DIFFERENCES IN DIETARY INTAKE, SENSORY PROCESSING, ANTHROPOMETRIC
MEASURES, MEALTIME BEHAVIORS, AND PARENTAL STRESS OF CHILDREN
WITH ASD AND OTHER NEURODEVELOPMENTAL
IMPAIRMENTS

by

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Feeding difficulty is a frequently reported feature of neurodevelopmental delays and disorders that affect children, including Autism Spectrum Disorder (ASD). According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), the diagnosis of ASD can include deficits in social interaction, restrictive and repetitive behaviors, rigid routines, fixated interests, and hypo- or hyperreactivity to sensory input. All of these factors can affect mealtime behaviors. Parents of children with a diagnosis of ASD frequently report problem behaviors at mealtime and decreased dietary variety. However, the extent to which specific characteristics of feeding difficulty are unique to children with ASD has not been determined. This study examined whether reported problem mealtime behaviors and decreased dietary variety are symptoms exclusive to children diagnosed with ASD or whether similar behaviors and patterns of dietary intake are present in other neurodevelopmentally delayed or impaired populations. The data for this project was collected through a variety of assessment measures that examined dietary patterns, problem mealtime behaviors, sensory processing, growth, and parental stress in children referred for evaluation by the University of Alabama’s ASD Clinic. The purpose of this study was to compare dietary intake, patterns of sensory processing, measures of growth, mealtime behaviors, and levels of parental stress among children with ASD to children with other neurodevelopmental diagnoses (speech-language delay, attention deficit disorder, or not otherwise specified). In this study, we found that children diagnosed with ASD did not exhibit significant differences in terms of dietary intake, patterns of sensory processing,
measures of growth, mealtine behaviors, and levels of parental stress when compared to age-
matched peers with other neurodevelopmental delays or disorders.
LIST OF ABBREVIATIONS AND SYMBOLS

α  Alpha
AD  Anxiety disorder
ADHD  Attention-deficit/hyperactivity disorder
ANOVA  Analysis of variance
ASD  Autism spectrum disorder
APA  American Psychological Association
BMI  Body Mass Index
BPFAS  Behavioral Pediatric Feeding Assessment Scale
CARS  Childhood Autism Rating Scale
CDC  Centers for Disease Control and Prevention
DD  Developmental delay
DRI  Dietary Reference Intake
DSM-5  Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
IBM SPSS  International Business Machines Corporation Statistical Package for the Social Sciences
IMNA  Institute of Medicine of the National Academics
LD  Language disorder
M  Mean
MANOVA  Multivariate analysis of variance
ND  No diagnosis
<table>
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<th>Symbol</th>
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<tr>
<td>$p$</td>
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<tr>
<td>PSI-SF</td>
<td>Parenting Stress Index—Short Form, Third Edition</td>
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<tr>
<td>RDA</td>
<td>Recommended Daily Amount</td>
</tr>
<tr>
<td>$SD$</td>
<td>Standard deviation</td>
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<tr>
<td>SPD</td>
<td>Sensory processing dysfunction</td>
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<tr>
<td>SSD</td>
<td>Speech sound disorder</td>
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<tr>
<td>TFS</td>
<td>Total frequency score</td>
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<td>Total problem score</td>
</tr>
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<td>United States</td>
</tr>
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<td>United States Department of Agriculture</td>
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<td>$\Pi$</td>
<td>Eta</td>
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I would like to thank all of the faculty members, advisors, colleagues, and friends who made this research project possible. Dr. Memorie Gosa, without your guidance and encouragement throughout this process, this paper would not have been possible. Thank you for the immeasurable amount of time and energy spent on this project. Also, thank you Dr. Barber, Dr. Ryan, and Dr. Buhr for your input and direction on how to shape this research study. Dr. Bolland, I am so grateful for the help you provided with the statistical analyses. You were so kind to share your time to help me with this project. Also, I would like to thank the families of the children at the UA ASD Clinic for their participation in the study. I am extremely grateful for my friends, family, and fellow graduate students who encouraged me through every step of this process.
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CHAPTER 1
INTRODUCTION

Autism Spectrum Disorder (ASD) is characterized by deficits in social communication, and it can include repetitive behaviors, restricted interests, rigid routines, and sensory processing dysfunction (APA, 2013). All of these features can cause disruptions to expected mealtime behaviors for a variety of reasons because restricted interests and rigid routines can prevent a child from trying new foods and make them insist on meals being prepared the same each time. Sensory processing dysfunction (SPD) encompasses deficits in successful integration of competing sensory stimuli for the typical interaction of the affected child with their surrounding environment. Recent literature has linked SPD with feeding problems (difficult to manage mealtime behaviors, overly restricted dietary variety, and trend for obesity) in children with ASD (Marshall, 2014). However, ASD is not the only neurodevelopmental impairment with features that include SPD. We know that all children engage taste, smell, hearing, touch, and sight simultaneously when they are eating because eating is a sensory-rich experience by nature. Food is tasted, smelled, heard, felt, and seen during a meal. The amount of sensory information that is processed during mealtime can cause disruptions in behavior and eating patterns if the child has difficulty with sensory integration. If there is a breakdown in any part of a child’s ability to successfully process sensory stimuli while eating, there can be a breakdown in their ability to engage in acceptable behaviors during mealtime. This can cause the child to avoid trying new foods and create stress for the parent or caregiver. It is also important to examine all factors to determine if the restricted interests in food affect growth. This study examined dietary patterns,
patterns of SPD, measures of growth, mealtime behaviors, and levels of parental stress among children with ASD to children with other neurodevelopmental diagnoses to establish if children with ASD exhibit distinctive patterns of dietary variety, SPD, growth, problematic mealtime behaviors, and parental stress as compared to children with other neurodevelopmental diagnoses. The prevalence of problem feeding behaviors in typically developing children and children with neurodevelopmental diagnoses has been investigated in the literature previously.

**Background & Literature Review**

**Typical feeding behavior.** Typically developing children ages two to six years old exhibit a specific set of predictable behaviors during mealtime. According to Morris and Klein (2000), by age two, children have already established their eating patterns. By this age, they are eating independently and should have developed the oral motor skills and coordination needed to consume most dietary consistencies. After age two, children continue to refine their eating skills as their oral cavity grows, and as they taste new foods and textures. However, during their toddler years (ages one to three), children do develop strong preferences for certain foods and textures (Brown et al., 2002). All children go through periods of refusing certain foods while showing preference towards others, and they tend to prefer sweet and slightly salty tastes while refusing bitter, sour, and spicy foods. The tendency to reject new foods is called food neophobia, and it is a known developmental phenomenon (Birch, 1999). Food neophobia typically peaks between two and six years of age (Dovey, Staples, Gibson, & Halford, 2008). Over time, children learn to accept initially undesired foods when they have repeated exposure to them. It can take at least ten oral exposures to a new food for children to develop a preference for those foods (Birch, McPhee, Shoba, Pirok & Steinberg, 1987). In order to better understand typical
feeding behaviors, typical and recommended diets for children in this age group were also explored.

**Recommended diet for children 2-6 years of age.** The United States Department of Agriculture (USDA) outlines the daily recommended amount of each food group for two- to six-year-olds in the United States (U.S.). They should consume between two and three servings of fruit, between two and three servings of vegetables, five servings of grains, three servings of protein, and between three and four servings of dairy. The Dietary Reference Intake (DRI) for children aged two to six years is 130 grams of carbohydrates, a non-determined amount of fat, and 13-19 grams of protein (Institute of Medicine of the National Academies [IMNA], 2005). The percent of energy that should come from carbohydrates is 45-65%, the percent of energy that should come from fat is 25-40%, and the percent of energy that should come from protein is 5-30% (IMNA, 2005). The current Recommended Daily Amount (RDA) of energy for one- to three-year-olds is 102 calories/kg of body weight, and for four- to six-year-olds, 90 calories/kg of body weight (Brown et al., 2002). Recent evidence suggests that the actual intake of food from the recommended food group for children two to five years of age is below minimum recommendations in all food groups, except for intake from the dairy group which is, on average, at or near the recommended daily amount (Brown et al., 2002). Typically developing children’s patterns of oral intake are influenced by their predisposition to certain foods, the child’s environment, media, and parental feedback (Birch & Fisher, 1998). In order to determine the short- and long-term effects of these diets, further investigation was needed into the growth patterns of typically developing children in the United States.

**Typical growth of children in the U.S.** The CDC reports measurements of height and weight for typically developing children using BMI growth charts that provide recommended
height and weight for children based on age and sex (CDC, 2015). Underweight is classified as having a BMI value below the 5th percentile for age/sex, healthy weight is classified as having a BMI value in the 5th to 85th percentile for age/sex, overweight is classified as having a BMI values in the 85th to 95th percentile for age/sex, and obese is classified as having a BMI value equal to or greater than 95th percentile for age/sex (CDC, 2015). For boys two- to six-years-old, the average weight is between 29 and 46 pounds. For girls two- to six-years-old, the average weight is between 26 and 44 pounds (CDC, 2000). According to the most recent data, between the years 2011 and 2014, the obesity rate for 2- to 19-year-olds in the U.S. was around 17% (CDC, 2016). According to the Centers for Disease Control and Prevention (CDC), about 12.7 million children and adolescents in the United States are obese (2016). Also, according to the CDC, among the population, the obesity rate of children aged two to five years is around 8.9%, which is lower than the overall rate of children and adolescents (CDC, 2016). While mealtime behaviors, diet, and growth patterns are well established in typically developing children, the impact of ASD and other neurodevelopmental disorders on these same features of feeding is still being explored.

**Autism spectrum disorder.** The *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) defines ASD as a developmental disability characterized by deficits in social communication in a variety of contexts, and it can also include any of the following behavioral patterns: repetitive motor movements, inflexible routines, fixated interests, and hypo- or hyperreactivity to sensory stimuli (APA, 2013). The DSM-5 also indicates that repetitive motor movements can include the use of objects or speech, and children with ASD that have an insistence on sameness have difficulty with transitions to things that are not routine. In addition, the DSM-5 outlines that children with ASD can have perseverative interests that are not typical
of their peers. Examples of impaired sensory responses may include “apparent indifference to pain/temperature, [an] adverse response to specific sounds or textures, excessive smelling or touching of objects, or a visual fascination with lights or movement” (APA, 2013). The current incidence rate of ASD according to the CDC is 1 in 68 children, and it is almost five times more common in boys than girls (CDC, 2015). Because of sensory processing impairments, perseverative behaviors, and deficits in communication, difficult behaviors can become more apparent at mealtimes. As mentioned before, eating is a sensory-rich experience that requires use of all of the senses simultaneously. Therefore, if a child has difficulty processing all of the sensory information and also has difficulty communicating with their caregivers, it can present itself in a variety of ways. Behaviors seen at mealtime in children with ASD can differ from behaviors seen in typically developing children because of the aforementioned characteristics of the disorder.

**Feeding behaviors in children with ASD.** ASD is a multifactorial diagnosis, and it is therefore important to examine how each factor contributes to difficult feeding behaviors. Overly restrictive patterns of dietary intake have been reported in children with a diagnosis of ASD, possibly due to co-occurring SPD (Brown et al., 2002). Nadon and colleagues (2011) reported that there was a decrease in overall intake for children with ASD as compared to typically developing peers. Zimmer and colleagues (2012) found that typically developing children tried an average of 54.5 foods per month, while children with ASD tried an average of 33.5 foods per month. Children with ASD have also been reported to eat fewer than 20 different food items overall (Nadon et al., 2011; Cornish, 1998) and refuse to stay seated during mealtimes (Nadon et al., 2011). Children with ASD also had greater amounts of food jagging and were more selective with respect to food textures, temperatures, and types of recipes consumed (Nadon, 2011). Food
jagging is a process seen in typically developing children as well as disordered populations. Food jagging is when a child only eats a specific food or small group of foods over a period of time. The DSM-5 diagnostic criteria specify that along with sensory processing dysfunction, children with ASD often have a strong insistence on sameness and routines (APA, 2013). This insistence on sameness has been documented in the feeding literature. For example, Cornish (1998) reported that children with ASD wanted their foods prepared the same way at each meal/snack. Limited formal parental stress measures are available. Multiple studies reported informal results about levels of parental stress, but Marshall and colleagues pointed out that reports of frequent nutrient supplementation in this population could suggest that significant amounts of parental stress exist (2013). They suggest that this indicates parents are concerned about their children receiving adequate nutrition from the foods that they eat. However, they do indicate that there is need for further research of parental stress in this population. Also, the literature was searched for instances of behaviors at mealtime affecting growth due to nutritional deficiencies or highly restricted diets.

**Growth in children with ASD.** Marshall and colleagues (2013) reported that being overweight was a more commonly reported issue for children with ASD than being underweight. They found that feeding problems in children with ASD are associated with problems in growth, with a trend for children with ASD to be overweight or obese. Other studies have found correlations with obesity and ASD. A study in Canada that examined nutrient intake and obesity in a group of children diagnosed with ASD found that 43% of the children included in the study were obese (Ho, Peabody, & Eaves, 1997). Curtin, Anderson, Must, and Bandini (2010) conducted a secondary data analysis of cross-sectional nationally representative data collected by telephone interview of parents/guardians in the United States, and they reported the prevalence
of obesity in children with ASD was 30.4% compared to typically developing children at a rate of 23.6%. Frequent reports of children with ASD being overweight as compared to typical population norms were evident across available literature (Curtin et al., 2010; Ho et al., 1997; Marshall et al., 2013). Although the characteristics of ASD are becoming more widely known, characteristics of other neurodevelopmental diagnoses are sometimes unknown. Further research is needed to explore the ways that these characteristics affect all aspects of life. One of the purposes of this paper was to explore the characteristics of neurodevelopmental disorders and how those characteristics affect mealtimes.

**Other neurodevelopmental diagnoses.** A neurodevelopmental disorder is defined as a condition that begins in the developmental period. This is a type of disorder that affects personal, social, academic, or occupational functioning (APA, 2013). Different types of neurodevelopmental disorders often occur simultaneously. ASD often occurs with intellectual disability, and children with attention-deficit/hyperactivity disorder (ADHD) often also have a co-existing learning disability. Due to overlapping conditions, it can be difficult to determine which characteristics are unique to one disorder. However, as defined by the APA (2013), ASD is diagnosed when social communication delays co-exist with repetitive behaviors, restricted interests, and/or an insistence on sameness. Because there is a considerable amount of research on feeding behaviors in children with ASD compared to typically developing peers, this study sought to identify known characteristics of feeding behaviors in children with other neurodevelopmental diagnoses.

**Feeding behaviors in other neurodevelopmental diagnoses.** There has been limited investigation into the types of feeding problems exhibited by children diagnosed with neurodevelopmental disorders other than ASD. A study by Williams and colleagues (2005)
compared selective eaters among cohorts of children with ASD, special needs other than ASD, and typically developing. They found that the group with ASD had more incidences of food jagging and needed routines at mealtime, while the group with other neurodevelopmental diagnoses had more oral motor delays as compared to the typically developing, age matched cohort (Williams et al., 2005). Another study published by Graf-Myles and colleagues (2013) also compared a group with ASD, a group with developmental delay, and a typically developing group. They found that there was not a significant difference between the group with ASD and the group with developmental delay (DD) with regards to their consumption of any nutrient except calcium and dairy. There were also no differences between the groups on how many fruits and vegetables they consumed. However, they found that the group with ASD consumed a higher percentage of calories from monounsaturated fats. The mean scores on the Short Sensory Profile indicated more sensitivity for both the group with ASD and the group with DD in this study; however, the scores on the Short Sensory Profile did not affect healthy eating patterns in either group (Graf-Myles et al., 2013). Also, according to a study published by Williams, Gibbons, and Schreck in 2005, problem feeding behaviors are common among children with developmental delays and especially SPD.

**Statement of the Problem**

Children with ASD have established differences in dietary intake, sensory profiles, growth, feeding behaviors, and reported levels of parental stress as compared to typically developing peers (Ahearn, 2001; Marshall et al., 2013; Martins, 2008; Nadon, 2011). However, currently, there are limited data that compare dietary intake, sensory processing, growth, feeding behaviors, and reports of parental stress between children with ASD and children with other neurodevelopmental disorders (Williams et al., 2005; Graf-Myles et al, 2013). Much of the
previously reported literature that found differences in growth, dietary intake, and problem feeding behaviors in children with ASD utilized a typically developing control group instead of a group diagnosed with other neurodevelopmental disorders (Crist & Napier-Phillips, 2001; Martins et al., 2008; Nadon et al., 2011; Zimmer et al., 2012). The purpose of this study was to determine if there are significant differences in dietary intake, sensory processing, growth, feeding behaviors, and levels of parental stress in children diagnosed with ASD and children with other neurodevelopmental diagnoses.
CHAPTER 2

METHODS & PROCEDURES

Participants

Participants for this study were recruited from the University of Alabama’s Autism Spectrum Disorders Clinic (UA ASD Clinic). The UA ASD Clinic is a resource on campus for families of children with ASD. Children are referred to the clinic for a full evaluation, and they are also able to receive therapy services. Participants included in this study agreed to participate after completing a consent form. The University of Alabama’s Institutional Review Board approved this research study prior to initiating recruitment. Each individual evaluated at the UA ASD Clinic received a psychological, speech/language, and medical evaluation that included a wide range of assessments. Criteria for inclusion in this study included: age between two and six years with completion of all the required assessments between January 2015 and December 2015. The measures included for analysis in this research study were scored by a trained graduate student and checked for accuracy by a qualified speech-language pathologist or psychologist. Study personnel measured height and weight using standardized methods. To capture accurate weight, children were required to stand barefoot and still on a balance scale. Two measurements were taken to ensure accuracy, and a third measurement was taken in the case of discrepancy. In the case that weight was unable to be measured, the parent reported the child’s weight according to their last doctor’s visit. A stadiometer attached to the balance scale was used to measure height. Children were required to complete this measurement with no shoes. Height was recorded to the nearest half-centimeter. As a measure of dietary variety, parents were
asked to answer a series of questions about the various foods their child eats across different food
groups as part of a multi-pass 24-hour diet recall inventory with standardized procedure. The
number of foods consumed overall and across each food group (fruits/vegetables, protein-rich
foods, and carbohydrate-rich foods) were analyzed. For this analysis, the total number of
unprocessed fruits and vegetables consumed was also documented.

A total of 44 participants were recruited from the UA ASD Clinic for this study. Of the
total, 28 were diagnosed with ASD, and 12 were diagnosed with other neurodevelopmental
diagnoses. The other diagnoses included developmental delay, speech sound disorder, language
disorder, and anxiety disorder. The remaining four received no diagnosis at the time of their
evaluation at the UA ASD Clinic, but were referred for follow-up evaluation.

A total of 15 participants were included in the final analysis. In this sample, nine children
were diagnosed with ASD, one was diagnosed with developmental delay, two were diagnosed
with a speech sound disorder, one was diagnosed with anxiety disorder, and the remaining two
received no diagnosis, but were referred for further assessment. The group of 15 was chosen for
further analysis because they had significantly high scores on the BPFAS (> 84 Total Frequency
Score, TFS). A significantly high score on the BPFAS indicated that problem-feeding behaviors
exist, so they were chosen to compare differences based solely upon diagnosis of ASD or
diagnosis of another neurodevelopmental disorder. Two of the participants were missing data
and were excluded from the final analysis. The remaining 13 participants, who had a high
frequency score on the BPFAS, were compared according to whether or not they were diagnosed
with ASD or another neurodevelopmental diagnosis. Among the final group of 13 participants,
seven were diagnosed with ASD and six were diagnosed with other neurodevelopmental
disorders. Figure 1 displays the selection process for inclusion in this study.
**Subject Selection**

![Flowchart of participant selection](chart.png)

**Figure 1.** Participant selection for inclusion in statistical analysis. BPFAS = Behavioral Pediatric Feeding Assessment Scale.

While Figure 1 describes the selection process, Table 1 shows the subject information for each participant included in the study. As seen in the table, eleven males were included, and two females were included. The Childhood Autism Rating Scale (CARS) is a behavioral rating scale that was administered to all the participants in the study as a measure of the severity of ASD symptoms. A total of seven children in our study were diagnosed with ASD. Four of the children were classified as having severe symptoms of ASD. The remaining three children were classified
as having mild-to-moderate symptoms of ASD. A score of below 30 is indicative of minimum-to-no symptoms of ASD, a score of 30-36.5 is indicative of mild-to-moderate symptoms of ASD, and a score above 36.5 is indicative of severe symptoms of ASD. The mean score for the group of 13 participants in this study was 30.5. For the seven children diagnosed with ASD, the mean score was 38. The mean score for the three children with mild-to-moderate symptoms of ASD was 32, and the mean score for the four children with severe symptoms of ASD was 43. The table shows demographic information, the diagnosis that each participant received upon evaluation, and it provides the standard score from the CARS for each participant diagnosed with ASD. For the children diagnosed with ASD, the mean CARS score was 38, indicating that this cohort of children with ASD presented with severe ASD symptoms.

Table 1

Subject Information

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Sex</th>
<th>Age in Months</th>
<th>Diagnosis</th>
<th>CARS Score</th>
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<td>39</td>
<td>ASD</td>
<td>43.5</td>
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<tr>
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<td>27</td>
<td>ASD</td>
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<td>62</td>
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<td>62</td>
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</table>

Note. Age is presented in months. ASD = Autism Spectrum Disorder; SSD = Speech Sound Disorder; LD = Language Disorder; ND = No Diagnosis; DD = Developmental Delay; AD = Anxiety Disorder. CARS scores range from 15-60.
Assessments & Measures

This study examined mealtime patterns of children with ASD as compared to children with other neurodevelopmental diagnoses using the following measures: a 24-hour diet recall, the Sensory Profile 2, anthropometric measures, the Behavioral Pediatric Feeding Assessment Scale (BPFAS), and the Parenting Stress Index—Short Form, Third Edition (PSI-SF). Parents completed these forms when they were first seen at the UA ASD Clinic. Subject’s dietary patterns were examined by collecting multi-pass 24-hour diet recalls administered by interview from a trained professional. Comparisons of SPD patterns were made between children with ASD and children with other neurodevelopmental diagnoses by administering the Sensory Profile 2. Differences in growth between the two groups were measured by collecting anthropometric measures. Mealtime behaviors were examined by administering the BPFAS. The study examined levels of parental stress among children with ASD to children with other neurodevelopmental diagnoses by administering the PSI-SF. As a part of the standard evaluation, parents complete a medical history form, and the child’s developmental level and general behavior is assessed using standardized and norm-referenced measures. All measures used in this project are described in detail below.

Dietary intake and variety. A trained staff member interviewed the parent/caregiver to complete a 24-hour diet inventory. The parent/caregiver was instructed to report all food and liquids consumed in the past 24-hour period for his/her child. This information is needed to assess the amount of servings each child consumes within each food group (fruits, vegetables, grains, protein and dairy). Also from this data, the researcher calculated the number of whole foods consumed, number of processed foods consumed, and total number of foods consumed. Whole foods are fruits, vegetables, and protein sources that are minimally processed and are not
chemically or mechanically changed in any way. Processed foods are food sources that have undergone extensive processing either chemically or mechanically. This information provides information about restrictive diets, because the researcher can examine if the child has restricted variety in their diet.

**Sensory processing.** Sensory processing was assessed using the *Sensory Profile 2* (Dunn, 1999), a standardized, 125-item parent-reported tool that evaluates a child’s sensory processing patterns in the context of everyday life. This tool allows clinicians to categorize children based on their responsiveness to sensory input. This also allows children to be categorized as having typical performance (within ±1SD of the mean), probable difference (±1-2SD from the mean), or definite difference (≥or≤2SD from the mean) across different sensory areas. The sensory areas assessed include: auditory, visual, touch, movement, body position, and oral. For this tool, the parent or caregiver rated each item as “Much Less Than Others,” “Less Than Others,” “The Same as Others,” “More Than Others,” or “Much More Than Others.” Each value was assigned a number for the purpose of data analysis. The values are as follows: “Much Less Than Others” equals one, “Less Than Others” equals two, “The Same as Others” equals three, “More Than Others” equals four, and “Much More Than Others” equals five. The most frequently reported categories were reported in values one through five. This standardized assessment also classifies the child into one of four categories as follows: seeker, avoider, sensor, and bystander. This information is needed for the clinical purpose of documenting sensory processing difficulties and making possible referrals for occupational therapy services. Because SPD is a possible characteristic of ASD, this assessment was included to compare sensory restrictions with their diet to examine patterns that exist.
**Anthropometry.** Study personnel, using standardized methods, measured height and weight. To capture accurate weight, children were required to stand barefoot and still on a balance scale. Two measurements were taken to ensure accuracy, and a third measurement was taken in the case of discrepancy. The stadiometer attached to the balance scale was used to measure height. Children were required to complete this measure with no shoes. Height was recorded to the nearest half centimeter. Measures were reported in kilograms and centimeters and converted to BMI values for plotting on BMI for age/gender growth charts. This assessment was included to examine differences in BMI compared to peers with other neurodevelopmental diagnoses, and to determine if dietary restrictions affected growth.

**Mealtime behaviors.** For this study, mealtime behaviors were assessed using the *Behavioural Pediatric Feeding Assessment Scale (BPFAS)* (Crist & Napier-Phillips, 2001), a parent-reported, norm-referenced measure. The scale contains 35 items, 25 of which relate to the mealtime behaviors of the child, and 10 of which relate to mealtime strategies used by the parent. Items are presented as a descriptive statement (e.g. ‘Eats fruits’), against which the parent rates the behavior frequency on a 5-point Likert scale (where 1=Never and 5=Always). Parents were also required to indicate whether they consider each specific behavior to be a problem (yes/no). This tool has been validated with children with and without feeding difficulties (Marshall et al., 2014). An overall total frequency score (TFS) and a total problem score (TPS) for both the child and parent questions were calculated. Maximum scores are TFS=165, TPS-Child=35. A TFS greater than 84 is significantly higher than the normative mean, and a TPS greater than 9 is significantly higher than the normative mean. This assessment was included to determine if a significant amount of problem behaviors exist, and how the amount of problem behaviors relates to dietary variety.
Parental stress. Parental stress was assessed using the Parenting Stress Index – Short Form, Third Edition (PSI-SF), a self-reported standardized assessment of parental stress, that collects information on behaviors of the parent, the child, and the interactions between them (Abidin, 1995). Measures for this assessment are scored using a five-point scale that ranges from “Strongly Agree” to “Strongly Disagree.” The short form assesses three areas: Parental Distress, Parent-Child Dysfunctional Interaction, and Difficult Child. Each of these scores combine to create the total stress score. The results are presented as a percentile, where scores above the 85th percentile are considered to be indicative of clinically significant stress levels. This assessment was included to determine if problem mealtime behaviors correlate to levels of parental stress.

Table 2

Description of Measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Measure</th>
<th>Purpose</th>
<th>Standardized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Intake</td>
<td>24-Hour Diet Recall</td>
<td>Report all foods and liquids consumed for the previous 24 hours for further analysis of types and number of foods</td>
<td>No</td>
</tr>
<tr>
<td>Sensory Processing</td>
<td>Sensory Profile 2</td>
<td>Evaluate a child’s sensory processing patterns and compare to peers</td>
<td>Yes</td>
</tr>
<tr>
<td>Growth</td>
<td>Body Mass Index</td>
<td>Measure height and weight to calculate BMI and classify</td>
<td>Yes</td>
</tr>
<tr>
<td>Feeding Behaviors</td>
<td>BPFAS</td>
<td>Determine if a significant amount of problem feeding behaviors exist</td>
<td>No</td>
</tr>
<tr>
<td>Parental Stress</td>
<td>PSI-SF</td>
<td>Assess levels of stress and the functionality of the relationship between the child and parent</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note. Height and weight measures are calculated in kilograms and centimeters for BMI.
Data Analysis

All measures were scored following provided instructions, and scores were transcribed into a dataset for statistical analyses. IBM SPSS Statistics version 21, a statistical package for the social sciences, was used for statistical analyses. One-way multivariate analyses of variance (MANOVA) were considered first to determine if there were statistically significant differences between the two groups (those with ASD and those with other diagnoses), with respect to dietary intake, SPD, growth, problem feeding behaviors, and parental stress. However, preliminary assumption checking revealed several violations of assumptions. It appeared, using boxplots, that univariate outliers were apparent in four different cases. However, due to sample size concerns, a decision was made to retain the cases. Also, upon consideration of the assumptions, it was observed that the data was not normally distributed, according to the Shapiro-Wilk test. Linear relationships did not exist between the dependent variables, as assessed by scatterplot. The assumption of homogeneity of variance-covariance matrices was also violated because Box’s M test was unable to be run. Lastly, there was not homogeneity of variances, according to Levene’s test. The difference between the groups on the combined dependent variables was not statistically significant, $F(11, 1) = 0.343, p = 0.884$; Wilks’ $\Lambda = 0.210$; partial $\eta^2 = 0.790$.

Because a majority of the assumptions were violated, one-way analysis of variance (ANOVA) with alpha adjustments were chosen. Due to the presence of the 12 variables, given $\alpha = .05$ for all analyses, the probability of committing a Type I error in one of the 12 analyses equals $0.5404 (= 1 - 0.95^{12})$. Thus, alpha was adjusted to .005, so that the probability of committing a Type I error in one of the 12 analyses equals $0.0584 (= 1 - 0.995^{12})$. One-way ANOVAs were run for each of the 12 dependent variables to determine if significant relationships existed between those who had significant scores on the BPFAS and dietary intake, sensory processing, BMI, and parental...
stress. All of the assumptions were met for one-way ANOVAs, except for the assumption that states that there must be no significant outliers. It was also determined that the outliers present in the study only varied by one-point difference. With a larger sample size, it is possible that the values would not qualify as outliers.
CHAPTER 3

RESULTS

Descriptive Statistics

Five different factors of diet and mealtime behaviors were assessed. For dietary intake, the following areas were assessed: number of whole foods consumed ($M = 0.61$, $SD = 0.87$, range: 0.06-1.17), number of processed foods consumed ($M = 6.08$, $SD = 2.63$, range: 4.48-7.76), ounces of fluid consumed ($M = 30.23$, $SD = 13.47$, range: 22.34-38.74), and total number of foods consumed ($M = 6.46$, $SD = 2.82$, range: 4.80-8.24). The following values of reported sensory processing were as follows: auditory SPD ($M = 4.08$, $SD = 0.64$, range: 3.68-4.49), visual SPD ($M = 3.31$, $SD = 0.75$, range: 2.83-3.79), touch SPD ($M = 4.23$, $SD = 0.93$, range: 3.73-4.79), movement SPD ($M = 4.08$, $SD = 0.86$, range: 3.54-4.63), body position SPD ($M = 4.08$, $SD = 1.04$, range: 3.66-4.60), and oral SPD ($M = 4.39$, $SD = 0.77$, range: 3.89-4.87). Growth was measured using BMI scores ($M = 19.14$, $SD = 4.17$, range: 16.46-21.71). Problem feeding behaviors were reported using the participant’s BPFAS frequency score ($M = 101.62$, $SD = 13.78$, range: 92.75-110.21). Parental stress was reported based on the total stress score on the PSI-SF ($M = 98.00$, $SD = 22.08$, range: 84.25-112.21). This information is presented in Table 3.
Table 3

Table 3

*Descriptive Statistics of the Study Variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>( M )</th>
<th>( SD )</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dietary Intake</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Foods Consumed</td>
<td>0.62</td>
<td>0.87</td>
<td>0.06-1.17</td>
</tr>
<tr>
<td>Processed Foods Consumed</td>
<td>6.08</td>
<td>2.63</td>
<td>4.48-7.76</td>
</tr>
<tr>
<td>Fluids Consumed</td>
<td>30.23</td>
<td>13.47</td>
<td>22.34-38.74</td>
</tr>
<tr>
<td>Total Number of Foods Consumed</td>
<td>6.46</td>
<td>2.82</td>
<td>4.80-8.24</td>
</tr>
<tr>
<td><strong>Sensory Processing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auditory SPD</td>
<td>4.08</td>
<td>0.64</td>
<td>3.68-4.49</td>
</tr>
<tr>
<td>Visual SPD</td>
<td>3.31</td>
<td>0.75</td>
<td>2.83-3.79</td>
</tr>
<tr>
<td>Touch SPD</td>
<td>4.23</td>
<td>0.93</td>
<td>3.73-4.79</td>
</tr>
<tr>
<td>Movement SPD</td>
<td>4.08</td>
<td>0.86</td>
<td>3.54-4.63</td>
</tr>
<tr>
<td>Body Position SPD</td>
<td>4.08</td>
<td>1.04</td>
<td>3.66-4.60</td>
</tr>
<tr>
<td>Oral SPD</td>
<td>4.39</td>
<td>0.77</td>
<td>3.89-4.87</td>
</tr>
<tr>
<td><strong>Growth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Feeding Behaviors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPFAS Frequency Score</td>
<td>101.62</td>
<td>13.78</td>
<td>92.75-110.21</td>
</tr>
<tr>
<td><strong>Parental Stress</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Stress Score</td>
<td>98.00</td>
<td>22.08</td>
<td>84.25-112.21</td>
</tr>
</tbody>
</table>

Note. \( n = 13 \). Fluids consumed are reported in ounces.

Also, the mean and standard deviation were compared between the group diagnosed with ASD and the group diagnosed with other neurodevelopmental impairments. While Table 3 includes the overall mean and standard deviation for all 13 participants, Table 4 includes a comparison of the two groups according to their scores on each measure, based solely upon differences in diagnosis.
Table 4

**Descriptive Statistics Compared**

<table>
<thead>
<tr>
<th>Variable</th>
<th>M</th>
<th>SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dietary Intake</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole Foods Consumed</td>
<td>0.57</td>
<td>0.67</td>
<td>0.18-1.33</td>
</tr>
<tr>
<td>Processed Foods Consumed</td>
<td>5.57</td>
<td>6.67</td>
<td>3.34-7.80</td>
</tr>
<tr>
<td>Fluids Consumed</td>
<td>26.57</td>
<td>34.50</td>
<td>13.79-22.47</td>
</tr>
<tr>
<td>Total Number of Foods Consumed</td>
<td>5.71</td>
<td>7.33</td>
<td>3.38-8.05</td>
</tr>
<tr>
<td><strong>Sensory Processing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auditory SPD</td>
<td>4.00</td>
<td>4.17</td>
<td>3.45-4.55</td>
</tr>
<tr>
<td>Visual SPD</td>
<td>3.29</td>
<td>3.33</td>
<td>2.63-3.94</td>
</tr>
<tr>
<td>Touch SPD</td>
<td>3.86</td>
<td>4.67</td>
<td>3.14-4.58</td>
</tr>
<tr>
<td>Movement SPD</td>
<td>4.00</td>
<td>4.17</td>
<td>3.26-4.75</td>
</tr>
<tr>
<td>Body Position SPD</td>
<td>3.43</td>
<td>4.83</td>
<td>2.79-4.07</td>
</tr>
<tr>
<td>Oral SPD</td>
<td>4.43</td>
<td>4.33</td>
<td>3.76-5.09</td>
</tr>
<tr>
<td><strong>Growth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>19.81</td>
<td>18.35</td>
<td>14.50-22.20</td>
</tr>
<tr>
<td><strong>Feeding Behaviors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPFAS Frequency Score</td>
<td>103.29</td>
<td>99.67</td>
<td>91.42-115.15</td>
</tr>
<tr>
<td><strong>Parental Stress</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Stress Score</td>
<td>95.29</td>
<td>101.17</td>
<td>80.65-112.48</td>
</tr>
</tbody>
</table>

Note. n=13. Based upon groups, ASD: n=7, Other: n=6. Fluids are reported in ounces. Scores on the PSI-SF represent percentiles. The table represents a comparison between the group diagnosed with ASD and the group diagnosed with other neurodevelopmental diagnoses on all scores.

**Analysis of Variance**

One-way ANOVA analyses were run, and alpha was adjusted for the number of dependent variables. Out of the 12 analyses, there were statistically significant differences.
between those diagnosed with ASD and those diagnosed with other neurodevelopmental disorders with respect to only Body Position from the *Sensory Profile*. All of the results, however, are presented below.

There were no statistically significant differences in the total parental stress score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.233, p = .637$. There were no statistically significant differences in the auditory component of the *Sensory Profile 2* score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.025, p = .876$. There were no statistically significant differences in the visual component of the *Sensory Profile 2* score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.084, p = .777$. There were no statistically significant differences in the touch component of the *Sensory Profile 2* score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 2.229, p = .159$. There were no statistically significant differences in the movement component of the *Sensory Profile 2* score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.120, p = .735$. However, there were statistically significant differences in the body position component of the *Sensory Profile 2* score between those with ASD ($M = 3.375$) and those diagnosed with other neurodevelopmental disorders ($M = 4.833$), $F(1, 12) = 13.043, p = .004$. There were no statistically significant differences in the oral component of the *Sensory Profile 2* score between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.000, p = 1.00$. There were no statistically significant differences in BMI between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 12) = 0.256, p = .622$. There were no statistically significant differences in the number of whole foods consumed between those with ASD and those
diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.114, p = .741$. There were no statistically significant differences in the number of processed foods consumed between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 0.214, p = .652$. There were no statistically significant differences in amount of fluids consumed between those with ASD and those diagnosed with other neurodevelopmental disorders, $F(1, 13) = 1.960, p = .185$. There were no statistically significant differences in total number of foods consumed between those with ASD and those diagnosed with other neurodevelopmental disorders, Welch’s $F(1, 7.082) = 0.205, p = .664$.

In addition to the five factors that affect mealtimes, the severity of diagnosis was explored for each of the children in this study. A total of seven children in our study were diagnosed with ASD. Four of the children were classified as having severe symptoms of ASD. The remaining three children were classified as having mild-to-moderate symptoms of ASD. A score of below 30 is indicative of minimum-to-no symptoms of ASD, a score of 30-36.5 is indicative of mild-to-moderate symptoms of ASD, and a score above 36.5 is indicative of severe symptoms of ASD. The mean score for the children in this study was 38. The mean for the children with mild-to-moderate symptoms was 32, and the mean for the children with severe symptoms was 43.
CHAPTER 4
DISCUSSION

No statistically significant differences were found between the group with ASD and the group with other neurodevelopmental disorders, with the exception of the body position component of the Sensory Profile 2. Previous literature described the feeding behaviors presented in children with ASD to be unique as compared to typically developing peers (Nadon et al., 2011; Brown et al., 2002). In this analysis, the reported features of feeding problems in children with ASD were compared to children with other neurodevelopmental disorders. The results of this study suggest that the type of problem feeding behaviors reported in populations of children with ASD are not unique to ASD, but similar features are also seen in children with related neurodevelopmental disorders. The results of this project are similar to the conclusions of Graf-Myles and colleagues (2013), who reported no significant differences between children with ASD and children with developmental delay with regards to dietary adequacy.

With regards to the data itself, sensory processing of body position was the only statistically significant factor between the group diagnosed with ASD and the group diagnosed with other neurodevelopmental disorders. The group diagnosed with ASD had a variety of scores, but the group diagnosed with other neurodevelopmental disorders all had a score of “much more than others.” This anomalous finding can be explained by a variety of factors. Body position is one of the six types of sensory processing that is measured on the Sensory Profile 2. On the Sensory Profile 2, the options that the parent/caregiver are given include: “moves stiffly,” “seems to have weak muscles,” “props to support self,” “clings to objects, walls, or banisters
more than same-aged children,” “drapes self over furniture or on other people.” These descriptions are related to the child’s ability to move their body effectively. Scoring in the “much more than others” would indicate that the limited number of children in this group would benefit from increasing the intensity of sensory experiences in regards to body position. An example intervention would be providing ankle weights to increase the intensity of the sensory experience. This unique finding requires further investigation to determine if it is anomalous due to the small sample size or if it is truly a significant difference between the two diagnostic groups.

The lack of statistically significant differences between the group with ASD and the group with other neurodevelopmental disorders has many clinical implications. Feeding assessments are not a typical element of speech and language or psychological evaluations when assessing for ASD or other neurodevelopmental diagnoses. The evidence from this study suggests a need for this type of assessment across all suspected neurodevelopmental diagnoses. According to the data presented here, problem-feeding behaviors were present in both children with ASD and children with other neurodevelopmental diagnoses. About half of the original group of 44 participants had a significantly high problem feeding score. According to the BPFAS, problem feeding behaviors can include restricted numbers and types of foods consumed, undesirable behaviors (choking, gagging, whining, spitting), or refusal to eat certain foods. The number of and types of foods consumed is the most apparent factor in the comparison of ASD and other neurodevelopmental diagnoses that differs from recommended diets for this age group.

The differences between actual consumption of food and nutrients to the recommended amounts were extensive. As reported by the USDA (2015), children should consume between two and three servings of fruit, between two and three servings of vegetables, five servings of
grains, three servings of protein, and between three and four servings of dairy per day. However, the average number of whole foods consumed for both groups was less than one per day. Overall, both groups averaged eating about five to seven foods during the day. Most foods consumed were highly processed and contained few micronutrients. Children diagnosed with ASD are known to exhibit behaviors that cause disruptions to mealtimes, for example, food refusal, food selectivity according to features, and food jagging (Nadon et al., 2011). Because they tend to refuse certain foods, it is suspected that children with ASD could have micronutrient deficiencies. A study conducted by Hyman and colleagues (2012) found that, when compared with a typically developing control group, children with ASD consumed significantly less of selected nutrients. They also found that children with ASD had a greater prevalence of being overweight and obese, which agrees with the findings of Marshall and colleagues (2013) that being overweight was a commonly reported problem for children diagnosed with ASD. This study suggests children with ASD and children with other neurodevelopmental diagnoses exhibit the same patterns of food selectivity and problem feeding behaviors. However, further research is needed to explore these trends with a larger sample size. It is suggested that these patterns of food selectivity and refusal can lead to shortages of important nutrients (Benton, 2008). It is also suggested that because of the rapidly developing brain throughout childhood, nutrition and diet can affect cognitive functioning and behavior in a variety of ways (Benton, 2008). There is a need for further assessment to determine the adequacy of consumption of vital macro- and micronutrients. Along with dietary intake, the children diagnosed with ASD and children diagnosed with other neurodevelopmental diagnoses exhibited differences between other variables when compared to typically developing peers.
Additionally, the descriptives of the sample warrant further investigation. The comparisons of the mean and standard deviation of the group diagnosed with ASD and group diagnosed with other neurodevelopmental diagnoses are presented in Table 4. It is important to note that the children diagnosed with ASD included in this cohort had a mean severity score from the CARS of 38, meaning that the children in this study had severe symptoms of ASD. The results of this study may not be easily generalized to children with more mild-to-moderate symptoms of ASD. With regards to sensory processing, the group diagnosed with ASD scored one SD from the mean on auditory, touch, and movement sensory processing. The group diagnosed with other neurodevelopmental diagnoses scored one SD from the mean on auditory, touch, movement, and body position sensory processing. With regards to BMI, the mean of both groups was comparable. Within the sample, six children were classified as obese (46% of the sample), three were classified as overweight (23% of the sample), and four were classified as an average weight (31% of the sample) for their age norms. As mentioned before, the PSI-SF is a parent-rated measure that presents results as percentiles. Scores above the 85th percentile are considered to be indicative of clinically significant stress levels. For our sample, the mean of both groups was in the 98th percentile. The mean of the group of parents of children diagnosed with ASD was in the 95th percentile, and the mean of the group of parents of children diagnosed with other neurodevelopmental disorders was in the 101st percentile. All were indicative of clinically significant stress levels. Further exploration is needed into all of the implications of how parental stress affects mealtimes.

Based on this small sample, there is a trend towards restricted variety, an increased number of processed foods, higher BMI, frequent problem feeding behaviors, and increased parental stress. These results indicate that there is an apparent need for further assessment and
referrals to the appropriate resources. Because of the small differences between the two groups, there is a need for further diet analysis and assessment for children with ASD and also children diagnosed with other neurodevelopmental diagnoses. Clinics do not typically include a feeding assessment as a part of their evaluation; however, given that half of the population in this study presented with significant problem feeding scores, using a feeding assessment must be considered for future use.

**Limitations**

This study was limited by the small sample size. The missing data from the already small sample contributed to the limited number of participants. Parents were asked to fill out the assessments upon arrival to the clinic for the full evaluation, and some assessments were not completed due to time constraints. Also, some measures were unable to be reported due to the child’s behaviors. The height and weight measurements required that the child stand barefoot and still on a scale. For children with sensory hypersensitivities and challenging behaviors, this was difficult to obtain. Also, when collecting the 24-hour diet recall, some parents/caregivers were unsure of what their child had eaten the day before or unsure of the amounts eaten when they were not present (e.g., at daycare, with another parent/caregiver, etc.). Another limitation of the 24-hour diet recall is that it only allows the researcher to examine the participant’s diet over a 24-hour period. It may not truly be representative of the amount and types of foods that the participant eats on a regular basis. A three-day or longer diet recall would be ideal for analysis of dietary intake, but for this population, this was the most effective method to ensure full participation.
Future Research

In terms of future research, this study provides opportunities for further analysis of problem feeding behaviors in children with neurodevelopmental diagnoses. There is a need to assess the feeding behaviors of all children with SPD, and not exclusively those diagnosed with ASD. There is limited research in the area of feeding disorders in children with ASD and other neurodevelopmental diagnoses, so more research is needed to determine how the characteristics of the diagnoses affect children’s diets and overall health. Also, the DSM-5 now includes SPD and the presence of other behaviors that affect mealtimes as part of the diagnosis of ASD, so further investigation is needed to determine the short and long-term effects of altered diets. Likewise, the Sensory Profile 2 and the BPFAS are now being used as a part of evaluations at the UA ASD Clinic, so this will provide an opportunity for researchers to investigate the diets of this population of children. An opportunity also exists for future researchers to compare a group with ASD, a group with other neurodevelopmental disorders, and a typically developing control group. Number of foods consumed, scores on the assessments, and BMI could be compared to norms for age references. There is also a need to explore the nutritional aspects of the foods consumed and their effects on behavior. Overall, a larger sample size will allow for more significant conclusions.
REFERENCES


APPENDIX

THE UNIVERSITY OF
ALABAMA

Office of the Vice President for
Research & Economic Development
Office for Research Compliance

January 9, 2017

Sarah M. Ryan, Ph.D.
Administrative Director of Autism Services
Department of Psychology
College of Arts & Sciences
The University of Alabama
Box 870348

Re: IRB # 06-OR-022-R11 “Autism Spectrum Disorders Clinic Research Database”

Dear Dr. Ryan:

The University of Alabama Institutional Review Board has granted approval for your proposed research. Your renewal application has been given expedited approval according to 45 CFR part 46. Approval has been given under expedited review category 7 as outlined below:

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Your application will expire on January 8, 2018. If your research will continue beyond this date, complete the relevant portions of the IRB Renewal Application. If you wish to modify the application, complete the Modification of an Approved Protocol Form. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants. When the study closes, complete the appropriate portions of the IRB Study Closure Form.

Please use reproductions of the IRB approved stamped consent/assent forms to obtain consent from your participants.

Should you need to submit any further correspondence regarding this proposal, please include the above application number.

Good luck with your research.

Sincerely,

Carpanuto T. Myles, MSM, CIC, CIP
Director & Research Compliance Officer
Office of Research Compliance

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