs to track their PF.

Multiple regressions revealed that increased parental fidelity resulted in more infant swats and reach attempts from pre to post-intervention for the intervention condition, but not the control condition. The findings from this study indicate the unique role that parental fidelity plays in explaining intervention effects or a lack of intervention effects in PMIs. The implications for parental fidelity in PMIs are discussed.
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INTRODUCTION

Down syndrome (DS), the most common chromosomal disorder associated with intellectual disability, affects approximately 1 in every 700 infants born each year (Shin et al., 2009). Infants with DS demonstrate more delayed and diminished motor skill acquisition that may impact other areas of development, including cognition (Ulrich, Ulrich, Angulo-Kinzler & Yun, 2001). As a way to address these delays, researchers have begun to develop early interventions to promote more adaptive outcomes for infants with DS (Ulrich, Ulrich, Angulo-Kinzler & Yun, 2001). However, the feasibility of interventions for young children with neurogenetic disorders is a common obstacle in developmental disabilities research. Recently, researchers have turned to parent-mediated interventions as a potential solution to address challenges related to feasibility (Rodger et al., 2008). The goal of parent-mediated interventions is to increase feasibility by training parents to administer an intervention to their children within their home, rather than having a research professional administer an intervention to their child in a laboratory setting. Through this type of intervention strategy, researchers can remove some of the barriers to successful implementation (e.g., excessive travel, new environments) and make participating in research more feasible for participants (Bradshaw, Koegel & Koegel, 2017). Furthermore, parents are given the opportunity for continued implementation that can support their child’s development long after the intervention has ended.

Despite these advantages, there are factors related to parent-mediated interventions that can negatively impact outcomes, including a lack of parental fidelity to the intervention protocol (Carr et al., 2016; McConnell et al., 2015; Pisterman et al., 1992). ‘Parental fidelity’ refers to the extent to which parents implementing a parent-mediated intervention follow the guidelines and implement the intervention based on the intervention protocol. The current study aims to explore
parental fidelity to an intervention protocol and how it might impact the outcomes of a parent-mediated intervention to promote early goal-directed behavior in infants with DS.
Parent-Mediated Interventions

Intervention science involves the development, testing, and dissemination of individual, family, and community-based programs that aim to alleviate issues or risks people may be facing (Cicchetti & Hinshaw, 2002). The intervention science field has grown to be important for helping individuals, families, and communities discover and implement innovative solutions to different problems (Cicchetti & Hinshaw, 2002; Santisteban, Muir-Malcolm, Mitrani & Szapocznik, 2002). This has been shown through many family-based early interventions that have been effective in promoting positive child outcomes (Cicchetti & Hinshaw, 2002; Santisteban et al., 2002). Researchers have commonly claimed that interventions that involve parents are more effective than those that do not (Desforges & Abouchaar, 2003; Hoover-Dempsey et al., 2005; White, Taylor & Moss, 1985). Bronfenbrenner (1979, 1988) argued for the importance of this approach when he proposed that, to be effective and impactful, early intervention programs need to involve the children's parents and communities so that the environments affecting children may support progress toward similar goals.

Parent-mediated interventions have not yet been widely tested in neurogenetic syndrome research. However, they have been tested in younger children with other neurodevelopmental conditions, particularly in autism spectrum disorder (ASD). Parent-mediated interventions in ASD have been used to support the development of joint engagement (Kasari et al., 2010; Kasari, Gulsrud, Paparella, Hellemann, & Berry, 2015), communication (Green et al., 2010; Oono, Honey & McConachie, 2013), and responsive parental behaviors (Siller, Hutman, & Sigman, 2013). This review of the literature will discuss the positive aspects of parent-mediated interventions, such as effectiveness and increased feasibility, as well as the complex issues
surrounding this line of research, including the varying nature of parental involvement and concerns regarding parental fidelity to the intervention protocol.

**The Effectiveness of Parent-Mediated Interventions.** Parent-mediated interventions have been effective in educating parents to be constructive supports for their child’s development (Diggle & McConachie, 2007). Diggle and McConachie (2007) conducted an extensive review of parent-mediated early interventions for young children with ASD to gain a deeper understanding of the benefits for both the children and their parents. These researchers compared data from nine studies, some of which implemented a parent-mediated intervention, while others involved trained professionals who delivered the intervention. Based on their review, the authors concluded that there is sufficient evidence of significant gains in social communication skills in children with ASD through parental training and education (Diggle & McConachie, 2007). Furthermore, parent involvement in an intervention has shown to be effective in improving social communication in children with ASD (Ingersoll & Wainer, 2013), parent emotional availability, and parent-child interactions (Siller et al., 2013). Ingersoll and Wainer (2013) tested Project IMPACT, a parent-mediated intervention that targets communication in young children with ASD through restructuring parent communication with their child. Researchers used a phased approach when teaching parents how to administer the intervention to better support them throughout the course of the intervention. Out of the eight parent-child dyads that participated in the study, six of them implemented the intervention with fidelity, and those six children exhibited the most improvement in their communication skills (Ingersoll & Wainer, 2013).

Siller and colleagues (2013) were also interested in improving communication skills in children with ASD and used a parent-mediated intervention that focused on parental responsiveness to improve communication in children with ASD, called Focused Playtime...
Interventions (FPI). This 12-week parent education program consisted of 12 at-home 90-minute parent-training sessions. In the sessions, parents were taught through a capacity-building approach to promote play between parent and child; the first 30-60 minutes of the session involved the interventionist training the parents on new intervention strategies to improve their children’s outcomes. During the rest of the visit, parents would play with their children to practice what they have learned and receive feedback from the interventionist in real-time. The research team found that responsive parental behaviors reliably predicted subsequent language gains in young children with ASD (Siller et al., 2013). Furthermore, parents in the intervention group displayed significant gains in their responsive behaviors and the children of those parents showed significant gains in their expressive language (Siller et al., 2013). Results revealed a significant medium-to-large treatment effect that accounted for 25% of the variance of the child language gains (Siller et al., 2013). This study provides evidence of the effectiveness of parent-mediated interventions due to the role of parents as the administrator. Since there is growing evidence for the effectiveness of parent-mediated interventions for young children with ASD, an important next step would be to test parent-mediated interventions in other neurodevelopmental conditions, like DS.

The Feasibility of Parent-Mediated Interventions. The rationale for implementing parent-mediated interventions is their high feasibility. The phrase "feasibility of an intervention" refers to how easy it is to implement an intervention. One way that parent-mediated interventions increase feasibility is through the elimination of travel-related challenges. By implementing an intervention at home, participants can cut back on travel time, the cost of travel, and travel-related stress. In 2008, Sylvia Rogder and colleagues were interested in learning more about mothers’ perceptions of a home-based intervention for children with ASD (Rodger, Keen,
Braithwaite & Cook, 2008). The research team found that on average, the majority of mothers who participated in the study were satisfied with the intervention, especially the home-based component (Roger et al., 2008). These findings exemplify the positive impact participants experience through participating in parent-mediated interventions and reducing travel requirements.

In addition to limiting the travel requirements of participants, parent-mediated interventions allow parents to incorporate the intervention into their families' daily routine (Bradshaw et al., 2017). By allowing parents to implement the intervention at home, they can fit the intervention into their schedule, rather than the research team's schedule. This type of intervention has the opportunity to increase parental adherence since parents are adapting it into their daily routine while taking ownership of the intervention and their child’s ability to improve (Bradshaw et al., 2017). In a 2017 study conducted by Bradshaw and colleagues on the feasibility and effectiveness of a parent-mediated intervention for children with ASD, parents were asked to fill out a post-intervention survey on their experiences with the intervention. Researchers found that parents felt the intervention was extremely feasible since they could work the intervention into their families' schedules and that the intervention improved the day-to-day routines of their families because it provided them with a novel and beneficial daily activity (Bradshaw et al., 2017). The survey also asked about parents' feelings of competence on the specific intervention techniques that they were taught, and all parents reported feeling increased competency (Bradshaw et al., 2017). By enabling parents to implement the intervention on their own time, parent-mediated interventions support parental fidelity to the intervention and encourage parents to become the expert in their child's development.
While there is ample evidence to support the effectiveness and feasibility of parent-mediated interventions, there is limited research that examines the parent’s role as the implementer of the intervention. The role of parents is a complex component of parent-mediated interventions; for most parents, this one of their first times implementing an intervention, which can be overwhelming and daunting. There are multiple approaches to parental involvement, each one with different strengths and weaknesses, which is why examining the effectiveness of each approach is critical.

**The Role of Parents in Parent-Mediated Interventions**

While parent-mediated interventions are becoming increasingly popular (Shalev, Lavine, & Di Martino, 2019), there is still much to learn about this relatively new form of intervention. For instance, due to the variability of parental involvement, the role of parents as the administrator of the intervention has yet to be standardized. Currently, there is a lack of literature on the standardization of the role that parents play in parent-mediated interventions. Previous research has suggested that parents play different roles in different intervention approaches, however, the role that works best in each intervention approach has yet to be identified (Dawson et al., 2010; Green et al., 2010). Understanding the different approaches to parental involvement is critical when expressing the need to standardize parental implementation. The following sections will review the different approaches to parental involvement within early interventions.

**Approaches to Parental Involvement.** There are several approaches to structuring parental involvement in different intervention designs. One approach partners parents with a researcher, who models the administration of the intervention while both parents and the researcher are engaged with the child receiving the intervention (Ulrich et al., 2001). Parents may also be asked to provide information for the study, but this information primarily includes
supplemental forms related to the intervention. For example, a study of treadmill training, an innovative physical therapy intervention for infants with DS to promote early walking, required that parents keep a log summarizing their infant’s training to obtain qualitative data while the staff videotaped the training to collect the complementary quantitative data (Ulrich et al., 2001). The design of this treadmill intervention combines the efforts of parents and the research team and encourages them to work together. This type of collaboration between parents and researchers provides parents with more opportunities to learn through working with experts in the field (White et al. 1985).

Another approach to parental involvement that targets family outcomes through parent education is the Part C Early Intervention Program (Adams & Tapia, 2013). Within this program, professionals in pediatric home practices provide at-home visits to parents of a child 0 to 3 years who has a developmental disability. This program has been shown to support nurturing relationships and family-centered care by providing parent education and coaching sessions in their natural home environment (Adams & Tapia, 2013). Parents have reported feeling more prepared in their role as a parent as well as seeing more improvements in their parent-child relationship after completing the intervention (Adams & Tapia, 2013). The Part C Early Intervention Program exemplifies how supporting parents of a child with a developmental disability can support change within the family dynamic, thus increasing the child’s positive development.

In the present study, parents implement the intervention, which is referred to as ‘parent-mediation’. As previously stated, in parent-mediated interventions, parents are trained by the research team to independently administer an intervention to their child at home. For example, in a study focused on early communication for toddlers with ASD, Dawson and colleagues (2010)
provided parents with formal training during the baseline visit and after, parents were expected to implement the intervention once per week for two hours and had weekly check-ins with the research team to monitor their progress. In those check-in meetings, the research team would have parents practice implementing the intervention and provide feedback to parents about what they were doing correctly, and what could be improved upon (Dawson et al., 2010). Through this approach, parents were encouraged to become experts in the intervention through iterative feedback from the research team. While there are different approaches to parental involvement in early interventions, it is not yet clear which approach is best for specific intervention designs. Since parent-mediation is a newer form of parental involvement, there is a need for more research on the characteristics and nature of parent-mediation to further understand the implications behind this approach.

**Measuring Parental Involvement.** Since there are multiple forms of parental involvement, measuring it can be complicated. By quantifying the level of parental involvement in a study, researchers can better understand what forms and dosages of involvement yield different findings. A deeper knowledge of parental involvement can provide a stronger foundation for future studies by laying out what type of parental involvement would be best for a particular study design and how to measure the different types of parental involvement. For interventions that include parents, it is important to have measures that track the nature and degree of parental involvement in the study. There are many different ways to measure parental involvement, including parent interviews (Castro, Bryant, Peisner-Feinberg & Skinner, 2004), telehealth-based data collection (McDuffie et al., 2016) and parent logs (Lam, Mahone, Mason & Scharf, 2011).
Parent interviews are typically completed at the end of the study and are conducted by a member of a research team. The parent interview allows researchers to ask parents questions about their thoughts, feelings, and opinions of the intervention program (Castro et al., 2004). In their study, Castro and colleagues (2004) used parent interviews to gather qualitative data on parent experiences with implementing the intervention. The questions the research team asked addressed parental satisfaction with the study, challenges parents encountered with implementation, and their overall experience with implementing the intervention (Castro et al., 2004). These types of open-ended questions allow parents to express themselves freely rather than having to rate their responses on a Likert type scale. Furthermore, they provide the researchers with more qualitative data on parent perceptions of the feasibility of the intervention program (Castro et al., 2004). These data can then be used to inform future parent-mediated early intervention programs.

Another approach to measuring parental involvement is through telehealth communication. ‘Telehealth’ describes the methods of improving health outcomes through telecommunications (Gellis, 2012). Through telehealth, researchers can follow up with participants, remotely, to improve their intervention to be more feasible to parents. McDuffie and colleagues (2016) conducted a study on young boys with fragile X syndrome to test the effects of their teleconferencing intervention on language development (McDuffie et al., 2016). After each session, parents and researchers met privately through a laptop webcam to discuss the implementation of the intervention and what could be improved upon. This study displays how telehealth can be a beneficial alternative to the traditional ways of intervention programs by staying in increased contact with the participants throughout the study using modern technology.
The most traditional form of measurement for parental involvement is parent logs (Voltaire & Teti, 2018). Parent participants fill out logs as a way to track their progress and experiences with implementing the intervention. These logs allow researchers to gather data on interactions and behaviors that they are unable to observe directly. In parent-mediated interventions, parents may be asked to record the date, length of time, and aspects of their experience implementing the intervention (Lam et al., 2011; Voltaire & Teti, 2018). One benefit of using parent logs is that researchers can gather direct information regarding parental adherence to the intervention protocol. Additionally, parents can express their experience with implementing the intervention, which can then better inform researchers on the feasibility of the intervention. However, a potential drawback to this approach is that parents may forget to fill out the log, or may not complete all sections (Lam et al., 2011). While this form of measurement is feasible and useful, there can be much variability between the amounts of entries in parent responses (Voltaire & Teti, 2018). Currently, there is a lack of literature on parental logs as a form of measurement of parental fidelity to the intervention protocol. This gap in the literature supports the need for new research on the nature of parental involvement in parent-mediated interventions and the measurements used to quantify parental involvement.

**The Challenges of Parental Adherence**

While the benefits of parent-mediated interventions include feasibility, effectiveness, and increased gains based on parental involvement in the intervention (McConnell, Parakkal, Savage & Rempel, 2015), it is important to recognize that there are challenges associated with implementing parent-mediated interventions. Researchers have proposed the idea that asking parents to implement an intervention on the researchers’ terms can be overwhelming and difficult
for a parent to maintain and uphold (McConnell et al., 2015). It is for this reason that a deeper look into the parental fidelity and the factors that impact this construct is needed.

**Parental Fidelity.** As previously stated, ‘parental fidelity’ to an intervention protocol describes the extent to which parents follow the guidelines of the intervention protocol while implementing a parent-mediated intervention. Parental fidelity, although extremely important, has posed a challenge to parent-mediated interventions (McConnell et al., 2015). Decreased parental fidelity could be due to a lack of investment by parents or insufficient training by the research team (McConachie & Diggle, 2007; McConnell et al., 2015; Pisterman et al., 1989). When parental fidelity to the intervention protocol is low, it may influence intervention effects and outcomes, as not all aspects of the intervention protocol may be in place to support developmental change.

Previous studies that surveyed parents about their experiences with implementing a parent-mediated intervention found that parents reporting low scores of parental investment were requesting more continual training from the research team throughout their time implementing the intervention (Pisterman et al., 1989; McConachie & Diggle, 2007). Although parent-mediated interventions are designed to provide proper and adequate training for parents, parents who have a child with a developmental disability have commonly expressed the need for more training and continued support to implement the intervention (McConachie & Diggle, 2007). McConachie and Diggle (2007) argued that since parents are asked to perform a novel task, they require not only initial training, but also on-going support throughout the intervention. The combination of taking on a new challenge and the daily stressors of having a child with a developmental disability can be overwhelming for some parents, which is why continued communication between parents and research team members throughout the intervention can
serve as a potential solution to this challenge. By studying how implementable interventions are for parents, researchers will have the opportunity to promote parental fidelity by constructing the intervention protocol to be more supportive of parent needs, which can, in turn, result in improved outcomes for their child.

**Summary.** Research studies that have used parent-mediated interventions for children with ASD have provided evidence of the benefits children with a developmental disability experience from participating in this line of intervention (Ketelaar, Vermeer, & Helders, 1998; McConnell et al., 2015; Ozonoff & Cathcart, 1998). There is ample evidence supporting the effectiveness of parent-mediated interventions in improving developmental outcomes for children with a developmental disability as well as educating parents to be the expert in their child's development (Diggle & McConachie, 2007; Ingersoll & Wainer, 2013; Siller et al., 2013). Furthermore, the feasibility of parent-mediated interventions is important since it requires less travel and allows parents to implement the intervention from the comfort of their own home (Roger et al., 2008; Cowan & Sheridan, 2003). While parent-mediated interventions are effective and feasible, it can be difficult for parents to implement the intervention with high fidelity to the intervention protocol. Further research is needed to understand why some parents fully adhere to the intervention protocol, while others do not. Additionally, there is a need to test these research questions within a sample of individuals with DS, since previous research has focused only on ASD. By testing these ideas among parents of infants with DS, researchers can refine the implementation design of parent-mediated interventions to promote more adaptive outcomes for infants with DS.
**Parent Mediated Intervention in Down Syndrome**

**Infants with Down Syndrome.** Down syndrome is a neurogenetic disorder that is most commonly caused by the presence of a third chromosome 21, also referred to as trisomy 21. Infants with DS demonstrate delayed motor skill acquisition that may impact other areas of development, including cognition (Ulrich, Ulrich, Angulo-Kinzler & Yun, 2001). However, the phenotypic outcomes an individual exhibits are contingent upon more than the presence of a neurogenetic syndrome.

The term *behavioral phenotype* refers to a probabilistic approach of classifying behavioral expressions of a genetic syndrome (Daunhauer & Fidler, 2011). Individuals with a specific syndrome are more likely to show aspects of that syndrome's behavioral phenotype than those without the syndrome. While there are some predictable relationships between syndrome and outcomes, there is also great variability in outcomes among individuals with the same syndrome (Cassidy & Morris, 2002; Skuse, 2000). Importantly, the emergence of phenotypic outcomes is dependent upon additional factors beyond genotype, including environmental inputs and age, and is therefore not static (O'Brien, 2006).

It is because of the potential for phenotypic modifiability that many researchers have focused their interests on phenotype-informed interventions (Fidler, Philofsky, & Hepburn, 2007; O'Brien, 2000; Skuse, 2000). Researchers that have created these specific interventions adapted traditional strategies to offset the delay in development that individuals with DS exhibit. This form of syndrome-specific intervention can provide more support for individuals by targeting their unique developmental delays.

**Syndrome-Specific Interventions**

Syndrome-specific interventions target not only a certain neurogenetic syndrome, but
also developmental features associated with the syndrome (Daunhauer, & Fidler, 2011). The benefit associated with having information about the early DS behavioral phenotype is that researchers, doctors, and parents can have a clearer understanding of the individuals’ abilities. For example, it is known that individuals with DS are at risk for pronounced motor delays (Ulrich et al., 2001). By targeting early walking skills in infants with DS through specific parent-child treadmill interventions, researchers have been successfully improved walking and gait performance for infants with DS (Ulrich et al., 2001). Currently, there is only a small number of studies that have implemented early syndrome-specific interventions. While previous studies have focused on gross motor skills, the current study focuses on a more specific form of motor skill development, object exploration. The following section will explain object exploration and why it is a relevant area of study when focusing on infants with DS.

**Object Exploration**

Infant object exploration refers to the examination of toys and objects using oral, manual, and visual techniques (Ruff, 1984; Palmer, 1989). Within the first six months of life, many developmental changes in oral and visual object exploration take place (Needham et al., 2002, Gibson & Pick, 2000; Rochat 1989). Through implementing an intervention that focuses on this construct, there is potential to improve infant object exploration, which can, in turn, build a better foundation of motor skills throughout the lifespan.

An example of an early intervention that targets infant object exploration skills is the Sticky Mittens intervention (Needham et al., 2002). This intervention was created to allow infants to interact with objects without having developed the motor skills required to physically grasp the toys (Needham et al., 2002). The mittens used in this intervention were designed with Velcro sewn into them and the toys used in the intervention had the complimentary piece of
Velcro adhered to them. This Velcro technique is what allowed infants to pick up the toys and interact with them. Needham and colleagues (2002) found that typically developing pre-reaching infants (age 3 months) who received the 2-week mittens enrichment intervention significantly outperformed infants who did not have experience with mittens (Needham et al., 2002). The mittens facilitated infant contact with objects without the need for grasping behavior, which had not yet emerged with competence in the infant sample (Needham et al., 2002). While this intervention was implemented within a sample of typically developing infants, Needham and colleagues made a call for researchers to implement the Sticky Mittens intervention with a sample of infants with a neurogenetic disorder to examine intervention effects in infants with atypical development.

**Object Exploration in Infants with Down Syndrome.** Within the first year of life, parents of typically developing infants can expect their infant to react to sound, fix his or her eyes on toys, interact with toys, and grab toys for play (Layton, 2004). Infants with DS experience predisposed delays in their reaction to sounds, their eye contact, fixation on toys, and their reaching skills (Layton, 2004). While there is only a small subset of studies that have looked into object exploration in infants with DS, these studies represent the strong foundational work on this construct that highlights the need for early intervention (Ruskin et al., 1994; Rast & Meltzoff, 1995).

Since infants with DS are genetically predisposed to exhibit delays in object exploration, early interventions that support the development of reaching skills could reduce that delay and improve object exploration skill acquisition (Needham et al., 2002). In a study of reaching in infants with DS, researchers found that once the action of reaching was initiated, an increased frequency of reaches was observed (Campos et al., 2013). Although the number of reaches
performed by the infants with DS was much fewer than that of the typically developing infants, the theme of increased reaching after initiation is similar to that of typically developing infants (Campos et al., 2013). Researchers also found that even though the infants with DS failed to make physical contact with the object, they exhibited more instances of reaching for the objects than previous studies had observed (Campos et al., 2013; MacTurk et al., 1985; Landry & Chapieski, 1989). By studying object exploration in infants with DS, there is the potential to initiate reaching skills and goal-directed behaviors earlier than infants with DS typically would. Infants with DS can benefit from early intervention, which is why there is a call to continue implementing more early interventions that target goal-directed behaviors to improve their skill acquisition. The literature on object exploration skills in infants with DS, while limited, provides support for the significance in utilizing early intervention to promote reaching skills and goal-directed behaviors.
CURRENT STUDY

This study examined how parental fidelity to an intervention protocol can impact the intervention effects of an early parent-mediated intervention on object exploration skills in infants with DS. It was hypothesized that parental fidelity to an intervention protocol would moderate the effects of the intervention on infant object exploration skills. Thus, as parent fidelity increases, the relationship between the intervention and infant object exploration would strengthen, resulting in increased infant object exploration skills. This study was part of a larger study that implemented a targeted micro parent-mediated intervention to improve reaching behaviors in infants with DS. The term ‘targeted micro-intervention’ describes an intervention that is specific and timely. For this study, secondary data analyses were conducted using a dataset that has already been compiled for a larger study. This study analyzed the data using multiple regressions to test the moderating effects of parental fidelity on infant object exploration.
METHODS

Participants

For this study, the target population was infants (4 to 12 months) with DS. Sample recruitment involved convenience sampling (e.g., setting up a booth at an event for DS awareness, sharing flyers with people, and participants referring friends).

Enrollment into the study involved an email and phone call from the lab coordinator, during which the lab coordinator screened participants to ensure the eligibility criteria were met. The eligibility criteria to participate in the study were that the infant had a confirmed diagnosis of trisomy 21 through genetic testing, the infant was between 4 and 12 months of age and that the infant was exhibiting less sophisticated reaching skills. Two items from the Bayley-III were used to determine whether or not the infant would qualify for the intervention. The first item, (#30) involved retaining a block in each hand simultaneously for at least three seconds. The second item, (#33) involved attending to a novel item while retaining block in each hand. If an infant was able to complete both tasks (#30 & #33), the infant was considered too advanced for the intervention and that the intervention would not have the opportunity to improve the infant skill development. Thus, if an infant was unable to complete one or both tasks, the infant would qualify for the intervention.

The final sample consisted of 37 infants from 4 to 12 months with trisomy 21 ($M=7.04$, $SD=2.44$). The sample was 43% female and 57% male. The majority of the participants were White and non-Hispanic. Of the 37 infants in the final sample, 16 infant participants were born prematurely, 15 infant participants had a heart defect, 3 infant participants experienced heart surgery and 3 infant participants had experienced a significant illness before the baseline visit. The intervention group consisted of 19 infant participants who were randomly assigned, while
the remaining 18 participants were randomly assigned to the control group and participants were naïve to the condition group they were in. It is important to note that random assignment was implemented at the individual level for participants who lived within the region of the university, but for the participants from cities outside of the state, cluster assignment was conducted based on the city, not the individual. Families from other states that were interested in participating in the study often learned about the study through word of mouth through friends, family, and social groups. Because of this, cluster assignment in the study was based on geographical region. This was to avoid the bias of knowing the groups (e.g., intervention vs. control) that participants were assigned to, which could then impact intervention fidelity and the data collected.

Measures

It was hypothesized that parental fidelity to the intervention protocol would moderate the effects of the intervention on infant object exploration. The independent variable was a nominal variable that measured whether participants were in the intervention or alternative group (1=intervention, 0=alternative), the dependent variable was a ratio variable that measured infant object exploration, and the moderating variable was a ratio variable that measured the amount of parental fidelity to the intervention protocol.

**Parental Fidelity.** For this study, parental fidelity was quantitatively conceptualized as ‘frequency’ (e.g., total number of days that the intervention was implemented) and ‘duration’ (e.g., total number of minutes spent implementing the intervention). These data were collected from the parent logs, which provided a place for parents to record the date, duration, and any comments about the intervention. Parents were also asked to fill out the parent logs after each time they administered the intervention to their infant. This was to ensure that parents administered the intervention with fidelity.
Parent Logs. Parent logs were used to collect the duration and frequency of the intervention as well as parent comments on the intervention. To quantify the parent log responses, a coding scheme was created based on the overall themes of the parents' responses. Thematic categories were created to classify parent responses in the open-ended sections of the parent log (Braun & Clarke, 2006). The thematic categories were created based on commonalities observed throughout the parent entries. If the themes created did not fully cover each entry, another theme would be created so that all the parent entries were able to be classified into the themes created and no entry was left out. The seven thematic categories created included: 1) positive infant interest, which refers to any mention of the infant being interested in or liking the toys (e.g., interested in the blue ring), 2) negative infant interest, which refers to any mention of the infant being disinterested or disliking the toys (e.g., did not like the foam letter), 3) positive infant emotion, which refers to any mention of joyful or happy emotions being expressed (e.g., he was excited when I brought the toys out), 4) negative infant emotion which refers to any mention of sad or angry emotions being expressed (e.g., he was not happy when the toy got stuck on the mitten), 5) positive infant action, which refers to any mention of the infant actions with the toys (e.g., she reached for the red ring), 6) negative infant action, which refers to any mention of the infant lack of action with the toys (e.g., she refused to do anything with the toys) and 7) negative infant characteristics, which refers to any mention of the infant irregular current physical state (e.g., he was tired today and didn’t interact with the toys). Percent agreement was used to determine inter-rater reliability. Coders reached 80% reliability on 100% of the sample and were unaware of the purpose of this study as well as the study hypotheses.
Once the logs were coded, variables were created to represent the total number of entries for each participant, as well as the total number of times each participant mentioned each theme (e.g., total positive infant interest, total negative infant interest). Then, the total number for each category was divided by the total number of entries to create a score variable (e.g., positive infant interest score, negative infant interest score). These scores were then used to examine the associations between parents’ descriptions in the parent logs and infant outcomes. It is important to acknowledge that the intervention log data were gathered via parent-report. As a result, the descriptives are estimations, as there was no way to verify the accuracy of the reports.

**Infant Object Exploration.** At the pre and posttest visits, infants were given different reaching and grasping tasks, which were videotaped and coded. The tasks involved giving infants four balls with different properties (e.g., craters, nubs, ridges, and stringy rubber ends) for 30 seconds each time. To control for the level of interest each ball would elicit in the infants, the order of presentation of the balls varied. However, the stringy rubber end ball was always presented last, as it would elicit a higher level of interest from the infant. When the four balls were presented to the infant, they were always presented with an open palm as to not show the infant how to grasp the object and allow the infant to explore it. The infant response to the presentation of each ball was videotaped and coded for total infant swats, total infant reach attempts and latency to make contact at pre and posttest. Videos of the infants interacting with the balls at the pre and posttest assessment were coded by undergraduate research assistants with at least 80% reliability ($k=.80$) (Cohen’s Kappa = 0.84; Landis & Koch 1977; Cohen 1960).

For this study, 'infant object exploration' was broken down into three variables; 1) change in reach attempts from pre to posttest, 2) change in swats from pre to posttest, and 3) change in mean latency to make contact from pre to posttest. 'Reach attempts' was conceptualized as
reaches where the infant did not grasp the toy or have hand in a grasping position. 'Swats' was conceptualized as contact with the toy in a swatting or swinging behavior. 'Latency to make contact' was conceptualized as the time it took from the presentation of the ball by the researcher for the infant to make physical contact with the toy.

**Procedures**

This project was conducted with approval from Colorado State University’s Institutional Review Board. Consent for the study was obtained at the beginning of the baseline visit. The research team provided parents with a consent form explaining the risks, benefits, and confidentiality of this study. Parents of infant participants provided written consent before the initiation and completion of any study measures.

In the intervention group, parents were given the intervention mittens, specific toys, instructions and training on the mittens intervention. The mittens had the soft piece of Velcro sewn into them while the toys had the complimentary piece of Velcro glued to them. Parents were taught how to put the mittens on their infant and then the research team explained the intervention protocol to parents. The research team stated where the intervention should take place (e.g., at a table), how long it should be implemented each day (e.g., 5-10 minutes), under what conditions it should take place in (e.g., when the infant is fed and awake), and how many days it should be implemented (e.g., 14 to 21 days). The alternative group parents were taught an "object dance" activity to partake in with their infants, daily, for the same length of time as the intervention group (e.g., two to three weeks) and journal their experience in their parent log. The alternative group and the intervention received the same toys and instructions, but the intervention group was the only group to receive the mittens.
At the baseline visit, the research team collected all the pretest measurements for the Bayley and infant and parent demographic forms. Additionally, at baseline, the research team trained parents on the intervention and left the intervention with parents to implement for the next two to three weeks. The same measures were administered at posttest to assess the effectiveness of the intervention. The mean number of days between baseline and posttest was 21.90 days ($SD=9.40$).

Data Analysis Plan

Independent T-tests were conducted with the entire sample to examine whether parents of infants with biomedical risk factors implemented the intervention with different degrees of fidelity (e.g., duration and frequency of the intervention). Multiple regressions were also conducted with the total sample to examine whether parental fidelity moderated the effects of the intervention on infant object exploration (e.g., change in infants swats from pre to posttest, change in infant reach attempts from pre to posttest, change in infant mean latency to make contact from pre to posttest). To test the association between parental fidelity and infant outcomes between the intervention and control group, the total sample was separated, then Pearson correlations were used to examine the relationship between parental fidelity and infant outcomes. Pearson correlations were also used to test the relationship between the parent log themes and parental fidelity as well as the parent log themes and infant outcomes.
RESULTS

Parental Fidelity

Descriptive data from the intervention and control groups revealed that both the average duration and frequency of the intervention was higher for the control group than the intervention group (see Table 1). On average, the intervention group implemented the intervention for 13 days and 89 minutes, while the control group implemented the alternative intervention for 14 days and 98 minutes (see Table 1).

Table 1

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Minimum</th>
<th>Maximum</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration for Control Group</td>
<td>15</td>
<td>29</td>
<td>165</td>
<td>98.60</td>
<td>39.50</td>
</tr>
<tr>
<td>Frequency for Control Group</td>
<td>15</td>
<td>3</td>
<td>21</td>
<td>14.40</td>
<td>6.12</td>
</tr>
<tr>
<td>Duration for Intervention Group</td>
<td>15</td>
<td>15</td>
<td>185</td>
<td>89.40</td>
<td>37.14</td>
</tr>
<tr>
<td>Frequency for Intervention Group</td>
<td>15</td>
<td>2</td>
<td>21</td>
<td>13.33</td>
<td>4.95</td>
</tr>
</tbody>
</table>

Note. M and SD are used to represent mean and standard deviation, respectively.

However, it is important to note that the average number of days between pre and posttest for the control group was 23.87 days (SD=12.53) while the intervention group was only 20.04 days (SD=4.57); thus the control group had the intervention for approximately three more days than the intervention group. Of the 37 participants, 30% of parents fully completed the log, 30% of parents completed more than half of the log, 14% of parents completed less than half of the log and 26% of parents did not utilize the logs.
Infant Demographics and Parental Fidelity

In addition to examining the different levels of parental fidelity, potential sources of variability in parental fidelity were also analyzed, to understand the differing levels of parental fidelity better. Because individuals with DS are at risk for additional health complications, the impact of infant biomedical risk on parent fidelity was examined. Independent Samples T-tests were performed to examine how infant biomedical factors were associated with parental fidelity to the intervention within each condition. Findings revealed that for the intervention group, parents of infants with a congenital heart defect implemented the intervention for significantly more minutes ($M=111.29$, $SD=36.47$) than parents whose infants did not ($M=70.25$, $SD=26.86$); $t=-2.45$, $p=.032$. There were no statistically significant differences in duration or frequency of the intervention based on prematurity status, having corrective surgery, or a report of significant illness for the intervention group ($p>.05$). For the control group, there were no significant differences in duration or frequency of the intervention based on biomedical factors ($p>.05$)

Parental Fidelity as a Moderator

To investigate whether parental fidelity moderated the effects of the intervention on infant object exploration skills, a simple moderator analysis was performed using multiple regressions in SPSS. The outcome variables for these analyses were the change scores for each infant object exploration dimension: change in swats, change in reach attempts, and change in mean latency to make contact with the object. The independent variable was treatment condition (intervention vs. control). The moderator variable evaluated for analysis was parental fidelity, which was operationalized as duration and frequency of the intervention implementation. A significant moderation effect was observed between the duration of the intervention and infant change in swats ($B=.016$, 95% C.I. (.006, .027), $p=.004$). Additionally, there was a significant
moderation effect between the frequency of intervention implementation and change in infant reach attempts (B=.106, 95% C.I. (.006, .207), p=.039). Subsequent analyses revealed a significant positive association between the duration of the intervention and improvement in infant swats. There was also a significant positive association between the duration of the intervention and infant change in reach attempts. Thus, increased duration of intervention was associated with an increase in infant swat and reach attempt frequency in the treatment condition (see Table 2). No significant correlations were observed between the frequency of the intervention and infant object exploration variables for the intervention group. Neither the duration nor the frequencies of the intervention were significantly associated with infant change in mean latency to make contact with the object (see Table 2). For the control group, there were no significant associations between both the duration and frequency of the intervention and change in infant object exploration (p<.05).

Table 2

*Pearson Correlations between Duration and Frequency of the Intervention and Change in Infant Object Exploration for the Intervention Group*

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Duration of the Intervention</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Frequency of the Intervention</td>
<td>.767**</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Change in Reach Attempts</td>
<td>.619*</td>
<td>.298</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Change in Swats</td>
<td>.432</td>
<td>.348</td>
<td>.232</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>5. Change in Latency to Make Contact</td>
<td>.058</td>
<td>.255</td>
<td>-.008</td>
<td>.009</td>
<td>-</td>
</tr>
</tbody>
</table>

*Note. ** Correlation is significant at the .01 level (2-tailed).
* Correlation is significant at the .05 level (2-tailed).
Parent Logs

Pearson correlations were used to examine the association between parent log entry themes and change in infant object exploration behavior within the total sample. There was a significant negative association between the frequency of negative interest entries and change in infant swat frequency \((r = -.412, p = .011)\). More negative interest entries was associated with less improvement in infant swats from pre to post-intervention. There was also a significant negative association between negative mood entries and change in infant mean latency to make contact with the object \((r = -.549, p = .008)\). A greater frequency of negative mood entries was associated with less improvement in infant mean latency to make contact. There were no other significant correlations between the log entry themes and changes in infant object exploration behavior.

Pearson correlations were also used to examine the association between parent log entry themes and parental fidelity. There was a significant positive association between the duration of the intervention and the frequency of negative emotion entries \((r = .393, p = .043)\). More minutes spent implementing the intervention was associated with more negative emotion entries. There was also a significant positive association between frequency of the intervention and the frequency of negative emotion entries \((r = .443, p = .021)\). More days spent implementing the intervention was associated with higher frequency of negative emotion entries. There were no other significant correlations between log entry themes and parental fidelity.
DISCUSSION

This study examined whether parental fidelity to an intervention protocol would moderate the effects of a parent-mediated intervention on infant object exploration skill development. Multiple regressions revealed that there were two significant moderation effects: first, increased duration of the intervention resulted in more infant swats from pre to post-intervention for the intervention condition, but not the control condition. Second, increased frequency of the intervention resulted in increased infant reach attempts from pre to post-intervention for the intervention condition, but not the control condition. It was also found that the frequency of negative themes from the parent log entries was associated with less improvement exhibited by infant. These findings support the hypothesis that parental fidelity to an intervention protocol moderates the relationship between intervention vs. control group and infant object exploration skill development. Furthermore, they provide novel findings related to the growing body of work on parent-mediated interventions.

Intervention Effects

The intervention examined in this study was a targeted parent-mediated micro-intervention designed to improve infant object exploration skills over a short period. While this type of intervention was created for, and tested among typically developing infants (Needham et al., 2002), there was a call to implement this intervention among infants with a neurogenetic disorder, in order to test the utility and effectiveness of the intervention. Overall, results demonstrated that infants who were in the intervention condition improved in aspects of object exploration significantly more than infants in the control condition. Infants in the intervention group exhibited significant improvements in both reach attempts and swats, while infants in the control group did not demonstrate any significant improvements in object exploration skills.
These findings match that of the previous study (Needham et al., 2002), but offer new insight into using parent-mediated interventions in developmental disabilities research. Furthermore, since this intervention was tested among infants with DS, these findings provide preliminary evidence for the utility of targeted micro parent-mediated interventions among participants with significant delays in development. Based on the effectiveness of this intervention in improving outcomes, future researchers should consider implementing early parent-mediated interventions among individuals with DS to improve developmental outcomes.

**Targeted Micro Parent-Mediated Intervention**

This targeted micro intervention was selected because it focuses on improving a specific development skill over a short period. Since this intervention was successful in improving areas of object exploration in infants with DS, it is important to understand how impactful these findings are. This intervention was implemented, on average, for 14 days for a total of 94 minutes, which means only 94 minutes of participation in the Sticky Mittens intervention can potentially positively impact the development of key skills. Given the time requirements of other parent-mediated intervention (e.g., eight to 12-week programs that required an hour of practice, each day), the Sticky Mittens Intervention required very little participant time. Targeted micro parent-mediated interventions can be an efficient and effective alternative to larger and more time-intensive studies.

**Parental Fidelity**

In the current study, parental fidelity to an intervention protocol varied between the intervention and control groups. Interestingly, parents in the control group implemented the alternative intervention with greater fidelity than parents in the intervention group. On average, parents in the control group implemented the intervention for one day and 10 minutes longer
than the intervention group. However, there were only significant associations between the duration and frequency of the intervention infant object exploration change found within the intervention group.

Within the intervention group, findings revealed that infants exhibited the greatest improvement in object exploration when parents implemented the intervention for 13 days or more days. Treatment effects were reduced when parents implemented the intervention with low fidelity, thus, even with an evidence-based intervention and proper parental training, if there is low fidelity to the intervention protocol, the intervention will not be effective in improving infant outcomes. A lack of parental fidelity may be able to explain the lack of intervention effects for other studies that were not successful in improving outcomes. In 2015, Green et al. found that a parent-mediated intervention was not effective in improving positive parenting and infant responsiveness in infants with ASD, however, the researchers did not measure parental fidelity and were therefore unable to know if a lack of fidelity to the intervention was causing the decreased intervention effects. These findings show that when implementing a parent-mediated intervention, it is critical to measure and examine parental fidelity as it can explain a lack of, or, a surplus of treatment effects from the intervention.

This study examined not only the effects of fidelity on infant outcomes but also the factors that impact parental fidelity. To further understand which factors could be associated with increased parental fidelity, the relationship between infant biomedical risk factors and parental fidelity was tested. When examining infant biomedical risks and parental fidelity, parents of infants who had a heart defect implemented the intervention longer than parents of infants who did not. A potential explanation for this relationship could be that increased infant medical
vulnerability motivates parents to implement the intervention with high fidelity because they are of the developmental challenges their infants face.

**Parent Logs**

In addition to providing data on the duration and frequency of the intervention, parent logs also included parent observations regarding intervention implementation. Interestingly, certain types of parent log entries were associated with infant object exploration outcomes. Across both samples, an increased frequency of negative entries was associated with fewer gains in infant object exploration. Additionally, increased fidelity was associated with an increase in negative entries. Thus, though infants received the intervention and parents implemented the intervention with fidelity, the negative quality of infant mood, temperament, and actions were still associated with less improvement in object exploration. This could be due to the infant being tired or hungry when participating in the intervention, which could impact their mood and willingness to interact with the toys. While the intervention protocol instructed parents to implement the intervention when the infant was well-rested and well-fed, it may have been unavoidable for parents to implement the intervention solely under the ideal circumstances, which may have impacted findings.

Alternatively, parents may not have fully understood the importance of implementing the intervention in the ideal conditions and prioritized simply implementing the intervention over implementing the intervention under ideal conditions. To avoid this in the future, researchers could emphasize the significance of implementing the intervention under recommended conditions by explaining that infant fatigue and hunger will likely render the intervention ineffective.
A third possible explanation for the negative relationship observed is that parents who were implementing the intervention may not have observed the gains they were expecting to see from their infant and continued to implement the intervention in the hopes that their infant would improve. These findings show that there are broad, unanswered questions regarding parental fidelity, parent log themes, and infant outcomes in parent-mediated interventions. Future research on parent-mediated intervention should consider these different explanations for the relationship and take a deeper look into parental fidelity and desired outcomes.

**Implications**

Overall, the main findings of the current study match the findings from previous studies that have analyzed parental fidelity in parent-mediated interventions among parents of young children with ASD. For example, Kasari and colleagues (2010) found that a parent-mediated joint attention intervention for children with ASD was successful in improving child outcomes and that children of parents who implemented the intervention with high fidelity and high investment improved significantly more than the children of parents who implemented the intervention with lower fidelity and investment (Kasari et al., 2010). While their findings are in line with the current study, Kasari and colleagues (2010) also measured an additional construct that the current study did not consider, parental investment, which was measured through a pre and post-intervention survey.

The term ‘parental investment’ describes more than just fidelity to treatment methods; it encapsulates parents’ enthusiasm and beliefs in their abilities to construct a change as well as their child’s ability to change (Kasari et al., 2010). Kasari and colleagues (2010) examined how parent-mediated interventions can improve core impairments in toddlers with ASD. They found that children of parents with high investment scores exhibited stronger joint attention skills than
children of parents with lower investment scores (Kasari et al., 2010). Additionally, it was noted that parents who exhibited scores of high investment also implemented the intervention with greater fidelity to the intervention protocol. The children of parents who implemented the intervention with a high degree of fidelity exhibited higher rates of joint attention that of the children whose parents demonstrated a lower degree of fidelity to the intervention (Kasari et al., 2010). Parental investment to an intervention can drastically impact parental fidelity to an intervention, which can, in turn, affect intervention effects (Kasari et al., 2010). For this reason, more research identifying the effects of parental investment in a parent-mediated intervention is needed. In the current study, parental investment was not examined and therefore, researchers are only able to infer about reasons for low parental fidelity. If parental investment was included in the current study, researchers would be able to definitively know the reasons for low parental fidelity, which can then better inform future researchers about the reasons for low parental fidelity and how to avoid it.

In trying to determine the most effective form of an intervention to improve skills acquisition in infants with DS, these findings show that receiving the intervention along with increased parental fidelity to the intervention provides infant participants with a greater opportunity to thrive. While these findings converge with current parent-mediated research that focuses on parents of children with ASD, they also contribute novel findings to the small subset of studies that have focused on parent-mediated interventions in children with DS.

**Limitations and Future Directions**

There are several limitations of this study that should be considered. One main limitation relates to the self-report data collected via parent logs. Parent participants in this study were aware of the expected duration and frequency of the intervention and the self-reported data
collected may have been impacted by social desirability bias and exaggerated to meet the requirements of the study. Future work that utilizes parent-mediated interventions may consider including telehealth communications in the study design to allow researchers to observe, first-hand, the duration, frequency, and implementation of the intervention.

An additional consideration of the current study is the lack of qualitative data collected on parental investment in the study. While the parent logs gathered some qualitative data on the observations parents noticed, the observations solely pertained to the characteristics or actions that the infant displayed. Gathering data that solely focused on parent experiences with implementing the intervention (e.g., the challenges parents faced, how easy it was for them) would provide the researchers with data on how to improve the intervention to better fit the needs of parents. Future work using parent-mediated interventions should create a post-intervention self-report survey for parent participants to describe their experiences with implementing the intervention.

Finally, the study results are limited due to a lack of generalizability of the sample as well as sample recruitment. The majority of participants were members of white, middle-class families and, while these patterns reflect the region where the study took place, they may not reflect the broader population of infants with DS and their families. Additionally, since the sample was recruited using solely convenience sampling techniques, this also decreases the generalizability of the findings. Future work should try to include a more diverse sample and different recruitment strategies.

Conclusion

The current study builds upon previous research regarding parent-mediated interventions for young children with disabilities and contributes novel findings regarding parent-mediated
interventions among a sample of infants with DS. Most importantly, this study found that parental fidelity to an intervention protocol strengthens the intervention effects of a parent-mediated intervention for infants with DS. This type of information can be used to inform future researchers to inspire and motivate parents to adhere to the intervention protocol since their child is more likely to show an increase in gains when parents implement the intervention with high fidelity. Based on the findings presented in this study, a further examination of the reasoning behind varied parental fidelity is needed. More research of the predictors of parental fidelity will provide researchers with the opportunity to refine parent-mediated interventions to better match the parent needs as implementers of the intervention. This can, in turn, improve their child outcomes through increased parental fidelity.

Through studying parental fidelity to an intervention protocol in parent-mediated interventions among individuals with DS, the current study provides more information about the important role of the parent and emphasizes the need to standardize the parental role as the implementer of the intervention in future studies. By fine-tuning what the intervention requires of the parent to promote success and what the parent needs to foster success, researchers will be able to better support parents to be a successful agent of change in their child's life. Moreover, researchers will further develop proper intervention implementation, thus advancing more valid and reliable data that can be used to better serve and educate parents of infants with DS; most importantly, infants will benefit by receiving effective interventions that will propel their motor cognition development forward.
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