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Repetitive Behaviors in Young Children with Autism Spectrum Disorder Across Two Parent-Implemented Intervention Conditions

Deanna Tracy
REPETITIVE BEHAVIORS IN YOUNG CHILDREN WITH AUTISM SPECTRUM DISORDER ACROSS TWO PARENT-IMPLEMENTED INTERVENTION CONDITIONS

By

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# TABLE OF CONTENTS

List of Tables ................................................................................................................................. iv
Abstract ........................................................................................................................................... v

INTRODUCTION ........................................................................................................................... 1

METHODS ...................................................................................................................................... 7

  Participants .................................................................................................................................. 7
  Procedures ................................................................................................................................... 7
  Measures ................................................................................................................................... 10

RESULTS ...................................................................................................................................... 14

  Data Considerations .................................................................................................................. 14
  Exploratory Factor Analysis of RRBs ...................................................................................... 18
  Latent Growth Curve Models of RRBs..................................................................................... 20

DISCUSSION ................................................................................................................................ 24

  Limitations ................................................................................................................................ 26
  Contributions and Future Directions ......................................................................................... 26

APPENDICES ............................................................................................................................... 28

  A. IRB Approval Forms ............................................................................................................. 28
  B. Consent Forms ....................................................................................................................... 32

REFERENCES ................................................................................................................................ 42

BIOGRAPHICAL SKETCH ......................................................................................................... 47
### LIST OF TABLES

<table>
<thead>
<tr>
<th></th>
<th>Table Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Participant Demographics and Baseline Characteristics</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>RMRIS Coding Definitions</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>Descriptive Statistics of Repetitive Behaviors (All Time Points Included)</td>
<td>14</td>
</tr>
<tr>
<td>4</td>
<td>Correlations between Repetitive Behaviors (All Time Points Included)</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>Correlations between Excessive Interest across Time Points</td>
<td>16</td>
</tr>
<tr>
<td>6</td>
<td>Correlations between Repetitive Body Movements across Time Points</td>
<td>16</td>
</tr>
<tr>
<td>7</td>
<td>Correlations between Dysregulation over Change across Time Points</td>
<td>16</td>
</tr>
<tr>
<td>8</td>
<td>Correlations between Clutching Objects across Time Points</td>
<td>17</td>
</tr>
<tr>
<td>9</td>
<td>Correlations between Sensory Interests across Time Points</td>
<td>17</td>
</tr>
<tr>
<td>10</td>
<td>Correlations between Repetitive Use of Objects across Time Points</td>
<td>17</td>
</tr>
<tr>
<td>11</td>
<td>Correlations between Dysregulation over Change across Time Points</td>
<td>18</td>
</tr>
<tr>
<td>12</td>
<td>Model Fit Statistics for EFA</td>
<td>19</td>
</tr>
</tbody>
</table>
ABSTRACT

This study examined latent growth curve modeling in restricted and repetitive behaviors (RRBs) in 82 children with autism spectrum disorder (ASD) enrolled in two parent-implemented treatment conditions. Home observations were coded using the *Repetitive Movement and Restricted Interest Scales (RMRIS)* at four time points across nine months of the first treatment condition, and data were dichotomized to indicate presence or absence of each type of RRB. Results from an exploratory factor analysis determined that the best-fitting model of RRBs was unidimensional and included repetitive movements of the body, repetitive use of objects, excessive interest, dysregulation over change, clutching objects, and unusual sensory interests. A latent growth curve analysis was then conducted with dichotomized data and demonstrated that the latent RRB factor did not change significantly over time. Children did not vary significantly in their rate of growth or initial level of RRBs, and the frequency of RRBs at the end of treatment did not impact rate of growth. Additionally, treatment group and baseline scores on the *ADOS, MSEL*, and *VABS-II* did not uniquely predict change in RRBs over time. Examination of growth curve models for each observed variable demonstrated significant increase in sensory interests and significant decrease in excessive interest, with a marginally significant increase in repetitive speech.
INTRODUCTION

Autism Spectrum Disorder (ASD) is characterized by deficits in social interaction and social communication, as well as the presence of restricted and repetitive patterns of behavior, interests, or activities. Recent changes to the newest edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013) require two of four diagnostic symptoms within the restricted and repetitive behavior (RRB) domain in order to meet diagnostic criteria for ASD. RRBs listed in the DSM-5 include: (1) stereotyped or repetitive speech or movements of the body or objects, (2) excessive adherence to ritualized patterns or routines or insistence on sameness, (3) restricted or fixated interests unusual in intensity or focus, and (4) unusual sensory interests or hyporesponsivity and/or hyperresponsivity to sensory stimuli. Requiring multiple RRB symptoms is a change from the prior edition (DSM-IV-TR; American Psychiatric Association, 1994), which did not specify a minimum criterion within the domain. Additionally, the social and communication domains were merged into one social communication domain in the DSM-5, making RRB the second of two domains in the diagnostic symptomatology of ASD. This change in diagnostic criteria is supported by evidence that the presence of RRBs considerably increases the stability of ASD diagnoses over time and improves the differentiation between ASD and other disorders (Kim & Lord, 2010; Lord et al, 2006; Gotham et al, 2007; Watt et al., 2008). It also makes the presence of RRBs essential to the diagnosis of ASD.

When comparing children with ASD to typically developing children and those with nonspectrum disorders and delays (e.g., intellectual disability, language disorder, developmental delay), the severity and prevalence of RRBs have been shown to differentiate children with ASD from others, even at a young age (Kim & Lord, 2010). Toddlers between 18 and 24 months of
age diagnosed with ASD demonstrated significantly higher frequency and longer duration of RRBs, including repetitive use of objects, repetitive movements of the body, and unusual sensory behaviors, when compared to typically developing (TD) and developmentally delayed (DD) children (Watt, Wetherby, Barber, & Morgan, 2008). Use of the Systematic Observation of Red Flags of ASD (SORF), a brief rating scale of RRBs and other early red flags of ASD, has also been shown to reliably distinguish children with ASD from TD and DD children at 21 months during a standardized clinical communication assessment (i.e., the Communication and Symbolic Behavior Scales; CSBS; Wetherby & Prizant, 1993; Wetherby et al., 2004).

The presence and severity of RRBs in young children also predicts a diagnosis of ASD several years later (Lord et al., 2006). In toddlers with communication delays between 18 and 24 months, repetitive behaviors predicted developmental outcomes and severity of autism symptoms at three years of age (Watt, Wetherby, Barber, & Morgan, 2008). Including RRBs in the scoring algorithm for a clinical diagnostic assessment of ASD (i.e., the Autism Diagnostic Observation Scale; ADOS; Lord, Rutter, & Le Couteur, 1994) increases the specificity of the measure without significantly decreasing sensitivity (Gotham et al., 2007). Furthermore, when using former DSM-IV-TR diagnostic criteria, the stability of Autistic Disorder is stronger than that of Pervasive Developmental Disorder – Not Otherwise Specified (PDD-NOS), which did not require the presence of RRBs (Lord et al., 2006).

In addition to evidence based on clinical diagnostic samples, caregivers also report more frequent and severe RRBs in young children who are later diagnosed with ASD, compared to children who are typically developing or later receive a nonspectrum diagnosis (Watson et al., 2007; Richler et al., 2007). Children with autism score significantly higher on RRB items at approximately 20 months of age on a parent interview measure (i.e., the Autism Diagnostic
Interview – Revised; ADI-R; Lord, Rutter, & Le Couteur, 1994) compared to their TD and DD peers (Cox et al., 1999). There are also significant differences in RRBs reported between groups (i.e., ASD, TD, and DD) at 16 to 18 months when using retrospective parent report of children between three and four years old (Werner et al., 2005). Parent report of repetitive behaviors is also relevant to diagnostic severity of ASD, as reports on specific RRBs on the Repetitive Behavior Scale (RBS; Bodfish, Symons, & Lewis, 1999) have been shown to predict the severity of the autism symptoms overall (Bodfish, Symons, Parker & Lewis, 2000).

Though the diagnostic significance of RRBs has been well documented, there remains a gap in the literature regarding whether interventions for ASD can improve RRB symptoms in toddlers with ASD. Evidence supporting the efficacy of early intervention services has focused primarily on improvements in cognitive abilities and reduction in symptoms within the social communication and social interaction domain, often without addressing the potential treatment target of reducing repetitive behaviors. It is largely unknown whether intervention methods to improve social and cognitive functioning in toddlers with ASD might also be able to reduce the frequency and severity of RRB symptoms.

Though RRB symptoms have not been a primary focus, early intervention has been shown to be effective for reducing symptoms associated with ASD in toddlers. Several clinician-implemented interventions have been examined for potential treatment effects. A randomized controlled trial (RCT) of the Early Start Denver Model (ESDM; Dawson et al., 2010) studied intervention effects in children 18 through 30 months, demonstrating that children enrolled in the treatment condition improved in cognitive and adaptive behavior after two years of intervention. Children enrolled in the ESDM were also more likely to demonstrate improvement in diagnosis from Autistic Disorder to Pervasive Developmental Disorder – Not Otherwise Specified
(according to *DSM-IV-TR* criteria). The ESDM treatment included up to 20 hours of therapist-delivered intervention per week (though an average of 15.2 hours was utilized), along with parent-implemented strategies (parents reported using the strategies an average of 16.3 hours per week).

Another RCT examined the impact of a supplemental classroom-based curriculum targeting social engagement skills (i.e., imitation, joint attention, and affect sharing) in children 21 through 33 months (Landa et al., 2011). Toddlers in the treatment condition demonstrated significantly more imitated acts (i.e., novel movements and actions) paired with eye gaze than those in the control condition six months following intervention. Modest treatment gains were also demonstrated for joint attention and affect sharing, though between-group differences were not statistically significant. The addition of this curriculum demonstrated improvement in social imitation skills that generalized across people, time, and context. Long-term follow-up of the children at 72 months of age suggested that IQ and Communication scores also increased significantly from the beginning of treatment, though ASD severity did not change (Landa & Kalb, 2012).

In comparison to clinician-implemented interventions, parent-implemented treatments are of particular interest, as they require fewer professional hours and therefore may be more feasible for implementation in community settings. However, RCTs examining parent-implemented techniques with toddlers have not found main effects on child outcomes. They have demonstrated improvements in parent use of supports such as interaction skills (Rogers et al., 2012) and frequency of synchronous response (Green et al., 2010). The lack of impact of the parent change on child outcomes may be related to the limited number and length of intervention
sessions, as well as the context in which the intervention took place (i.e., a clinic setting instead of the home; Wetherby et al., 2014).

The present study examines archived video records from the Early Social Interaction (ESI) Project (Wetherby et al., 2014), an intervention approach that emphasizes collaborative coaching of parent implementation techniques in natural environments. The ESI Project examined two parent-implemented intervention conditions, both of which required far less professional time than the ESDM treatment (i.e., a maximum of three sessions per week). Recent analysis has shown that children in both ESI conditions demonstrated a reduction in symptom severity in the social interaction and social communication domain measured on the ADOS and improvements in expressive language skills (Wetherby et al., 2014). Children enrolled in the more intensive condition (i.e., Individual-ESI) also showed significant improvements in receptive language and adaptive communication skills.

While children in both ESI intervention conditions demonstrated improvements in ASD symptoms within the social interaction and communication domain, they also showed an increase in RRBs measured by the ADOS. Though this may seem contrary to the improvements in other ASD symptoms, it is consistent with some findings that RRBs may increase over time (Bishop, Richler, & Lord, 2006; Richler, Huerta, Bishop, & Lord, 2010) and unfold over the first few years of life (Baranek et al., 1999; Cox et al., 1999; Stone et al., 1999; Charman et al., 2005). There is also evidence that RRBs may be less likely than social and communication skills to improve with age (Piven, Harper, Palmer, & Arndt, 1996), though this has not been shown in very young children. A study on patterns of developmental trajectories in children with ASD from 18 through 36 months of age demonstrated that children with an “improving” trajectory exhibited a decrease in social affect symptoms over time but no significant improvement in RRB
symptoms (Lord, Luyster, Guthrie, & Pickles, 2012). Past evidence suggests that RRBs may be more stable in children with ASD and less malleable within intervention contexts targeting social deficits.

While evidence suggests the unfolding or increase of RRBs in the first few years of life, it is reasonable to believe that parents who are skilled in strategies to support their child’s active engagement may be able to reduce the amount of time their child spends engaging in RRBs. The ADOS provides children with objects and opportunities that increase the likelihood of eliciting RRBs (e.g., inclusion of a lid, cylinder, and ring that may elicit repetitive use of objects in the Toddler module; frequent transitions between objects and activities that may elicit distress for children who have difficulty with sudden changes), while the home context is a more naturalistic environment where parents can engage their child in various activities that encourage active engagement and participation, including family chores, social games such as “Ring Around the Rosy” or chase, and caregiving activities. The present study examined RRBs in home observations throughout the first nine months of treatment in order to understand trajectories of children in both ESI treatment conditions. It was hypothesized that children enrolled in the more intensive Individual-ESI condition would demonstrate less growth in RRB symptoms compared to children in the Group-ESI condition during the first nine months of treatment. Baseline scores of developmental level, adaptive behavior ability, and autism symptoms were also included in the model as predictors to examine whether initial child factors predict the trajectory of RRBs over time. It was hypothesized that children with higher initial scores on both the RRB and SC domains of the ADOS and lower initial scores on the cognitive and adaptive behavior subscales would demonstrate greater increases in their trajectories of RRBs over time.
METHODS

Participants

The sample included all 82 children who participated in the ESI project, regardless of dropout status: 42 initially randomized to the Individual condition, and 40 initially randomized to the Group condition. Participants were recruited at two research sites, Florida State University in Tallahassee, Florida, and the University of Michigan in Ann Arbor, Michigan. Table 1 (Wetherby et al., 2014) presents demographics and developmental characteristics at baseline for all participants. There were no significant differences between the two groups at baseline. The mean age of children at baseline was 19.64 months (SD = 1.93) for the Individual-ESI condition and 19.58 months (SD = 1.42) for the Group-ESI condition. The majority of the participants were white (73.8% of Individual-ESI; 72.5% of Group-ESI). Maternal age (Individual-ESI: 31.98 (SD = 1.93); Group-ESI: 31.71 (SD = 5.44)) and education level (Individual-ESI: 15.64 (SD = 2.07); Group-ESI: 15.51 (SD = 2.26) were also similar for both groups. There were no significant differences between conditions in developmental characteristics at baseline on the CSBS, ADOS, MSEL, or VABS-II.

Procedures

Children participating in the ESI Project at Florida State University were recruited through voluntary completion at pediatricians’ offices of the Infant-Toddler Checklist, a parent-report screening tool that is part of the CSBS. Parents were contacted for a follow-up evaluation if they received a positive screen or if parents expressed concern about their child’s development. Children recruited for the ESI Project at the University of Michigan were referred because of increased genetic risk (i.e., an older sibling with ASD) or concern for ASD. All participants were diagnosed with ASD and enrolled in the study between 16 and 20 months.
Table 1: Participant Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Individual-ESI (N=42)</th>
<th>Group-ESI (N=40)</th>
<th>p</th>
<th>Hedge’s g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>19.64 (1.93)</td>
<td>19.58 (1.42)</td>
<td>.86</td>
<td>.04</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td>.58</td>
<td>--</td>
</tr>
<tr>
<td>White (%)</td>
<td>73.8%</td>
<td>72.5%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Black (%)</td>
<td>7.1%</td>
<td>10.0%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Other (%)</td>
<td>14.3%</td>
<td>15.0%</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Maternal Age</td>
<td>31.98 (5.74)</td>
<td>31.71 (5.44)</td>
<td>.83</td>
<td>.05</td>
</tr>
<tr>
<td>Maternal Education</td>
<td>15.64 (2.07)</td>
<td>15.51 (2.26)</td>
<td>.80</td>
<td>.06</td>
</tr>
<tr>
<td>Communication and Symbolic Behavior Scales</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Composite</td>
<td>37.02 (17.25)</td>
<td>39.49 (21.11)</td>
<td>.57</td>
<td>.13</td>
</tr>
<tr>
<td>Speech Composite</td>
<td>8.61 (2.32)</td>
<td>6.50 (10.03)</td>
<td>.42</td>
<td>.18</td>
</tr>
<tr>
<td>Symbolic Composite</td>
<td>24.00 (16.60)</td>
<td>21.54 (15.15)</td>
<td>.49</td>
<td>.15</td>
</tr>
<tr>
<td>Autism Diagnostic Observation Schedule</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Affect (SA)</td>
<td>13.50 (4.28)</td>
<td>14.43 (3.86)</td>
<td>.47</td>
<td>.17</td>
</tr>
<tr>
<td>Restricted and Repetitive Behaviors (RRB)</td>
<td>3.05 (1.50)</td>
<td>2.85 (1.55)</td>
<td>.66</td>
<td>.10</td>
</tr>
<tr>
<td>Vineland Adaptive Behavior Scales</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>78.83 (13.06)</td>
<td>79.79 (13.51)</td>
<td>.98</td>
<td>.01</td>
</tr>
<tr>
<td>Daily Living</td>
<td>86.60 (10.98)</td>
<td>87.42 (11.97)</td>
<td>.97</td>
<td>.01</td>
</tr>
<tr>
<td>Socialization</td>
<td>84.55 (8.77)</td>
<td>87.21 (9.62)</td>
<td>.52</td>
<td>.15</td>
</tr>
<tr>
<td>Motor</td>
<td>94.55 (8.85)</td>
<td>95.34 (11.66)</td>
<td>.72</td>
<td>.08</td>
</tr>
<tr>
<td>Mullen Scales of Early Learning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visual Reception</td>
<td>42.07 (13.01)</td>
<td>40.42 (10.44)</td>
<td>.45</td>
<td>.17</td>
</tr>
<tr>
<td>Fine Motor</td>
<td>46.20 (11.59)</td>
<td>42.48 (12.65)</td>
<td>.15</td>
<td>.33</td>
</tr>
<tr>
<td>Receptive Language</td>
<td>29.27 (12.34)</td>
<td>31.35 (12.61)</td>
<td>.39</td>
<td>.19</td>
</tr>
<tr>
<td>Expressive Language</td>
<td>29.61 (11.22)</td>
<td>28.68 (10.95)</td>
<td>.66</td>
<td>.10</td>
</tr>
</tbody>
</table>

*Note. P and Hedge’s g values refer comparison of Individual ESI and Group ESI groups.*

ESI = Early Social Interaction Project

After baseline assessments were completed, families were randomly assigned to either Individual-ESI or Group-ESI for the first nine months of treatment before beginning the second condition, for a total enrollment time of 18 months. Individual-ESI aims to teach parents skills to support their child’s communication, social, and play skills in everyday activities in familiar
settings (e.g., the home, familiar community settings). During this RCT, Individual-ESI was offered in three weekly sessions for the first six months (two in the home and one in the clinic) and two weekly sessions for the following three months (one in the home and one in a community setting, such as a grocery store or restaurant). The number of sessions was reduced at the end of treatment in order to encourage parents to generalize their skills and maintain implementation independently. Interventionists were trained to utilize a four-step coaching model when collaborating with parents: 1) identifying successful strategies and working directly with the child, if needed; 2) actively guiding parents through use of strategies while giving consistent feedback during activities; 3) allowing parents to take the lead in implementation of skills and giving feedback; and 4) giving parents an active role to encourage independence. Parents were also encouraged to employ strategies 25 hours per week within everyday activities and to track the hours that they implemented the treatment skills every week.

Group-ESI allows families to receive information about social communication development based on the SCERTS curriculum (Prizant et al., 2006) in educational meetings and to engage in toddler playgroups led by an interventionist. In this RCT, Group-ESI was offered weekly for a period of nine months. The first session of every month provided parents with information about the main topic of focus (e.g., emotional regulation, play) in education meetings without their children, and subsequent sessions throughout each month were spent in a playroom where parents practiced implementing skills with their children while the interventionist provided feedback and support.

Data used in the current study were coded from video-recorded home observations during the first condition of treatment for each family to measure parent implementation of intervention strategies and supports without the interventionist present. Home videos were obtained once per
month during treatment, at which time a videographer visited the family’s home to document a naturalistic observation of the parent and child interacting for approximately one hour. One home observation was selected at baseline and approximately every three months of treatment for nine months, until the families crossed over into the second treatment condition. During the home observations, parents were instructed to implement intervention strategies that they had been learning while participating in at least five of six different types of activities for an hour. The six activity categories included playing with people, playing with toys, looking at books, meals and snacks, caregiving, and family chores.

**Measures**

As recommended by the National Research Council (NCR; NRC, 2001), multiple settings and contexts (i.e., clinic, home, and parent report) were observed and rated using diagnostic measurement tools in order to determine a best estimate diagnosis of ASD for children enrolled in the ESI Study. Diagnosticians were blind to condition for re-evaluations throughout treatment.

** Autism Symptoms.** The *ADOS – T Module* is a semi-structured, standardized assessment of communication, social interaction, and play for children referred because of possible autism. It was selected because it is the most accurate measure of autism symptoms for children in this age range. The algorithm subtotals (Social Affect, Restricted and Repetitive Behavior) from the *ADOS - T* were be used as ratings of autism symptoms.

**Adaptive Behavior.** The *Vineland Adaptive Behavior Scale, Second Edition (VABS-II; Sparrow, Cichetti, & Balla, 2004)* yields a standard score in four domains: Communication, Daily Living, Social, and Motor, as well as an Adaptive Behavior Composite. The *VABS-II* uses a parent or caregiver report of the child’s behavior and abilities to determine adaptive functioning level.
Developmental Level. The *Mullen Scales of Early Learning* (MSEL: Mullen, 1995) is a standardized assessment of cognitive functioning for children between birth and 5 years, 8 months of age that is administered directly to the child. Standard scores on Visual Reception, Fine and Gross Motor skills, and Expressive and Receptive Language abilities were obtained and combined to yield an overall developmental ability score.

Repetitive Behavior. Coding definitions from the *Repetitive Movement and Restricted Interest Scales* (RMRIS; Wetherby, Morgan, & Stronach, 2011) were used. The RMRIS was adapted from the *Repetitive and Stereotyped Movement Scales: Companion to the CSBS* (Morgan et al., 2008) to include behaviors in all four categories in the *DSM-5*. Coding definitions are included in Table 2.

Archival video files coded according to the RMRIS definitions in *Noldus Pro Observer®* were used to analyze RRBs within home observation sessions. Use of this software allowed for precise coding of the frequency of behaviors of interest. Coders rated up to four home observations during the first condition of treatment for all participants in the study at baseline and approximately every three months until crossover into the second condition. RRBs, including clutching objects, repetitive movements of the body, repetitive movements with objects, repetitive speech, dysregulation over change, and unusual sensory interests, were coded for frequency within each home observation. A partial-interval coding system (Merrell, 2003) was used to code for presence of excessive interest, as this behavior is judged qualitatively over a period of time. After each three-minute interval, a code was entered to indicate presence or absence of excessive interest within the segment. Frequency of each of the behaviors was calculated to indicate how many times a behavior was observed within the hour.
Table 2: RMRIS Coding Definitions

**Repetitive or stereotyped speech or movements with the body or objects**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repetitive and stereotyped movements or posturing of body, arms, hands, or fingers</td>
<td>Displays at least three consecutive movements in the following categories: flaps arms or hands; rubs body part; pats, taps, or presses body part; or stiffens fingers, hands, or arms</td>
</tr>
<tr>
<td>Repetitive or stereotyped movements with objects</td>
<td>Displays at least three movements with an object in the following eight categories: swipes object away; rubs or squeezes object; rolls object or knocks over to roll object; rocks, flips, turns over, or flicks object; spins or wobbles object; collects object; moves or places objects to one location; and lines up or stacks objects</td>
</tr>
</tbody>
</table>

**Excessive insistence on sameness or adherence to ritualized patterns or routines**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clutches object across activities</td>
<td>Holds onto an object from the previous activity and does not release the object easily with either offer of a new object or at least one attempt by an adult to remove the object</td>
</tr>
<tr>
<td>Dysregulation over object removal</td>
<td>Shows an episode of negative affect that is a clear vocal expression of frustration or distress lasting at least 5 seconds in response to removing an object</td>
</tr>
</tbody>
</table>

**Restricted or fixated interests unusual in intensity or focus**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sticky attention to objects</td>
<td>After a new object is presented and available to the child to control, looks at and does not disengage attention from that object until at least 10 seconds</td>
</tr>
<tr>
<td>Excessive interest in specific objects or actions</td>
<td>Overly focused on, preoccupied with, or intensely interested in a particular object, set of objects, or a particular action on objects</td>
</tr>
</tbody>
</table>

**Unusual sensory interests or hyporesponsivity and/or hyperresponsivity to sensory stimuli**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unusual sensory interests</td>
<td>Unusual, detailed, or prolonged sensory exploration or examination (i.e. licks, smells, rubs to feel textures, stares or visually fixates)</td>
</tr>
</tbody>
</table>
Interrater reliability was calculated prior to data coding using *Noldus Pro Observer*®. Coders completed 10 hour-long training videos of children with ASD who were not participating in this study. Reliability of at least a kappa (κ) coefficient of .80 was obtained for all coders before they were considered reliable. For adequate interrater reliability, κ coefficients should be .80 or higher (Landis & Koch, 1977). Interrater reliability was also calculated between coders for randomly selected video recordings to measure drift for 10% of the data (29 videos). κ coefficients ranged from .81 to .99 with a mean κ coefficient of .91. Reliability between coders was also examined for each behavior, and low reliability was observed for repetitive movements of the body (κ = .69), likely due to the high rate of these behaviors observed in some children and greater chance for variability in coding. Interrater reliability for other behaviors was within the expected range (repetitive use of objects: κ = .94; repetitive speech: κ = .97; clutch: κ = .91; dysregulation over change: κ = .99; excessive interest: κ = .99; sensory interest: κ = .96)
RESULTS

Data Considerations

The data demonstrated a non-normal distribution (see Table 3 below for descriptive statistics), which can be expected because (1) numerous children did not exhibit a given RRB (e.g., repetitive speech) within the hour-long observation, and (2) the variability in frequency between children was substantial, as some children exhibited several instances of specific RRBs (e.g., repetitive movements of the body) throughout the observation, while others did not exhibit any.

Because of the high likelihood of a repetitive behavior not occurring within the home observation, there was a large proportion of the data coded as zeros (clutching objects: 65.2%; repetitive body movements: 41.0%; repetitive use of objects: 65.5%; repetitive speech: 89.9%; dysregulation over change: 73.0%; excessive interest: 78.2%; unusual sensory interest: 64.2%). This resulted in data that were highly positively skewed and leptokurtic. In order to account for the inflation of zeros, data were recoded with each RRB as a dichotomous variable representing the presence or absence of the behavior within the home observation. Children who exhibited the

Table 3: Descriptive Statistics of Repetitive Behaviors (All Time Points Included)

<table>
<thead>
<tr>
<th>Repetitive Behavior</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Skewness</th>
<th>Kurtosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clutches Objects</td>
<td>0</td>
<td>33</td>
<td>1.48</td>
<td>3.41</td>
<td>4.35</td>
<td>28.18</td>
</tr>
<tr>
<td>Repetitive Body Movements</td>
<td>0</td>
<td>333</td>
<td>7.06</td>
<td>23.81</td>
<td>10.05</td>
<td>124.92</td>
</tr>
<tr>
<td>Repetitive Use of Objects</td>
<td>0</td>
<td>32</td>
<td>1.46</td>
<td>3.71</td>
<td>4.64</td>
<td>25.81</td>
</tr>
<tr>
<td>Repetitive Speech</td>
<td>0</td>
<td>22</td>
<td>0.47</td>
<td>2.13</td>
<td>6.96</td>
<td>57.16</td>
</tr>
<tr>
<td>Excessive Interest</td>
<td>0</td>
<td>6</td>
<td>0.32</td>
<td>0.77</td>
<td>3.92</td>
<td>21.66</td>
</tr>
<tr>
<td>Dysregulation over Change</td>
<td>0</td>
<td>13</td>
<td>0.49</td>
<td>1.30</td>
<td>6.08</td>
<td>49.92</td>
</tr>
<tr>
<td>Unusual Sensory Interest</td>
<td>0</td>
<td>27</td>
<td>1.31</td>
<td>3.19</td>
<td>4.4</td>
<td>24.11</td>
</tr>
</tbody>
</table>
RRB at any time during the observation received a code of one, while children who did not demonstrate the behavior received a code of zero.

Correlations between variables were also examined using Pearson’s product-moment correlation coefficients (see Table 4). All relationships were negligible ($r < .2$), except the relationship between dysregulation over change and repetitive movements of the body, which demonstrated a strong positive correlation ($r = .63$). The data demonstrate that RRBs did not frequently and consistently co-occur. Correlations for each RRB observed variable were also examined across the four time points (see Tables 5-11). Results demonstrated that several RRBs were not significantly correlated with each other at different observational time points, indicating that these behaviors are not consistent over time. Exceptions to this pattern of results included excessive interest at times two and four, repetitive body movements at times two and three, dysregulation over change at times two and three, repetitive use of objects at times three at four, repetitive speech at times one and three, and unusual sensory interests at times one and two, two and three, and two and four.
Table 5: Correlations between Excessive Interest across Time Points

<table>
<thead>
<tr>
<th></th>
<th>E1</th>
<th>E2</th>
<th>E3</th>
<th>E4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Excessive Interest at time 1 (E1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Excessive Interest at time 2 (E2)</td>
<td>-0.11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Excessive Interest at time 3 (E3)</td>
<td>-0.11</td>
<td>-0.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Excessive Interest at time 4 (E4)</td>
<td>-0.09</td>
<td>0.27*</td>
<td>-0.08</td>
<td></td>
</tr>
</tbody>
</table>

**Significant at .01

Table 6: Correlations between Repetitive Body Movements across Time Points

<table>
<thead>
<tr>
<th></th>
<th>RB1</th>
<th>RB2</th>
<th>RB3</th>
<th>RB4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Repetitive Body Movements at time 1 (RB1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Repetitive Body Movements at time 2 (RB2)</td>
<td>0.12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Repetitive Body Movements at time 3 (RB3)</td>
<td>-0.06</td>
<td>0.88**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Repetitive Body Movements at time 4 (RB4)</td>
<td>-0.01</td>
<td>0.16</td>
<td>0.02</td>
<td></td>
</tr>
</tbody>
</table>

**Significant at .01

Table 7: Correlations between Dysregulation over Change across Time Points

<table>
<thead>
<tr>
<th></th>
<th>D1</th>
<th>D2</th>
<th>D3</th>
<th>D4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Dysregulation over Change at time 1 (D1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Dysregulation over Change at time 2 (D2)</td>
<td>0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Dysregulation over Change at time 3 (D3)</td>
<td>0.19</td>
<td>0.80**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Dysregulation over Change at time 4 (D4)</td>
<td>0.18</td>
<td>0.09</td>
<td>-0.03</td>
<td></td>
</tr>
</tbody>
</table>

**Significant at .01
Table 8: Correlations between Clutching Objects across Time Points

<table>
<thead>
<tr>
<th></th>
<th>C1</th>
<th>C2</th>
<th>C3</th>
<th>C4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Clutches at time 1 (C1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Clutches at time 2 (C2)</td>
<td>0.03</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Clutches at time 3 (C3)</td>
<td>0.19</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Clutches at time 4 (C4)</td>
<td>0.23</td>
<td>0.06</td>
<td>0.13</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Correlations between Sensory Interests across Time Points

<table>
<thead>
<tr>
<th></th>
<th>S1</th>
<th>S2</th>
<th>S3</th>
<th>S4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unusual Sensory Interests at time 1 (S1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Unusual Sensory Interests at time 2 (S2)</td>
<td>0.31**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Unusual Sensory Interests at time 3 (S3)</td>
<td>0.06</td>
<td>0.52**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Unusual Sensory Interests at time 4 (S4)</td>
<td>0.09</td>
<td>0.44**</td>
<td>0.18</td>
<td></td>
</tr>
</tbody>
</table>

**Significant at .01

Table 10: Correlations between Repetitive Use of Objects across Time Points

<table>
<thead>
<tr>
<th></th>
<th>RO1</th>
<th>RO2</th>
<th>RO3</th>
<th>RO4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Repetitive Use of Objects at time 1 (RO1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Repetitive Use of Objects at time 2 (RO2)</td>
<td>-0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Repetitive Use of Objects at time 3 (RO3)</td>
<td>-0.04</td>
<td>-0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Repetitive Use of Objects at time 4 (RO4)</td>
<td>-0.02</td>
<td>0.05</td>
<td>0.28*</td>
<td></td>
</tr>
</tbody>
</table>

* Significant at .05
Because of the nature of longitudinal studies, 19 of the 82 children (23%) did not have observation footage for all four time points due to attrition. Using an intent-to-treat model, all participants were included in the analysis regardless of dropout status. Growth modeling procedures allow for flexibility in handling longitudinal data, as they do not require that all subjects have data for all time points, nor do they require all time points to be equally spaced. Because the data were coded dichotomously as present or absent, weighted least squares estimation (using the WLSMV estimator in MPLUS) was used to handle missing data. Though WLSMV is more restrictive than a maximum-likelihood estimator in regard to assumptions about missing data, it yields relatively consistent estimates under general missing data assumptions (Asparouhov & Muthen, 2010).

**Exploratory Factor Analysis of RRBs**

Seven repetitive behaviors were included in the initial analysis as potential indicators of a latent RRB construct based on observational data in the home context. These variables were based on DSM-5 criteria using RMRIS coding definitions, including repetitive use of objects, repetitive movements of the body, repetitive speech, clutching, unusual sensory interests,
dysregulation over change, and excessive interest. All seven variables were examined for fit at baseline using an exploratory factor analysis (EFA) with geomin oblique rotation.

Fit indices were examined using an EFA conducted in MPLUS 7.2 (Muthen & Muthen, 2011), and a one-factor model demonstrated the best fit to the data (see Table 12 for model fit statistics), with the first eigenvalue accounting for 36% of the variance, which is close to the recommended amount (i.e., 40%) of variance that a unidimensional measure should capture (Reckase, 1979; Sinar & Zickar, 2002). Chi-square difference testing demonstrated that the two-factor model was not preferable because of similar model fit and reduced parsimony. A three-factor model did not converge. Examination of the scree plot (Cattell, 1996) also supported a unidimensional model, with the “elbow” between the first and second eigenvalues.

Comparative Fit Index (CFI) and Tucker Lewis Index (TLI) values that are greater than or equal to .95 indicate a good fit of the model to the data (Hu & Bentler, 1999). Additionally, small root mean square error of approximation (RMSEA) values indicate better fit, with RMSEA values less than or equal to .05 indicating good fit (Hu & Bentler, 1999). CFI, TLI, and RMSEA values were similar for the one- and two-factor model, all within the recommended range. However, TLI values exceeded 1.0, CFI values were exactly one, and RMSEA values were exactly zero, which may indicate problems with the model.

<table>
<thead>
<tr>
<th>Model</th>
<th>$\chi^2$</th>
<th>$df$</th>
<th>$\chi^2/df$</th>
<th>CFI</th>
<th>TLI</th>
<th>RMSEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Factor</td>
<td>9.617</td>
<td>14</td>
<td>0.687</td>
<td>1.000</td>
<td>1.203</td>
<td>0.000</td>
</tr>
<tr>
<td>2-Factor</td>
<td>3.809</td>
<td>8</td>
<td>0.476</td>
<td>1.000</td>
<td>1.339</td>
<td>0.000</td>
</tr>
</tbody>
</table>
Variables were then examined based on their correlation to the unidimensional factor using geomin rotated loadings. Repetitive movements of the body demonstrated the highest loading (.73), followed by repetitive use of objects (.67), dysregulation over change (.66), clutching objects (.48), unusual sensory interests (-.44), and excessive interest (.30). Repetitive speech was eliminated from the model because of its low frequency (89% of the participants did not exhibit this behavior) and small loading (-.02).

**Latent Growth Curve Models of RRBs**

Latent growth curve modeling was conducted using MPLUS 7.2 (Muthen & Muthen, 2011) to assess for change in RRBs over time and to determine the degree to which treatment group and baseline scores on the MSEL, VABS-II, and ADOS were predictive of RRB change across the four observation points. There are several advantages to using growth curve models over traditional methods that assess for change. Growth curves decrease Type I error associated with repeated measures, distinguishing true change from measurement error (Hertzog & Rovine, 1985; Vasey & Thayer, 1987). Including all four time points available also offers increased reliability compared to pre-post designs (Rogosa, Brandt, & Zimowski, 1982), which provides more sensitivity when assessing for behavioral changes over time (Speer & Greenbaum, 1995). An unconditional model for the RRB latent construct was first fit to the data before adding predictor variables. Dichotomous data indicating presence or absence of behaviors was also used in this analysis because of the zero-inflated nature of the data. The WLSMV estimator in MPLUS was utilized to handle missing data. The complete model is shown in Figure 1. Time was centered at the end of treatment. To account for measurement invariance, factor loadings were constrained to equality across observations. Nesting was not accounted for in the analysis because treatment group and coders were randomly assigned to children, and treatment was also
used to predict change. Correlated error terms were allowed for each observational code across all observation periods, as is recommended for longitudinal structural models (Hoyle & Smith, 1994).

The LGM model of RRBs did not provide a good fit to the data ($\chi^2 = 312.59 \ [df = 281]$, $p = .09$, CFI = 0.65, TLI = 0.65, RMSEA = 0.04). The predicted value increase in RRB for one unit increase in time was slightly negative and marginally significant (slope = -.07, $p = 0.09$), demonstrating that RRBs decreased slightly, but did not change significantly over time. The correlation between the predicted value increase in RRB latent factor intercept and slope was also not significant (estimate = 0.04, $p = 0.45$), indicating that the level of RRBs at the end of treatment did not impact rate of growth. Additionally, the variance for the slope (variance = .03, $p = .43$) and intercept (variance = .20, $p = .14$) were not significant, indicating that children did not vary in their rate of growth or final level of RRBs.

Adding in treatment as a predictor to the RRB latent factor model did not significantly improve the fit of the model ($\chi^2 = 331.56 \ [df = 303]$, $p = .12$, CFI = 0.69, TLI = 0.70, RMSEA = 0.03), and treatment did not predict change in RRB (estimate = 0.06, $p = 0.52$). The ADOS, MSEL, and VABS-II baseline scores were also examined to determine whether they predicted change in RRBs. The Motor Skills standard score on the VABS-II was the only score that showed significant results, but the effect was minimal (estimate = -.01, $p = .03$). All other scores did not significantly predict change in RRB (estimates = -.00 - .01, $p = .17 - .89$). Baseline measure scores were also not significantly associated with the intercept.

Because of the poor fit of the LGM model, further analyses were conducted to examine potential change using growth models for each observed variable. Unusual sensory interests (slope = 0.42, $p = 0.01$) and excessive interest (slope = -0.07, $p = 0.02$) demonstrated
Figure 1: Latent Growth Curve Model
significant change over time, with frequency of sensory interests increasing and frequency of excessive interests decreasing. Repetitive speech showed moderately significant results with an increase over time (slope = 0.10, \( p = .06 \)). No other variables demonstrated significant change over time (repetitive use of objects: \( p = -.48, 0.45 \); repetitive body movements: slope = 0.55, \( p = 0.46 \); dysregulation over change: -0.01, \( p = 0.87 \); clutching objects: slope = -.15, \( p = .33 \)). The slope variance was also not significant for any of the variables.
DISCUSSION

Results of this study demonstrated that RRBs in the home could be coded reliably; however, examination of the relations between the frequency of specific RRBs over time suggested that, in most cases, children’s displays of RRBs in the home setting were not consistent over three-month time intervals. That is, for most RRBs, whether a child displayed a high or low level at any one point in time had little relation to the level of that RRB displayed at another point in time. Moreover, although the results of this study indicate that RRBs can be represented as a single factor, there was little evidence that there was either reliable overall change across time in RRBs or reliable individual differences in changes in RRBs across time. That is, upon examination of a latent growth curve model, results demonstrated that the RRB unidimensional factor did not change significantly over time. Given this finding, it was unsurprising that neither treatment group nor baseline measures (i.e., ADOS, MSEL, and VABS-II) predicted growth of RRBs. The one exception to this pattern of results was that the Motor Skills subscale on the VABS-II did predict change in RRBS; however, the effect was small. When growth models were examined for each observed variable, unusual sensory interests demonstrated a significant increase over time, excessive interest decreased significantly over time, and repetitive speech showed moderately significant change with a small increase over time. There were no significant individual differences in growth, as evidenced by nonsignificant slope variances for all variables.

There are several potential reasons to explain why the RRB factor did not show significant change over time in the home context, despite evidence that RRBs increased when assessed through standardized clinical measures. First, evidence from the growth curve models on individual observed variables demonstrated that while most RRBs did not change over time,
others showed both an increase (i.e., unusual sensory interests) and a decrease (i.e., excessive interest) over time. When examined as a unidimensional factor, these combined increases and decreases could result in no change overall. Second, the home context may elicit fewer RRBs than would be expected in a more structured setting in which RRBs are elicited. Third, because parents had been encouraged to utilize intervention strategies during these observations and to engage in naturalistic daily activities, RRBs may have occurred less frequently throughout all time points, giving them a lower likelihood of exhibiting change over time. Finally, there may be inconsistencies in the opportunities available for the child to engage in RRBs within the home observations, which is unlike a controlled research setting. For example, a child who demonstrates repetitive use of objects frequently in one observation may not demonstrate the behavior at all in another observation if the preferred object is unavailable, allowing frequency to occur conditionally based on the presence of the object. Because of these factors, observing consistent change may be unlikely in the home context during parent-implemented intervention sessions.

The results also did not demonstrate that baseline scores on the ADOS, MSEL, and VABS-II predicted change of RRBs over time, which was likely due to the fact that there was no reliable change over time and, therefore, no reliable variance to predict change. The results could also suggest that RRBs remain consistent over time despite cognitive level and severity of autism symptoms at the beginning of treatment. One of the subscales (i.e., the Gross Motor subscale on the VABS-II) did significantly predict change. This may be a result of adding the predictor into the model, which can increase power and the likelihood of obtaining significant results. The results demonstrate that children who have better motor skills show a greater decrease in RRBs over time. This could suggest that children with more advanced motor skills (e.g., climbing
stairs, kicking a ball, balancing on one foot) at the beginning of treatment show a better trajectory in their frequency of RRBs during the first nine months of treatment compared to those with further delayed motor skills.

Limitations

There were several issues with the data that could limit the interpretability of the results, including non-normality and negligible relationships between most variables conducted in the EFA. Because of these difficulties and restrictions with handling zero-inflated data in MPLUS, results should be interpreted with caution.

It should also be noted that the RMRIS coding system is not yet a validated tool, and as such, its accuracy in measuring RRB constructs is unknown. Additionally, the procedure of coding each type of RRB separately may have limited use with this type of data set, which consists of numerous children who did not demonstrate certain behaviors at all within the hour-long observation. Using a Likert-scale coding system to rate overall level of RRBs based on frequency and severity may have provided data that were more synonymous to a normal distribution and more likely to achieve good model fit.

Contributions and Future Directions

Use of coding methods for symptoms in the home could be informative when assessing the overall impairment of children with ASD in naturalistic contexts to understand the impairment in daily living skills and during interactions with familiar caregivers. Clinical assessments in structured settings may elicit RRBs at a higher rate than if the child were engaged in typical daily activities. This study provides information on the low frequency at which RRBs are demonstrated in naturalistic home settings when a parent is interacting with the child and potentially applying intervention strategies. The importance of RRBs in more structured settings,
however, is also clinically significant in determining impairment in unfamiliar settings or in more demanding contexts, such as a classroom.

When considering the current diagnostic criteria for ASD, the use of a clinical assessment tool (e.g., the *ADOS*) that elicits RRBs may be essential to obtain evidence of two types of RRBs required to receive a diagnosis. Due to the low frequency of these behaviors in naturalistic settings, caregiver report and home observations may not be sufficient in determining the presence or severity of the RRB symptoms. This evidence suggests that professionals should rely on structured assessments when determining diagnoses, using questionnaires, parent interviews, and other observations as additional information informing the diagnosis.

Although it may be crucial to elicit RRBs when assessing the presence of ASD symptoms, it may also be important to understand the extent to which symptoms are impairing in naturalistic environments. The low frequency at which RRBs occurred in this sample of children with ASD demonstrates the extensive range of information on severity of symptoms and impairment that can be gathered from observing a child in multiple contexts. Future research should examine additional observational methods of assessing symptoms in the home to explore whether supplementing *ADOS* scores in a clinical setting with more comprehensive data on RRBs across contexts might better predict prognosis and treatment outcomes.
APPENDIX A

IRB APPROVAL FORMS

Florida State University
Office of the Vice President For Research
Human Subjects Committee
P. O. Box 3062742
Tallahassee, Florida 32306-2742
(850) 644-8673 · FAX (850) 644-4392

RE-APPROVAL MEMORANDUM

Date: 11/13/2014

To: Amy Wetherby

Address: MC 7814

Dept.: COLLEGE OF MEDICINE

From: Thomas L. Jacobson, Chair

Re: Re-approval of Use of Human subjects in Research:
   Early Social Interaction Project: Parent Implemented Intervention for Toddlers with Autism Spectrum (Grant Title: 1/2-Effects of Parent-Implemented Intervention for Toddlers with Autism Spectrum)

Your request to continue the research project listed above involving human subjects has been approved by the Human Subjects Committee. If your project has not been completed by 02/11/2015, you are must request renewed approval by the Committee.

If you submitted a proposed consent form with your renewal request, the approved stamped consent form is attached to this re-approval notice. Only the stamped version of the consent form may be used in recruiting of research subjects. You are reminded that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report in writing, any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chairman of your department and/or your major professor are reminded of their responsibility for being informed concerning research projects involving human subjects in their department. They are advised to review the protocols as often as necessary to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

Cc:
HSC No. 2014.12131
Office of the Vice President For Research
Human Subjects Committee
P O Box 3062742
Tallahassee, Florida 32306-2742
(850) 644-8673 · FAX (850) 644-4392

APPROVAL MEMORANDUM (for change in research protocol)

Date: 06/20/2014

To: [Redacted]

Address: MC 7814

Dept: COLLEGE OF MEDICINE

From: Thomas L. Jacobson, Chair

Re: Use of Human subjects in Research
Project entitled: Early Social Interaction Project: Parent Implemented Intervention for Toddlers with Autism Spectrum
(Grant Title: 1/2-Effects of Parent-Implemented Intervention for Toddlers with Autism Spectrum)

The application that you submitted to this office in regard to the requested change/amendment to your research protocol for the above-referenced project has been reviewed and approved.

Please be reminded that if the project has not been completed by 02/11/2015, you must request renewed approval for continuation of the project.

By copy of this memorandum, the chairman of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance Number is IRB00000446.

Cc:
HSC NO. 2014.13160
Revision(s) to an Approved Study Form

Revisions may range from a request to change a typographical error in the consent form to a significant change in the study design. Federal regulations and University policy require that each change must be reviewed and approved by the IRB prior to initiation. Revisions include amendments, modifications, addenda, updates, and administrative changes, additions, and other labels identified with study changes.

Minor revisions involve procedures that are no more than minimal risk, or risks to subjects are not increased, and/or the revision is not a significant alteration of the study design.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. At FSU, the Chair is designated to review and approve minor revisions to approved studies. Examples may include changes in telephone numbers, addition or deletion of associates or staff, reduction in the number or research participants, or the deletion of questions in a survey.

Substantive (major) revisions: Any revision to a study that involves increased risk to subjects or significantly affects the nature of the study must be reviewed by the full IRB. Examples may include revisions to the recruitment plan, adding, revising, eligibility criteria, adding or changing a research site, changing the Principal Investigator, or changing the consent form to include a newly identified side effect.

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Early Social Interaction Project: Parent Implemented Intervention for Toddlers with Autism Spectrum (Grant Title: 1/2-Effects of Parent-Implemented Intervention for Toddlers with Autism Spectrum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Number</td>
<td>2014.12131</td>
</tr>
<tr>
<td>Review Type</td>
<td>Full Committee</td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>Amy Wetherby</td>
</tr>
</tbody>
</table>

Changes are requested to the followings:

- Protocol

Describe the proposed revision(s) to the study and justification (rationale) for the revision. If changes are requested in the protocol state each section in which changes are requested and fill out those sections in the application provided:

The study is complete and we are in the data coding and analysis stage. I would like to add the following doctoral student as a new research staff to code and analyze data from this study:
Revision(s) to an Approved Study Form

Name: Tracy, Deanna
Role on Project: Research Staff
Highest Earned Degree: Bachelor's
Mailing Address: MC 7814
Phone Number: 644-4367
University Department: College of Medicine
Email: [REDACTED]
The training and education completed in the protection of human subjects or human subjects records: NIH (Certificate is uploaded)
Occupational Position: Doctoral Student in Clinical Psychology

There are not changes in the protocol.

State whether the proposed revision(s) increases or decreases the risk to participants (thereby changing the risk/benefit ratio) and if so, describe. If the level of risk remains the same, please describe this as well.

- Same

Description:
No change in risk/benefit ratio

Uploaded Documents
- Deanna Tracy NIH Human Research Training Certificate 6-15-14.pdf (75.2KB)
APPENDIX B

CONSENT FORMS

FLORIDA STATE UNIVERSITY
CONSENT TO BE PART OF A CLINICAL RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians who are giving permission for a child, please note: in the sections that follow the word ‘you’ refers to ‘you and your child.’

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Early Social Interaction Project

1.2 Agency or foundation sponsoring the study:
This study is a collaboration between Florida State University and University of Michigan researchers who will have funding from the National Institute of Mental Health, the National Institute of Deafness and Communicative Disorders, the National Institute of Child Health and Human Development, the Simons Foundation, the US Department of Education, Office of Special Education Programs, the US Department of Education, Institute of Education Science, and the Centers for Disease Control and Prevention. Autism Speaks foundation is also a sponsor of the study.

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Amy M. Wetherby, Ph.D.
Director of the FSU Autism Institute
Professor of Clinical Sciences and Communication Disorders
Florida State University

Catherine Lord, Ph.D.
Director of the University of Michigan Autism and Communication Disorders Center
Professor of Psychology and Psychiatry
University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
The Autism Institute in the College of Medicine at Florida State University (FSU), in collaboration with the University of Michigan Autism and Communication Disorders Center (UMACC), seeks to provide diagnostic and treatment services and to advance understanding of autism spectrum disorders (ASD) in very young children. Previous research has suggested that intervention beginning by 3 years of age may contribute to better outcomes in children with ASD than waiting until school age. Little research is available on the treatment of children with ASD under 3 years of age. The purpose of this study is to evaluate how well two specific interventions work for very young children who show red flags of ASD. Each intervention lasts 8 months and is designed to train parents how to support social communication.
skills for their child. Overall, our goal is to identify interventions involving parents that are effective in building social communication skills in toddlers with ASD.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Children 18 months of age or younger, who show red flags of autism spectrum disorder based on parent report and a diagnostic testing, and their family may participate in this study.

3.2 How many people (subjects) are expected to take part in this study?

We expect to include about 120 children and their families in this study, 60 at Florida State University and 60 at University of Michigan.

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What will happen to me in this study?

The study will involve teaching parents how to support social communication in everyday activities with their child using one of two different parent interventions, one that involves a parent education group, and the other that involves home-based intervention sessions.

Before you can participate in the intervention, you and your child will be asked to do the following:

- Your child will be given a battery of standardized tests of verbal and nonverbal skills and a standardized observation to assess his/her communication and social skills. Some of these measures will be videotaped so that the clinician and another person can verify the assessment of your child’s skills. You will be present during all testing with your child.
- You also will complete questionnaires and interviews about your child’s communication and social development.

Following this battery of tests, it will be determined if your child meets the criteria to participate in this study. Then your child will be assigned to begin with either the parent education group or the home-based intervention group. Your group assignment will determine the intervention that is offered first for 9 months, and will be followed by the other intervention for 9 months. Therefore, no matter which group your child is assigned to, you will eventually be able to participate in both parent interventions. We will assign your child to a group randomly (e.g., by flipping a coin).

We will ask you to complete a set of questionnaires focusing on family resources as well as social emotional issues. We will ask you to complete these questionnaires 3 times; before intervention begins, at 9 months when intervention conditions change, and at 18 months when intervention ends. Completion of these questionnaires is voluntary and does not impact your ability to participate in the study or limit the services available to you.

If your child is assigned to the parent education group, you will be asked to participate in group meetings every week and in monthly assessments.

- We are asking you and your child to attend parent education groups that meet for 75 minute sessions at least two times a month for 9 months. The parent education groups will be directed by one or two professionals who will provide information and resources about ASD and how to
support social communication development in your child. There will be up to 5 other families attending the parent education group, which will give you the chance to see your child interacting with other children and network with other families.

- We will ask you and your child to play during the parent education group and the professionals will give you feedback on how to support social communication skills with your child and will answer questions that you have.
- We will make video recordings of you and your child once a month at home for an hour during everyday activities to see how you and your child are interacting.
- We will ask you to bring your child to our center each month to repeat the standardized observation to see if there were any changes over time. Some of these measures will be videotaped so that the clinician and another person can verify the assessment of your child’s skills.
- We will offer you a one-hour monthly consultation or counseling session to address your priority needs scheduled with the monthly assessment.
- We will ask you to bring your child to our center at the end of the 9 months to repeat the full battery of tests that was administered before intervention began.

If your child is assigned to the home-based intervention group, you will be asked to participate in three (3) intervention sessions each week and in monthly assessments.
- We are asking you and your child to participate in individual intervention sessions that meet for 75 minutes three times a week, twice at your home and once our center for 7 months, followed by two times a week, once at your home and once at a site you pick in the community, for 2 months. The intervention sessions will be directed by one professional who will teach you how to use specific supports to target specific intervention objectives for your child.
- During the individual intervention session, we will ask you and your child to play and interact during everyday activities and the professional will give you feedback on how to support social communication skills with your child and will answer questions that you have.
- During each week of the home-based intervention group, we are asking you to use the specific supports taught to you during everyday activities with your child for 5 hours a day 5 days a week. We will need you to keep a log or diary of these activities on a daily basis.
- In addition to the intervention sessions, we will make videotapes of you and your child once a week at home for an hour during everyday activities to see how you and your child are interacting.
- We will ask you to bring your child to our center each month to repeat the standardized observation to see if there were any changes over time. Some of these measures will be videotaped so that the clinician and another person can verify the assessment of your child’s skills.
- We will offer you a one-hour monthly consultation or counseling session to address your priority needs scheduled with the monthly assessment.
- We will ask you to bring your child to our center at the end of the 9 months to repeat the full battery of tests that was administered before intervention began.

When you have completed the first 9-month intervention, either the parent education group or home-based intervention group, we will then ask you to participate in the other parent intervention for the next 9 months. Therefore, no matter which group your child is assigned to, we are asking you to participate in parent intervention for 18 months.

If you choose to participate, information obtained from you as part of this study will be put into the FSU FIRST WORDS Project Database. It will also be shared with the National Institutes of Health National Database for Autism Research (NIH NDAR). The information will be available for researchers to use in research about autism and other social-communication disorders to answer questions about etiology, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of this database. No video records will be

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Document prepared December 16, 2010

provided to NDAR. If you agree to be in this study, that means that your child’s research information will be used in this way. If you change your mind later, we can ask to remove your child’s data from NDAR. However, NDAR cannot get back information that was shared before you changed your mind.

4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

- The initial assessment takes about five (5) hours. You may choose to complete the testing across 2 or more days. If your child already took some of these tests through the FSU FIRST WORDS Project, then s/he will not have to retake them. In that situation, parent(s) will only have to fill out a subset of forms, and your child will only complete assessments that you have not already completed.
- The monthly assessment takes about one (1) hour.
- The consultation and counseling session will take 1 hour.
- The parent questionnaires will take about 1 hour.
- Time you or your partner agrees to spend engaged with your child, which can include any ordinary daily activities (such as meals, bathing, playing, shopping), using strategies that you learn during intervention will be 25 hours a week.
- Weekly in-home videotaping during home-based intervention will take about 1 hour.
- Monthly in-home videotaping during the parent education group intervention will take about 1 hour.
- At the end of the 9-month intervention period, we will repeat the battery of tests given at the initial assessment, which will take about 5 hours.
- We will repeat these tests again after the second 9-month intervention period. These assessments also will last about 5 hours.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Since the initial assessment portion of this study takes about 5 hours, there is a risk that your child may become bored or tired. This amount of time is typical for an assessment with children, so we minimize this risk by allowing breaks and snacks as needed. We will take breaks and can reschedule as necessary. Additionally, about half of the assessment is play-based involving toys and/or fun activities that are not test-like or school-related. You will be with your child during all testing and can let the professional know if your child needs a break or you want to end the session.
- Since this study involves personal information, there is always the risk of breach of confidentiality. To minimize this risk, all clinical and videotaped records will be kept by project staff in a locked room. We will use identification codes on all research records; no names or other personal identifying information about you or your child will be included.
- Because this is a collaborative project with Florida State University and University of Michigan, we will need to share research information with staff at the other site. All personal details identifying you or your child will be removed before information is shared with the other site. If you do not want you or your child’s research information to be used in this way, you should not participate in this study.

As with any research study, there may be additional risks that are unknown or unexpected.
5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Please note: It is important that you tell the researchers about any injuries, side effects, or other problems that you experience during this study.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you or make it difficult to determine which treatment is working. It may also affect the results of the studies. If you decide to take part in more than one study, we would appreciate you keeping us informed of this. You can participate in any services or programs you choose for you and your child in the community.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, you and your child may benefit from involvement in this project in a few ways. First, we will provide you with a written summary of test results before and after each intervention. This information may be of benefit in planning future school and treatment choices. Second, the parent intervention may improve your ability to support your child’s social communication development. We hope findings for this research will contribute to better and more effective services for other young children with autism spectrum disorders and their families.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your access to services here at Florida State University for yourself and/or your child will not be affected if you do not participate in this study. We will refer you to intervention programs available in your community, whether you participate in this study or not.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of your record.

Page 5 of 9  Initials ________

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the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no foreseeable harm if you decide to leave this study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are some reasons why the researchers may need to end your participation in the study. Some examples are:

- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You miss or cancel more than 6 consecutive intervention sessions without rescheduling.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything?
All assessments and intervention sessions conducted by research personnel for this study are offered at no cost.

8.2 Will I be paid or given anything for taking part in this study?
You will receive $50 for completing each monthly assessment to compensate for the time involved.

8.3 Who could profit or financially benefit from the study results?
The researchers conducting the study:
Dr. Amy Wetherby and Dr. Catherine Lord, along with the other authors of some of the instruments used in the assessment, receive 1 to 5% of the profit in royalties from the distribution of these instruments when they are purchased by others; profits from the use of the instruments at FSU or UMACC are donated to charity. Dr. Amy Wetherby and other project staff may receive royalties in the future on educational tools developed for commercial use from this project.

9. CONFIDENTIALITY OF SUBJECT RECORDS

Florida State University and University of Michigan policies require that private information about you be protected. This is especially true for your personal information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

We will keep your research record confidential, to the extent provided by federal, state and local law. All information collected about you and your child will be maintained in a manner specified by professional ethics and codes. Written records will be kept in locked cabinets in locked offices at our Center. All research information maintained in an electronic database will use identification codes (i.e., no names). We will not allow anyone to see your record, other than people who have a right to see it. Any research reports will carry no identifying information of individual children, parents or families.

Page 6 of 9

Initials ________

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In general, we will not disclose any information about you or your child without your written permission. However, there are some exceptions to sharing your information as required by law. We will disclose your identity if it is necessary to protect your rights or welfare; for example if you are injured or lost consciousness and need emergency medical care. We will disclose your identity and information if a researcher becomes aware that you may be a danger to yourself or to others. We will disclose your information if the researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

This study is being initiated at Florida State University in conjunction with an ongoing study at the University of Michigan with whom we are collaborating on other studies. We have made every effort for our protocols to be identical and we will share data collected from each site with staff at the other site.

9.2 What written or videotaped information about me or my child could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from your clinical records at the FSU FIRST WORDS Project.

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration [FDA], and other government officials may need the information to make sure that the study is done properly.
- Organizations that are funding the study may need the information to make sure that the study is done properly.
- If you receive any payments for taking part in this study, the Florida State University accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If you choose to seek clinical services either during or after the study, you may elect to have the assessments involved in this study available and used in your clinical care. We would not release any clinical records without you signing a release of information form.

You and your child will be videotaped by the clinician during the evaluation and intervention sessions. These videotapes will be kept by the project staff in a locked room and will be saved indefinitely. These videotapes will be accessible only to research staff, unless otherwise specified by you. We may ask your permission to use segments of these videotapes for educational purposes; however, this is optional and you will be presented with a different consent form for that purpose.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

After the study is over, we will send the data collected during this study to our co-researchers at the University of Michigan. The data will not have any identifying information about you or your child; your child’s name will be changed to a coded identifier and all identifying information will be removed before we share it with UMACC. Only Florida State University will have the information linking your child’s name to his/her code. After the study, if you choose to seek clinical services, you may elect to have the assessments involved in this study available and used in your child’s clinical care.
Document prepared December 16, 2010

If you cancel your permission to be in the study, we will not continue to use or disclose information about you or your child. We will not share any data with University of Michigan until the study is over; therefore, if you cancel your permission, we will not send your child’s data to that institution.

Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study or the study is over. Examples of reasons for this include:

• To avoid losing study results that have already included your information
• To provide information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
• To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the FSU Early Social Interaction Project and the FSU FIRST WORDS Project, it is protected by the federal privacy policies.

10. CONTACT INFORMATION

10.1 Whom can I contact about this study?

Please contact the researchers listed below to:

• Obtain more information about the study
• Ask a question about the study procedures or treatments
• Report an illness, injury, or other problem (you may also need to tell your regular doctors)
• Leave the study before it is finished
• Express a concern about the study

Principal Investigator: Amy Wetherby, Ph.D.
Co-Investigator: Juliann Woods, Ph.D.
Mailing Address: Autism Institute, Florida State University, Tallahassee, FL 32306-7814
Telephone: 850-644-

If you have any questions about your or your child’s rights as a participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Committee, Institutional Review Board, through the Vice President for the Office of Research at Florida State University at (850) 644-8633.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of this "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file by the Principal Investigator at Florida State University.)

Page 8 of 9

Initials

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Research Subject:
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with ________. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Name of Child: (Print legal name):

Name of Parent/Guardian (Print legal name):

Signature of Parent/Guardian: ___________________________ Date: __________

Principal Investigator (or Designee):
I have given this research subject (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The subject has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name: ___________________________ Title: ___________________________

Signature: ___________________________ Date of Signature: __________

Page 9 of 9  Initials ________

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PERMISSION FOR USING VIDEOTAPEs FOR EDUCATIONAL PURPOSES

I, ________________________________ (Parent’s or Guardian’s name), as parent or guardian of ________________________________ (child’s names) hereby give my consent that the edited videotape clips that I have viewed of my child and myself or any reproduction of these same materials made by Dr. Amy Wetherby and research assistants in the Early Social Interaction Project may be used for instruction or educational purposes. Signing this form does not in any way obligate me to give permission for broader use of these video clips.

I understand that I will receive no financial compensation for the use of these recorded materials. I also understand that if in the future, I decide to revoke permission to use the video clip of me and/or my child, a concerted effort will be made to remove that segment of the educational video, but this cannot be guaranteed. The reason for this is that once the educational video has been developed, it is difficult to remove a segment without needing to rework the entire product.

I have read the foregoing statements and agree to abide by them.

______________________________ Date: ______________________

Signature of Patient/Legal Guardian

625B North Adams Street Tallahassee, Florida 32301
Telephone 850.922.9817 Fax 850.644.3644

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REFERENCES


BIOGRAPHICAL SKETCH

Deanna Tracy graduated with honors from the University of Michigan in 2008 with a Bachelor of Arts in Psychology. While at Michigan, she worked as an undergraduate research assistant on the FIRST WORDS Project at the University of Michigan Autism and Communication Disorders Center (UMACC). She also completed an honors thesis on the relationship between sensory behaviors and socialization in young children with autism. Following her undergraduate education, she worked as a research assistant at the Carolina Institute for Developmental Disabilities on two projects: the North American Extended Family Study of Autism and the Neural Circuitry of Social Cognition in the Broad Autism Phenotype Study. She currently assists with data collection on the FIRST WORDS Project at the FSU Autism Institute and supervises a team of coders utilizing archival data from the Early Social Interaction Project. Her research interests include parent-implemented intervention techniques, restricted and repetitive behaviors, and early detection of autism spectrum disorders.