Research Proposal: A Quasi Experimental Study to Determine the Effects

of a Yoga with Pranayama Breathing Intervention for Increased Food Acceptance in Children

with Autism Spectrum Disorder and a Co-Occurring Feeding Disorder

By

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Abstract

Feeding disorders can be complex and exist to a greater degree in those with autism spectrum disorder (ASD). As the medical world expands to adopt diverse therapies for treatment, exploring a variety of care is advantageous due to the variation in symptoms and presentation. Yoga practice has been shown to benefit children with ASD in a range of ways, though there is no research to date that directly connects yoga to improved nutrition intake. The purpose of this proposal is to advocate for a study that teaches yoga with pranayama breathing to children with ASD and a co-occurring feeding disorder. It is hypothesized that the yoga intervention will significantly increase the acceptance of food groups, colors, and textures as well as overall calories consumed. The 6-month quasi-experimental study will have 75 participants. Data will be collected from lab-based nutrition assessments and home food records. The proposed study will support a complementary and alternative medicine approach for feeding difficulties in children with ASD and promote a non-invasive adjunct therapy that may offer additional mental and physical health benefits.

Keywords: autism spectrum disorder, feeding disorder, food acceptance, oral motor, oral sensory, yoga with pranayama breathing

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Chapter 1: Introduction to the Study

The growing application of complementary and alternative medicine approaches to disease management warrants new developments in research. In that vein, yoga and breath-based exercises are increasingly more common as an adjunct treatment to many physiologic and psychologic conditions as well for behavioral purposes. While not overtly tied to nutrition, yoga is often associated with general wellness and a healthy lifestyle, which can assume a positive relationship with food. From a physiologic perspective, breathing exercises, which are a part of yoga practice, may, in theory, present an opportunity to strengthen structures used in the process of eating (American Speech Language and Hearing Association [ASLH], 2018; Manno, et al., 2005). Be it a clinical or classroom setting, yoga for children is a novel intervention with demonstrated benefit but has limited research supporting is efficacy for use in the treatment of nutrition-related concerns (Garg et al., 2013, Narasingarao et al., 2017, Radhakrishna et al., 2010, Sotoodeh et al 2017).

Children with autism spectrum disorder (ASD) are 70.4% more likely to develop atypical eating behaviors, also known as a feeding disorder, as compared to those without (Mayes, Zickgraf, & Baweja, 2019). A pediatric feeding disorder can be defined as "impaired oral intake

that is not age-appropriate and is associated with medical, nutritional, feeding skill, and/or psychosocial dysfunction" (Goday et al., 2019, p.1). Food preference is learned over time and can be influenced by oral sensory and oral motor experiences and developmental milestones. Autism can influence these oral abilities and may adversely affect food sensory processing ability (Aswathy et al., 2016). In addition to this, children with ASD may also experience mealtime anxiety due to sensory aversions or unfamiliarity of foods (Autism Speaks, 2015). These factors, in turn, may impact food choice and the ability to obtain adequate nutrition. Theoretically, children with ASD and a co-occurring feeding disorder may benefit from yoga practices like mindfulness and breath-based exercises to address these symptoms as breathing exercises may train and strengthen oral muscles as well as decrease associated anxiety around eating. At this time there is no research to date that directly connects yoga practice or breathing exercises in this population to improved dietary outcomes. This research proposal will present a possible method to investigate if such a connection exists.

Background

A feeding disorder can lead to problems including malnutrition, poor growth, nutritional deficiency, or problems with daily functioning (Goday et al., 2019; Lumen Learning, n.d.). Feeding disorders often co-occur in children with developmental disabilities, including ASD (Kennedy Krieger Institute, 2021; The Recovery Village, 2021). Existing strategies to increase food acceptance in children with ASD are diverse, though usually do not directly incorporate complementary and alternative medicine practices. Some strategies include family meals, scheduled mealtimes, involving the child in cooking, gradual exposure to new foods, taking time to relax prior to mealtimes, and working to improve posture at the table (Autism Speaks, 2015). Research suggests the feasibility of applied yoga-based interventions in pediatric populations

(Birdee et al., 2009), patients with eating disorders (Carei et al., 2010), and patients with related physical or psychological disorders (Bussing et al., 2012). Research has also demonstrated that breathing or yoga-type interventions may benefit children with and without ASD (Birdee et al., 2009; Manno et al., 2005). However, future studies are needed to directly link breathing exercises or yoga practice to dietary intake, growth, and other nutrition parameters.

Yoga is not a dietary intervention itself but has been used as an adjunct treatment for medical diagnosis with and without nutrition-related factors. The current body of literature indicates that yoga practice and/or breathing exercises can support the physical structures involved in the feeding process. The respiratory and digestive system share functional structures, however breathing supersedes swallowing during feeding (Manno et al., 2005). Breathing habits may influence an individual's food preference based on how these structures develop and thus influence feeding ability or food acceptance (Goday, et al., 2019; Manno et al., 2005). Children with ASD may also experience low muscle tone that affects posture, making it difficult to maintain an upright seated position at a table (Autism Speaks, 2015). Body posture is also associated with oral motor movements, swallowing, and breathing ability (Adolph & Franchak, 2017; Manno et al., 2005; Marrow et a.l, 2016). Both breathing and physical alignment are addressed in yoga practice.

Problem Statement

At this time there is no research to demonstrate if yoga will improve elements of feeding difficulties involving mastication and swallowing ability that can be related to overall food acceptance. Additionally, the efficacy of yoga with pranayama breathing for children with a diagnosed feeding disorder has not been studied. More research is necessary to explore the

influence of yoga and breathing exercises on oral motor and oral sensory abilities as well as nutrition-related implications.

Purpose of the Study

The purpose of this quasi-experimental study is to investigate the influence of yoga with pranayama breathing on food acceptance in children ASD and a co-occurring feeding disorder. This includes the number of food groups, food colors, food textures, and calories consumed.

Research Question(s) and Hypotheses

Research Question 1

Can yoga practice with pranayama breathing influence the variety of food groups accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number food groups accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food groups by children with ASD and a co-occurring feeding disorder as compared to baseline.

Research Question 2

Can yoga practice with pranayama breathing influence the number of food colors accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number of food colors accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food colors accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

Research Question 3

Can yoga practice with pranayama breathing influence the number of food textures accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number food textures accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food textures accepted by children with ASD and a co-occurring feeding as compared to baseline.

Research Question 4

Can yoga practice with pranayama breathing influence the number of calories consumed by children with ASD and a co-occurring feeding disorder?

Hypothesis

H_o: After six months of yoga-based intervention there is no significant difference in the number of calories consumed by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of calories consumed by children with ASD and a co-occurring feeding disorder as compared to baseline.

Nature of the Study

The proposed study will utilize a six-month, quasi-experimental, single-group, longitudinal design. It will assess the effects of a yoga-based intervention with pranayama breathing on dietary choices of children with ASD and a co-occurring feeding disorder. Dietary measures include food groups, food colors, food textures, and calories consumed. The study may determine if the yoga intervention can influence increased food acceptance among these categories. The primary outcome of this study is the overall change in the diversity of foods consumed as measured by the number of food groups, food colors, and food textures accepted. The study will also assess the change in average number of calories consumed. A repeated measures analysis of variance ANOVA will be used to measure the influence of the one independent variable on the four dependent variables before the intervention, at the intervention midpoint (3 months), and post intervention (6 months). This test will quantify the results and determine if any significant differences between means exist at each measurement period.

Definitions

Asana – Any variety of yoga postures (Dictionary.com, n.d.).

Breath Exercise – Exercises intended to engage and strengthen the muscles involved in breathing.

Complementary and Alternative Medicine – Additional therapy methods that are used along with traditional medical approaches.

Developmental Disability – A group of conditions that begins during the developmental period and results in an impairment in physical, learning, language, or behavior areas. These impairments usually last throughout a person's lifetime and may impact day-to-day functioning (CDC, 2021).

Eating Disorder – Concern with weight, shape, and/or body image that results in restrictive eating behaviors.

Pediatric Feeding Disorder – "Impaired oral intake that is not age-appropriate, and is associated with medical, nutritional, feeding skill, and/or psychosocial dysfunction" (Goday et al., 2019, para. 1). A feeding disorder may result in disruptions in nutritional and caloric intake, food preference, or interest in eating. **The term "feeding disorder" will be used synonymously throughout this proposal.*

Feeding Challenge/Difficulty – Inability to typically masticate and/or swallow.

Food Acceptance – consumption of a variety of foods including food groups, food colors, and food textures that are appropriate for optimal nutrition and growth.

Food Avoidance – Rejection of a food to the extent it may include behavioral difficulties. Rejection may be related fear of a food/food group and/or a physical or psychological reason.

Food Colors – The variety of colors that naturally occur in foods. This includes red, orange/yellow, purple/blue, green, white, brown/black.

Food Diversity – A diet that represents a variety of food groups, food colors, and food textures.

Food Groups – Classification of foods based on composition and adapted from the USDA. This includes fruits, vegetables, grains, protein foods, and dairy/dairy-like foods.

Food Texture – Properties of food that can be felt with the fingers, tongue, palate, and teeth. This includes firm, crispy/crunchy, smooth, soft, and chewy.

Food Selectivity – Picky eating that may be related to a sensory response to characteristics of a food. More commonly reported in children with ASD (Bandini, Anderson, & Must, 2010).

Oral Motor Skills – The aspect of eating that involves movement of the muscles of the face including the jaw, mouth, tongue, and lips to engage in feeding skills. Involves muscle tone,

muscle strength, range of motion, coordination, and dissociation to engage in sucking, biting, and chewing (Bean, 2013).

Oral Sensory– The aspect of eating that involves how the tissues of the mouth perceive sensory information such as taste, temperature, and texture of food (Children's Wisconsin, n.d.)

Pranayama – The regulation of breath through exercises and techniques. It is a primary component of yoga practice can be practices independent of asanas.

Assumptions

It is assumed that the yoga with pranayama intervention will be feasible among the target population. Another assumption is that the intervention will result in increased food acceptance among participants; this includes calorie intake as well as variety of food groups, food colors, and food textures. An additional assumption is that parents/caregivers will participate in supporting their child during the yoga sessions. It is also assumed that parents will be consistent in completing home food records at the study intervals. Lastly, it is assumed that this study will be of value in the field of dietetics as well as in the field of complementary and alternative medicine.

Limitations

A primary limitation is the absence of randomization due to the nature of the quasiexperimental design. Additionally, the intervention is only a small population and cannot be generalized to other populations. Another limitation is parent bias in subjective data collection. Attrition is also a limitation due to the length of the study. The length of the study itself is also limiting as we do not know if it will be long enough to determine any effects. Another limitation among the populations is participants must be independently ambulatory and deemed safe to engage in yoga exercise by their primary care provider, which may limit available participants.

Delimitations

The delimitations of this study define the parameters based on inclusion and exclusion criteria. The leading delimitation is that this study is limited to children 6-12 years old with a diagnosis of ASD and a co-occurring diagnosed feeding disorder. The population of interest is also a threat to both internal and external validity. This includes the varying extent of disability of each participant and variation in ASD characteristics as well as the influence of other treatments participants may be engaging in. The proposed study will not discern participants based on these factors. Another delimitation may be the diversity of socioeconomic factors of families as it may limit variety of foods available in each household. Lastly, this study will exclude children with diagnosed *eating* disorders (anorexia nervosa or bulimia nervosa).

Significance

This study will lend to the body of research surrounding complementary and alternative medicine approaches for children with ASD and feeding disorders and may provide insight on yoga as an adjunct treatment. Implementing a yoga-based intervention for children with ASD and feeding disorders will provide data that may help address eating challenges from a whole-health perspective though mindfulness, relaxation, and muscle strengthening. This will contribute to the larger body of literature concerning treatment for feeding difficulties in children with ASD and encourage those with ASD to consume a greater variety of foods.

Summary

Yoga practice involves mindfulness, physical posture, and breath exercise which could offer a unique treatment for children with ASD and a co-occurring feeding disorder. Wholehealth approaches to healthcare involve both the mind and body and are important in managing disease and encouraging general wellness. The results from the proposed study may support future studies on this topic and add to the body of literature concerning complementary and alternative medicine for children. The study may also promote a novel intervention for feeding disorder which may be a useful strategy for some families as symptoms of both ASD and feeding disorders are diverse. The following chapter will review literature on yoga and breath-based exercises for a variety of related medical conditions in children and adults.

Chapter 2: Review of Literature

Eating habits mature in with the skills of nutritive suckling, swallowing, and breathing. Suckling patterns initiate the learned process of feeding, and, in due time, most palates will advance to foods diverse in flavor and texture. In some cases, however, children may struggle with learning to feed as result of poor oral motor skills (Children's Wisconsin, 2021; Manno, et al., 2005). What may present as picky eating behaviors could be due to an oral sensory (OS) or oral motor (OM) challenge.

Poor oral motor skills present in 5-10% of typically developing children and are prevalent in approximately 80% with developmental disabilities (DD) (Children's Wisconsin, 2021). Babies develop sensory and orofacial abilities through facial expressions, teething, speech, and coordination, all of which facilitate oral motor strength. An absence of engaging in these activities, or delayed milestone experiences such as spoon feeding or advancing to solid foods, may impair a child's ability to use their oral sensory or motor system and can subsequently advance into a feeding disorder. Feeding disorders can progress to developmental delays, behavioral disorders, and poor growth (Goday et al., 2019; Manno, et al., 2005). Existing literature suggests that breathing or yoga-based interventions may be beneficial for physiologic, psychologic, and behavioral challenges in children (Wei, 2016). Although benefits have been realized, yoga is not an established intervention for nutrition-related medical concerns. While future studies are needed to directly link breathing exercises or yoga practice to dietary outcomes, current research has demonstrated the benefits of applied interventions in general pediatric (Birdee et al., 2009) and adult populations (Birken & Edgren, 2000; Sharma et al., 2014), children with DD (Radhakrishna et al., 2010; Garg et al., 2013; Sotoodeh et al., 2017), and patients with eating disorders (Carei et al., 2010; Pancanowski et al., 2017). While no literature found at this time directly assesses the use of yoga and breathing exercises for improving dietary intake and growth in children with autism and a co-occurring feeding disorder, this literature review investigates related research and identifies the gap in current research, explores intervention methods, and determines appropriate study designs.

Literature Research Strategy

Literature was obtained through online searches from June 2021 to August 2021. The databases explored were Mount Mary University Library's PubMed, Primo, and Google Scholar. Search terms used were: "pediatric feeding disorders," "yoga and feeding disorders," "yoga and eating disorders," "yoga and swallowing," "pranayama oral myofunctional disorders," "oral motor skill and feeding disorders," "yoga and swallowing," "pranayama and eating disorders," "yoga picky eating," "breathing interventions in pediatrics," "oral motor skill and breathing," "oral motor skill exercises," "feeding disorders in children with developmental disabilities," "developmental disabilities and swallowing," "breath interventions for feeding disorders," "breath interventions fo

disorders," "breath interventions for children," "diaphragmatic breathing," "diaphragmatic breathing eating disorders," "diaphragmatic breathing pediatrics." Terms were not truncated in initial searches but were thereafter. Journal articles were also collected via the reference page of reviewed studies as well as from meta-analysis that were excluded in this literature review. Pilot studies with control cohorts were included to explore efficacy and study designs; uncontrolled pilot studies were excluded. Journal articles included in this review include physiologic, psychologic, or behavioral measures both directly or indirectly related to dietary or OM/OS skill outcomes.

Background

Feeding Disorders in Children

A feeding disorder is a condition that hinders the consumption of certain foods in response to palatability, color, texture, temperature, physical swallowing ability, or similar factors (Lumen Learning, n.d.). A feeding disorder can lead to problems including malnutrition, poor growth, nutritional deficiency, or problems with daily functioning (Goday et al., 2019; Lumen Learning, n.d.). Feeding disorders often co-occur in patients with palate defects, autism spectrum disorder (ASD), attention-deficit hyperactivity disorder (ADHD), gastrointestinal motility disorders, oral motor dysfunctions, food allergies, behavioral challenges, delayed exposure to a variety of foods, and prematurity (Kennedy Krieger Institute, 2021; The Recovery Village, 2021). Children diagnosed with a feeding disorder are at greater risk for compromised physical and cognitive development. Resulting delayed development and behavioral problems are common comorbidities, which for children with developmental disabilities (DD) presents a significant concern for failure to thrive (FTT) (Kennedy Krieger Institute, 2021). While different in its entirety to eating disorders, *feeding* disorders share several characteristics. Feeding disorders lack a universally accepted definition (Goday et al., 2019). In the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), the diagnosis of Feeding Disorder of Infancy or Early Childhood was renamed to Avoidant/Restrictive Food Intake Disorder (ARFID). Avoidant/Restrictive Food Intake Disorder describes disordered eating patterns related to physiologic and psychologic factors that do not fall under the definition of a typical *eating* disorder such as anorexia nervosa and bulimia nervosa (American Psychiatric Association [APA], 2013). Though, a feeding disorder differs from ARFID in that ARFID excludes children whose primary challenge is a skill deficit (Goday et al., 2019). Eating disorders (such as anorexia nervosa and bulimia nervosa), however, include a fear of gaining weight and body dysmorphia; feeding disorders do not include these psychological symptoms but do share symptoms of food selectivity and mealtime/eating anxiety as seen in eating disorders (APA, 2013).

Oral Motor and Oral Sensory

Gross motor development is not driven solely by maturation, it is also dependent on successful practice of skills. The practice of feeding directly influences oral motor patterns, which then directly influences physiologic responses to feeding (Manno et al., 2005). The American Speech Language and Hearing Association (2018) describes feeding in four stages: Oral Preparation Stage, Oral Transit Phase, Pharyngeal Phase, and Esophageal Phase. In the oral cavity food is first prepared for swallowing by way of sucking liquids, manipulating soft boluses, and chewing solid food. The processed bolus is then propelled posteriorly through the oral cavity where the initiation of swallowing and moving the bolus through the pharynx can occur. The swallowed bolus then moves through the esophagus and into the stomach via esophageal peristalsis (American Speech Language and Hearing Association [ASLH], 2018; Matsuo & Palmer, 2008). The advancement of these feeding stages develop overtime with practice, and if delayed, can affect OM and OS ability.

Oral motor refers to the use and function of the lips, tongue, jaw, teeth, and the hard and soft palates. The movement and coordination of these structures is necessary for safe swallowing and processing food textures. Typical oral motor development begins prior to birth and advances in childhood (Adolph & Franchak, 2017). Oral sensory processing, however, is threefold – tactile (touch), proprioception (deep pressure), and taste are the sensory systems that receive input in the oral cavity (Grogran, n.d.). Tactile sense offers feedback on temperature and physical sensation form the lips, tongue, gums, and cheeks. Proprioception receptors send input from chewing and sucking and occurs primarily from jaw movements. Taste sensory response comes from the tongue and signals flavors such as salty, sweet, sour, spicy, etc. (Grogran, n.d.).

Sensory issues present in many ways. Over processing can result in avoidant behaviors while under processing may express as seeking tendencies (Grogran, n.d). Licking, sucking, or chewing non-food items; sucking own lips or chewing own cheeks; and preference for crunchy, salty, spicy, or sweet foods can be a sign of reduced oral sensory skills. Conversely, heightened sensory processing can present in behaviors such as gaging in response to texture; preference for bland and specific textured foods; preference for small pieces of foods; and avoidance of mixed foods (Cheng & Boggett-Carsjens, 2006; Grogran, n.d.). Similarly, low sensory processing can also occur. This differentiates from under or heightened oral sensory response as resulting issues are solely physical and are associated with undeveloped or impaired oral motor skills. Low sensory processing can trigger challenges in mastication; frequent drooling and spitting; spitting of food while eating (with or without intention); and gaging and choking (Grogran, n.d.).

Oral Posture, Physical Alignment, and Feeding/Eating Ability

Oral and orofacial musculature can affect palate texture, mastication, and swallowing ability which can also influence dietary choices (Le Reverend et al., 2013; Walsh, 2020). Atypical oral and orofacial development are classified as orofacial myofunctional disorders (OMD) and are a group of physical disabilities that interfere with normal growth or function of the structures that make up the face, nose, and mouth (ASLH, n.d.). Breathing habits may influence an individual's food preference based on the development of their oral and orofacial musculature as underlying structural issues that impact the airway can coincide with OMDs and thus impair feeding ability or food acceptance (Goday, et al., 2019; Manno et al., 2005).

Typical oral posture, or proper tongue resting position, occurs when the tongue rests at the roof of the mouth away from the teeth; teeth should be slightly parted, and lips should be closed (Kahn & Ehrlich, 2018). The importance of proper oral posture is like that of physical posture – proper physical alignment balances the tension of muscles and ligaments to minimize physical stress and preserve their ability to function, while proper oral posture supports oral health, OM and OS functions, jaw movement, swallowing, and breathing ability.

Physical alignment, or body posture, is associated with movements of the face and head including swallowing and breathing ability (Adolph & Franchak, 2017; Manno et al., 2005; Marrow et al., 2016). With poor physical alignment, the head may rest in a forward position in which the jaw is unable to move freely for proper OM functions (Manno et al., 2005). Consequently, referred pain or disability may present as muscles and joints rely on other areas of the body in a compensatory fashion. The head, neck, and chest muscles work collaboratively to aid in breathing and swallowing ability. Prolonged compensatory patterns can hinder the development of OM skills and subsequently OS response due to the compromised physiologic functions of these muscles (Manno et al., 2005).

Myofunctional therapy is a standard intervention for orofacial posture and oral motorsensory issues (Manno et al., 2005; Walsh, 2020). Myofunctional therapy targets range of motion and strength of orofacial muscles to improve breathing patterns and aim to resolve related issues such as sleep apnea, posture, cervical neck tension, and temporomandibular joint dysfunction (TMJ) (The Breath Institute, 2021). Myofunctional therapy may be involved in treatment of feeding disorders with OM or OS impairment because it can aid in training related muscle groups and practicing necessary functional skills (Walsh, 2020). *Note that the proposed study is *not* intended to be a replacement to this therapy.

Breathing Patterns and Nutrition Implications

Nutrition and breathing are connected in more ways than just metabolism. The respiratory and digestive tract share functional structures, though breathing supersedes swallowing during feeding (Manno et al., 2005). Breathing is also part of the autonomic nervous system (ANS) and is a passive body function. Digestion, blood pressure, and metabolic processes are also part of the ANS. The sympathetic (fight-or-flight) and parasympathetic (rest-and-digest) nervous systems are branches of the ANS and are both involved in processes with nutrition-related functions and breathing (McCorry, 2007).

Impaired oral skeletal and muscle development is more likely to occur in children with developmental disabilities and can also influence respiratory patterns (Vidotto et al., 2019). Secondary poor muscle development can result in dysfunctional breathing patterns (Vidotto et al., 2019). Dysfunctional breathing is a respiratory condition characterized by atypical breathing

patterns that interfere with the normal respiratory processes. Dysfunctional breathing can occur in the absence of or secondary to a disease but is not a disease process itself (Vidotto et al., 2019).

Primary inhalation and exhalation should occur through the nose with expanding breaths through abdomen (American Lung Association [ALA], 2021). In inspiration, the diaphragm contracts down and flattens to pull air into the lungs, while in expiration it relaxes as air is forced out through the nasal or oral cavities. Muscles in the chest, neck, collarbone, and ribcage are also involved in breathing (ALA, 2021).

Nasal and oral breathing both carry oxygen to the lungs, however there are differences in the efficiency between the types of inspiration (Cleveland Clinic, 2020). Nasal breathing produces nitric oxide (NO) which acts as a vasodilator to widen blood vessels. Vasodilation improves blood flow which increases oxygen and nutrient circulation in the body (Ichinose, Roberts, & Zapol, 2008; Lundberg et al., 1996). Nasal breathing also helps with oral posture as it forces the body to properly position the tongue and successively strengthen oral and orofacial muscles (The Breath Institute, n.d.). Conversely, while oral breathing is advantageous in situations such as nasal congestion and some exercise, chronic oral breathing may be consequential. Due to weakened oral posture, primary oral breathing can result in nutritionrelated medical complications such as OM or OS disability and poor oral health (Guilleminault & Sullivan, 2014).

Chronic oral breathing is a marker of OMDs and is a form of dysfunctional breathing. Dysfunctional breathing has been shown to lead to changes in muscle involvement in the upper airway which influences craniofacial growth (Guilleminault & Sullivan, 2014). Proper development can become impaired in the setting of continuous dysfunctional breathing and may affect muscle tone and subsequently influence mastication, swallowing ability, OM skills, and OS responses, all of which can consequently affect food preference (Guilleminault & Sullivan, 2014). Oral breathing patterns can be indicative of undeveloped or impaired OS or OM skills, which can in turn influence selective eating patterns (Associates in Pediatric Therapy, n.d.; Children's Wisconsin, 2021; Guilleminault & Sullivan, 2014). This is particularly prevalent in children with DD and/or delayed or missed sensory and oral milestones (Manno et al., 2005; Van Den Engel-Hoek et al., 2015).

Breath-Based Exercises: Types and Applications

Diaphragmatic Breathing

Diaphragmatic breathing, also called belly breathing, is a breathing exercise intended to train and strengthen the diaphragm (American Lung Association, 2020; Cleveland Clinic, 2018). Diaphragmatic breathing practice involves mindfully inhaling through the nose and expanding the breaths through the abdomen with extended exhales through the mouth (American Lung Association, 2020). This type of breathing can aid in minimizing the effort and energy used to breath as well as support full oxygen exchange which slows the heart rate and stabilizes blood pressure (Cleveland Clinic, 2018; Harvard Health Publishing, 2016). Engaging the diaphragm also activates the vagus nerve which triggers the parasympathetic nervous system to reduce the body's stress response (Johns Hopkins, n.d.). Diaphragmatic breathing is a common intervention for chronic obstructive pulmonary disease (COPD) to improve breathing efficiency and is also used in managing pain or as a relaxation practice (Johns Hopkins, n.d.; Harvard Health

Publishing, 2016). In pediatric populations, diaphragmatic breathing is primarily used for reducing stress and anxiety as well as managing mood and behaviors (Children's Health, n.d.)

Pranayama Breathing

Pranayama is the formal practice of controlled breathing in yoga (Yoga Journal, n.d.). *Prana* is defined as "breath" or "life force" and *yama* is "control" or "restraint" (Tomlinson, n.d; Yogapoint, n.d.). Regular pranayama practice is recognized to stimulate the parasympathetic nervous system and influence physical and emotional states (Sinha et al., 2013; Tomlinson, n.d.). Like diaphragmatic breathing, pranayama focuses on abdomen expansion, however, it differs in that there are many types of inhalation and exhalation patterns in pranayama. Pranayama has been recognized to have many physical and psychological benefits including improves pulmonary function (Shankarappa et al., 2012), reduced stress (Nemati, 2013), reduced depression and anxiety (Bussing et al., 2012), reduced inflammatory markers (Falkenberg et al., 2018), improved cardiovascular health (Pramanik et al., 201), and reduced symptoms of digestive diseases (Kavuri et al., 2015). Pranayama has been successfully applied in pediatric populations and articles in this review investigate such interventions.

The Rational for Yoga as a Treatment Approach for Feeding Disorders

Yoga is a holistic approach to health and is classified by the National Institute of Health as a form of complementary and alternative medicine (Khushcboo et al., 2019). Yoga is a meditative practice comprised of physical exercise (asana) and breath exercise (pranayama) and has been practiced for over 5,000 years (Google Arts and Culture, n.d.). Yoga has been brought into clinical settings as an adjunct therapy for many ailments including cardiovascular and respiratory diseases, chronic fatigue, stress, anxiety, depression, musculoskeletal or endocrine conditions, and eating disorders (Bussing et al., 2012).

Yoga is reported to suppress sympathetic activity through neurohormonal mechanisms to improve autonomic functions and improve muscle strength, respiratory capacity, and posture (Sengupta, 2012). Harvard Medical School (2016) reports that yoga and mindfulness can benefit mental and physical health in pediatric populations specifically through improved balance, strength, endurance, aerobic capacity, memory, self-esteem, classroom behavior, and academic performance. There is minimal research to date that directly connects such interventions to improved dietary outcomes and feeding ability, however researchers have demonstrated a relationship with associated conditions and improved OM/OS ability (Bhalla et al., 2019) and symptoms of eating disorders (Carei et al., 2010; Pancanowski et al., 2017).

Children with DD may feel amplified experiences of stress (Scotoodeh, 2017). Researchers suggest that yoga can strengthen the parasympathetic nervous system to better respond to stress (Frank et al., 2020; Scotoodeh, 2017). Drawing attention to breathing patterns permits voluntary breaths and subsequently the regulation of ANS signaling (Shotoodeh, 2017). Yoga practice puts attention on *both* physical posture and breath exercise, which could offer a comprehensive intervention for children with ASD and a co-occurring feeding disorder.

Current Research

Yoga and Breath-Type Interventions in Pediatric Populations

Yoga practice is becoming more common among children and adolescents. Many benefits have been explored to date including physical fitness, cardiovascular ability, motor skills/strength, mental health, behavior, and gastrointestinal disorders (Birdee et al., 2009). Some researchers attest to positive outcomes though continued studies are warranted due to the limited power of research available, small sample size of many related studies, and the novelty of yogatype interventions in this population.

The use of yoga as a complementary therapy for children with autism spectrum disorder (ASD) has some research surrounding its efficacy. Yoga is commonly taught by demonstration which involves imitation learning. While not *directly* related to feeding ability, imitation learning is a type of learning whereby skills are developed through replication of an observed behavior. Imitation is a skill that is acquired in infancy and supports the learning of speech, facial expression, and gross motor movements (Meltzoff & Moore, 1997). Through understanding another individual's actions, imitative skills enable non-verbal information processing. Children with ASD often fail to demonstrate these skills, especially in motor imitation and body imitation, both of which relate to physiologic development (Radhakrishna, et al 2010). Therefore, yoga therapy in children with ASD optimally involves practicing and improving imitation skills.

Radhakrishna et al (2010) investigated the integrated approach to yoga therapy (IAYT) as a treatment for improving imitation skills in children with ASD. Six children diagnosed with ASD along with their parents participated in a 10-month intervention of 5-week yoga sessions with regular practice at home. Yoga therapy was practiced five times each week for 45-minute sessions under maternal supervision. The yoga therapy included asanas (postures) and pranayama breathing exercises selected to specifically address imitation difficulties with ASD and focused on strengthening, tension release, calming, and breathing. Participants who did not imitate the therapist were offered physical guidance to complete the asana. Related imitation skills measured included imitating oral facial movements (lips, tongue, and jaw exercises) and breathing exercises (inhale/exhale and sectional breathing). Special educators and parents

participated in data measurement through observation and questionnaires pre, mid, and postintervention.

Researchers of this study found that IAYT practice may improve imitation skills related to play, posture, body movements, and oral facial movements (Radhakrishna et al., 2010). Significant changes were noted at mid assessment in imitating gross motor action, oral facial movements, and breath exercise, and across all parameters post intervention. Participants were observed engaging with and watching peers. Maternal participation and prompting of behaviors were also observed. Radhakrishna et al (2010) suggested that peer models and parental participation may aid in higher generalization of IAYT. Radhakrishna et al recommended that future controlled IAYT research with larger sample sizes should include teachers and parents. While this study demonstrated efficacy of imitation to teach yoga and offered measurable parameters, it was a pilot study with a small sample size and was not designed to assess the treatment effect. The benefit of this study is that is explored the feasibility of a larger study and offers insight on intervention strategies.

In a related study, Sotoodeh et al (2017) investigated the effect of a yoga training program (YTP) on ASD severity in a randomized control trial. A cohort of 29 students with high functioning autism (HFA) 7-15 years old were randomized to participate in 24, 30-minute yoga sessions over an eight-week period. The YTP intervention used had been previously applied in children with ASD and was implemented by instructors who were certified to teach yoga to this population. Children were instructed to observe instructors demonstrate a yoga pose and then preform the pose. Yoga poses in the intervention included a warmup, strengthening poses, and calming poses. Baseline and post intervention data was collected on both the intervention group and control group via the Autism Treatment Evaluation Checklist (ATEC). Relevant measures

included speech/language/communication, sensory/cognitive/awareness, and health/physical/behavior. Significant improvement in sensory/cognitive/awareness and health/behavior/physical was observed, but no statistically significant change for speech/language/communication was seen. These results are consistent with the findings of the Radhakrishna et al (2010) study. The larger sample size, randomized control design, and statistical analysis provide greater casual evidence to support yoga-based interventions for improved imitation skills.

Developmental disabilities themselves may present learning barriers due to cognitive delay and/or heightened behaviors. As discussed in these two studies, demonstrating yoga was a feasible way to teach children with ASD. While available related studies cannot speak to the influence of yoga or breathing exercises on food selectivity specifically, behavior-focused studies may present research that considers the feasibility of related interventions for the target demographic.

In a pilot study, Garg et al (2013) examined the effectiveness of the Get Ready to Learn (GRTL) program to improve classroom behaviors of elementary students with developmental disabilities. The GRTL program is a classroom-based curriculum that applies yoga postures, relaxation, chanting, and breathing exercise to enhance the functional and academic performance of students with disabilities (Garg et al., 2013). Researchers used a pre and post-test design to assess the intervention outcomes at baseline and between 12 and 26 weeks. Participants were 51 students, 5-9 years old, with a diagnosis of handicapping conditions, developmental disabilities, or ASD and receiving special education services. Trained special education teachers delivered the 20-minute intervention in three phases: 1) classroom preparation, 2) observation of a DVD with adult instruction on centering, deep breathing, chanting, physical postures, and relaxation

exercises, and 3) participation in clean-up and return to academic coursework. Researchers found statistically significant improvement across all measured classroom behaviors indicating that the GTRL program has potential as a school-based intervention for elementary-aged students with developmental disabilities. As a pilot study with no control group this study lacks statistical power and therefore findings cannot be definitive. The absence of blinding was also a limitation of this study as the teachers served as both the implementor of the intervention and the observer of the participants. Despite these faults, this study presented a minimally invasive and brief classroom-based intervention that may be appropriate for pediatric populations with developmental disabilities. The GTRL intervention incorporated breathing and postural activities which, as other reviewed studies suggest, may aid oral functioning skills.

In another pilot study, Narasingaro, Pradhan, & Navaneetham (2017) explored the efficacy of a structured yoga interventions for disordered sleep patterns, gastrointestinal issues, and behavioral challenges using a randomized pre and post-test control design. A 90-day school-based intervention was implemented in 64 children 5-16 years old along with one accompanying parent. Yoga practices were selected from the IAYT yoga modules and included lessons that lasted 75 minutes during the morning hours prior to academic learning. The intervention group was divided into two groups and alternately practiced the same asanas. Asanas practiced included breathing exercises and pranayama, wind releasing practices, sun salutations, relaxation, chanting, and various postures (Narasingarao et al., 2017). Three separate questionnaires on sleep, food and digestion, and behavior were administered to parents pre and post yoga intervention. Narasingarao et al suggests that yoga-based interventions are feasible in large groups of children with ASD with the involvement of parents and teachers and may benefit secondary gastrointestinal problems. A limitation was that data collection was dependent on

subjective parental reporting. While a pilot study, this intervention did use a control, however, the lack of objective data minimized the implications of the findings. Although lacking empirical evidence due to its design, this study did incorporate parental involvement and modules from IAYT which aligns with the Radhakrishna et al intervention. Both studies demonstrated statistically significant outcomes using an alike intervention which may suggest feasibility.

In different classroom-based study, Folleto, Pereira, and Valentini (2016) explored yoga practice for motor ability and social behavior. In a quasi-experimental study, 16 children aged 6-8 years old participated in a 12-week intervention that occurred bi-weekly for 45-minute periods during physical education class. All participants had no previous yoga experience, and one child had a diagnosis of autism. Participants engaged in a sequential yoga practice and were instructed directly and indirectly via modeling and verbal cues. Teachers also implemented paired stretching and massage; breath awareness, meditation, and relaxation, as well as music, stories and games that related to yoga practice (Foletto et al., 2016). Statistical analysis determined positive changes in balance, running speed and agility, and strength and flexibility. Participants also had positive verbal feedback on the intervention. Findings of this study are similar to related research in classroom settings and further supports the conclusion that suggests that yoga practice is feasible in the school environment.

In a different pediatric population, Chambers, Hardial, Israel, Jacobson, and Evans (2006) explored the impact of yoga as a treatment for irritable bowel syndrome in a randomized control trial. While not directly related to feeding ability, incidence of IBS is related to the gut-brain axis, which is also involved in sensory and motor responses (Carabotti et al., 2015). In this study, 28 adolescents with IBS were randomized into an intervention or control group. The intervention group (n = 14) participated in ten minutes of daily yoga practice via video for four weeks. The intervention included asanas with breathing instructions to target abdominal sensory changes and tension release (Chambers et al., 2006). Outcomes were measured pre and post intervention through a questionnaire. Statistical analysis showed that the adolescents who received the yoga intervention reported lower levels of functional disability, emotion-focused avoidance, anxiety, and overall gastrointestinal symptoms (Chambers et al., 2006). While designed with a small sample size with low statistical power, this study further demonstrated the feasibility of yoga in pediatric populations as well as its positive effects on anxiety which is a component of feeding disorders.

Yoga and Breath-Type interventions for Feeding and Eating Disorders

Yoga is a common adjunct treatment therapy for eating disorders. Psychologically, yoga may benefit those with disordered eating patterns and body dysmorphia as it may aid in mindfulness and embodiment (Eating Recovery Center, 2019; Pancanowski et al., 2017). Physiologically, breath exercises and pranayama breathing in yoga may strengthen oral and respiratory muscle functions (Arulmozhi et al., 2018). As noted, both food-related anxiety and orofacial muscle challenges are tied to feeding disorders. Thus, yoga-type breathing may be a valuable tool for *both* eating and feeding disorders.

In a randomized control trial Pacanowski, Diers, Crosby, and Neumark-Sztainer (2017) investigated the influence yoga on eating disorder risks factor (negative affect) and symptoms in patients at a residential eating disorder treatment program. Participants were randomized into a control and yoga treatment group. One-hour yoga classes were taught by trained yoga teachers to the treatment group before dinner over a 5-day intervention period. Classes incorporated yoga movements and breathing techniques aimed at increasing parasympathetic nervous system

activation and reducing anxiety and eating disorder thoughts/behaviors. Affirmations were incorporated into the yoga practice and the classes ended with a relaxation pose. While a short intervention period, Pacanowski et al found that yoga improved pre-meal negative affect compared to usual residential treatment with attenuated effects post-mealtime. Researchers suggest that incorporating principles of yoga during mealtimes may further aid in reducing symptoms. Pacanowski et al also found that anxiety at mealtimes was reduced in the intervention group during the intervention period which does offer research to support the use of yoga for this element of feeding disorders (Pacanowski et al., 2017).

Carei, Fyfe-Johnson, Breuner, and Marshall (2010) implemented an earlier randomized trial that also explored the effect of individualized yoga practice among adolescents receiving outpatient care for diagnosed eating disorders. Fifty-four participants 11-21 years-old were randomized in an 8-week trial of standard care or yoga as an adjunct to standard care (Carei et al., 2010). Standard care included bi-monthly meetings with a physician and dietitian. The yoga intervention involved one hour of yoga twice per week that was taught by certified yoga instructors and was held in clinical research rooms that were adapted to facilitate a less clinical atmosphere. Statistical analysis demonstrated that the intervention group had greater decreases in eating disorder symptoms per Eating Disorder Examination (EDE) scores and the Food Preoccupation questionnaire; however, EDE scores returned to baseline at 12-weeks. Secondary measures of anxiety and depression showed significant improvements in both groups over time which indicates that standard care was the probable cause for this (Carei et al., 2010). While a pilot study designed to explore the application of the yoga as part of the treatment regimen, the randomization offered evidence to support the use of yoga for the target population when the

intervention was being implemented. While this intervention did not address motor ability, it did address the possible impact of yoga on anxiety.

Yoga and Breath-Type Interventions for Respiratory Disease

The connection between respiratory impairment and feeding disorders is known. Respiratory diseases that influence inspiration and expiration can also affect swallowing ability as the respiratory and digestive tract share functional structures (Manno et al., 2005). The scope of research for yoga in the treatment of respiratory diseases is narrow and no articles identified include dietary measures or OM/OS outcomes. Despite this, the literature explored relating to respiratory benefits offers evidence to support the efficacy of yoga and breath-based interventions.

Respiratory diseases are a group of lung ailments that block the airway and make it difficult to breathe. Emphysema, asthma, chronic obstructive pulmonary disease (COPD), and chronic bronchitis, are the common respiratory diseases across all ages. Pediatric cases of cerebral palsy, cystic fibrosis, and neuromuscular dysfunction may also lead to impaired breathing ability (Toder, 2000). Respiratory problems in children with these and alike disabilities can occur secondary to muscle weakness, compromised coordination ability, and poor nutrition status. Resulting feeding disorders can prevail with chronic drooling, gastroesophageal reflux, and aspiration and may also contribute to sleep apnea (Toder, 2000).

In a randomized control study, Saxena and Saxena (2009) investigated the effects of pranayama in unmedicated patients with mild to severe bronchial asthma. Fifty participants were divided into an intervention and control group and were studied for 12 weeks with a pre- and post-subjective assessment of Forced Expiratory Volume in one second (FEV1%) and Peak
Expiratory Flow Rate (PEFR). Participants in the intervention group were treated with 40 minutes of breathing exercises each day (20 minutes twice each day). Participants in the intervention group were instructed on deep breathing pranavama exercises. The control group was treated with 20 minutes of meditation twice each day for the same 12-week duration. Saxena and Saxena concluded that pranayama expiratory exercises improved lung function. Findings demonstrate significant reduction in cough, wheezing, and dyspnea, as well as improvement in FEV1 and PEFT compared to the control group. Researchers note that the forced expiratory breathing exercise and prolonged expiratory exercises of the lower respiratory tract were most helpful for participants. Saxena and Saxena suggested that the significant effects in this study were not attributed to a decrease in psychosomatic factors as the control meditation group did not show improvement in those measures. A limitation of this study is that researchers were unable to statistically conclude which of the pranayama breathing patterns used was most efficacious. Given the contraindications to some breath exercises, separating them would be necessary for any clinical implications. Furthermore, Saxena & Saxena claim that the exercises improved lung function both subjectively and objectively, though there is no stated methodology for gathering subjective data. Future research using multimodal interventions should measure each practice individually to provide detailed and complete findings appropriate for further research and use in practice.

In another study using breath-based exercise, Marrow, Brink, Grace, Pritchard, and Lupton-Smith (2016) applied a diaphragmatic breathing intervention and body posture positioning intervention for respiratory muscle activity in adults with chronic obstructive pulmonary disease (COPD). The prospective descriptive study used objective measures of diaphragm and intercostal muscle activity via surface electromyography (sEMG) following upright positioning during diaphragmatic breathing. At baseline COPD severity, comorbidities, and nutritional status based on BMI was assessed. The eighteen participants engaged in posture correction positioning in which they were sitting upright with arms forward or at the sides and then instructed to practice diaphragmatic breathing (Marrow et al., 2016). Statistical analysis indicated change in total diaphragmatic activity during diaphragmatic breathing from baseline to measurement 3 and between posture change at measurement 2 and during diaphragmatic breathing. However, there was no significant change in intercostal muscle activity across the study period (Marrow et al., 2016). Researchers noted that nutrition status (based on BMI) taken at baseline had significant effect on diaphragmatic activity and reported that participants who were underweight as determined by BMI demonstrated the greatest diaphragmatic activity but had the least response to posture positioning while participants with a normal BMI had the greatest response to both factors (Marrow et al., 2016). The lack of a control group and the small sample size are limitations that reduce the power of this study. However, the intervention itself and the significant findings suggest which elements of breath-focused exercises should be incorporated in future studies and align with outcomes of related studies.

Yoga and Breath-Type Interventions in Other Populations

Studies exploring pranayama-based interventions have been conducted in diverse adult populations. These studies add value to this review of the literature as they contribute to the evidence that supports the efficacy of yoga and breath-type interventions for related ailments. While unable to further support feasibility in pediatric populations specifically, these studies do demonstrate further application for the intervention of interest.

While not directly evaluating nutrition outcomes, Bhalla, Nagaraju, Malik, Goel, and Gupta (2019) compared conventional pharmacologic therapy with holistic interventions (naturopathy and voga) in a randomized trial focusing on patients with chronic orofacial pain disorders (COFP). Chronic orofacial pain disorders involve the head, face, and neck and can be the cause of a secondary feeding disorder (Goday, et al., 2019; Manno et al., 2005). Sixty participants with a COFP disorder were randomized into three groups: group A was prescribed a pharmacologic medication for their condition (either ibuprofen and chlorzoxazone or carbamazepine); group B was prescribed the same medications and given adjunct holistic interventions (acupuncture, facial massage, hot/cold therapy, facial exercises, voga asanas and pranayama, and meditation); and group C was given only the holistic interventions. The intervention occurred over a three-month period and participants were evaluated on stress, pain, and quality of life (QOL) every 10 days (Bhalla et al., 2019). Findings suggested that holistic approaches when combined with pharmacologic therapies (group B) offered statistically significant benefit for patients with myofascial pain as compared to pharmacologic therapies alone (Bhalla et al., 2019). Improvements in quality of life were seen in group B and C but not in group A, suggesting that the holistic therapies aided in participants' psychological wellbeing (Bhalla et al., 2019). This study offers an approach to integrating yoga-based interventions with pharmacological treatments as many people seeking complementary and alternative medicine may currently be engaging in other interventions at the same time. Additionally, this holistic intervention targeted disorders that may influence OM and OS skills.

In a different study, Birkel & Edgren (2000) explored the influence of yoga postures on vital capacity in college students. Vital capacity is the greatest volume of air that can be expelled from the lungs after the deepest possible breath and is a concern in respiratory and

cardiovascular diseases. In this study, 287 participants were taught yoga poses, breathing techniques, and relaxation in two 50-minute group sessions per week for 15 weeks. Participants were people with asthma, people who smoke, and individuals with no known lung disease. The study showed statistically significant improvement in vital capacity; however, researchers were unable to discern whether these findings were a result of the yoga poses, breathing techniques, relaxation, or uncontrolled external factors, which is a fault of this study (Birkel & Edgren, 2000). Conversely, a strength of this study was the participant adherence of 99.96% which may indirectly demonstrate satisfaction with the intervention. While not directly related to pediatrics or OM/OS functioning, this study supports the proposition that yoga-based interventions will improve breathing patterns and ability as vital capacity is a measure of respiratory muscle function.

In a blinded 12-week intervention, Sharma et al (2014) explored the effects of fast and slow pranayama on cognitive function, perceived stress, executive function, and reaction time. Eighty-four healthy individuals were randomized into three groups: fast pranayama, slow pranayama, and a control. Participants engaged in a one-week training with a trained yoga instructor prior to the intervention and then engaged in fast or slow pranayama practice. Statistical analysis indicated significant improvement in both intervention groups as compared to the control and reduced perceived stress and improved attention, visual motor speed, and memory capacity was observed (Sharma et al., 2014). Researchers suggest that the reduction in perceived stress may have enabled improved cognitive function as results were consistent with related studies (Sharma et al., 2014). However, Sharma et al acknowledge that their study does not determine the mechanism of action for pranayama but theorize that these developments may be related to improved parasympathetic tone (Sharma et al., 2014). While indirectly related to

nutrition-related factors, findings of this study relate to auditory and visual reaction time which are also motor skills. Future studies should explore the effect of pranayama on *other* motor skills including oral motor ability.

Research Methodology

The studies analyzed in this review of the literature included both qualitative and quantitative measures and varied in design and included pilot studies. Research reviewed suggests feasibility of a yoga and breath-based interventions in pediatric populations and demonstrated a need for further research as well as application in a larger population. A randomized study with an adequate sample size will be ideal in evaluating the efficacy of breathing exercises for increased food acceptance in children with feeding disorders. Randomization is favorable as it enables isolation of measurable outcomes and variable comparison between cohorts, however, it presents a challenge with the population of interest (ASD). Given this, other designs that allow for repeated measures within the same cohort may be a reasonable strategy as it could provide evidence when it would be unethical or impractical for randomization.

In the reviewed literature few studies identified *specific* pranayama techniques and asana poses so specifics were excluded from this review as authors used varying terminology which made accuracy in summarizing unreliable. Given this, intervention practices for future studies should be identified through technical manuals on yoga practice, professional resources for yoga instructors, physical and occupational therapy resources, OMD treatment resources, and diaphragmatic breathing guides. Included postural and breathing exercises should target related psychological and physical benefits including anxiety, oral movement, and posture.

Summary

At this time yoga is not considered an evidence-based treatment for feeding disorders as there is limited empirical research. Despite the gap in literature recommending yoga for use in clinical practice, the available studies do demonstrate positive effects on a variety of ailments and behavioral problems as well as feasibility in the target population and with related conditions. Research suggests that breath-based interventions aid in stress reduction and train involved muscle groups for proper breathing and oral structure (Manno et al., 2005; The Breath Institute, 2021). Given that these are concerns that present in children with feeding disorders, and that yoga-type interventions have shown benefit in children with ASD, there is reason to investigate the direct relationship between breathing interventions and increased food acceptance (Garg et al., 2013; Radhakrishna et al., 2010; Sotoodeh et al., 2017).

There is a moderate amount of research that demonstrates the benefit of yoga in pediatric populations (Chambers et al., 2006; Foletto et al., 2016; Garg et al., 2013; Narasingaro et al., 2017; Radhakrishna et al., 2010; Sotoodeh et al., 2017). Radhakrishna et al (2010) and Narasingaro et al (2017) both implemented IAYT modules for children with ASD and had similar findings. This suggests that the constructs of IAYT may be beneficial for this population. Similarly, Sotoodeh et al (2017) and Garg et al (2013) both found that children with ASD who engaged in a yoga intervention had positive physical and mental benefits however, as with Radhakrishna et al and Narasingaro, these studies also did not evaluate whether the pranayama elements of yoga are directly related to dietary or OM/OS measures. Conversely, Folletto et al (2016) and Chambers et al (2006) explored yoga interventions on children without DD and both had positive findings among that population though they did not incorporate direct dietary measures. Current literature on yoga in pediatric population demonstrates a variety of benefits to

physical and psychological wellbeing, however further research is needed to connect the benefits with improvements in feeding disorder symptoms specifically.

There is limited relevant research on yoga for nutrition-related symptoms of feeding and eating disorders despite it being a known adjunct intervention in this population for other purposes. The related literature investigated in this review attests to the feasibility of yoga for eating disorder patients and showed benefit to symptoms, however studies to date do not distinguish the influence of pranayama practice specifically. Foundationally, there is literature to suggest the benefits of yoga for reduced eating disorder thoughts and behaviors, however more research is needed to connect the pranayama practice in yoga with dietary intake and feeding ability in feeding disorders seen in children with ASD (Carei et al., 2010; Pacanowski et al., 2017).

There is also a narrow body of research on breath-based interventions for respiratory diseases. Saxena & Saxena (2009) identified positive outcomes on respiratory symptom measures with direct pranayama intervention, however, did not measure the effect of each pranayama type individually. Future studies could measure each exercise individually to discern which pranayama breathing patterns confer benefits. Conversely, Marrow et al implemented a posture and diaphragmatic breathing intervention with that demonstrated greater diaphragmatic activity in participants with an underweight or normal BMI. Both pranayama and diaphragmatic breathing are known practices that have recognized benefits. However, there is limited research that explores these interventions in pediatric populations, ASD, or with eating or feeding disorder patients. The scope of research for yoga specifically in the treatment of respiratory diseases is small and no articles to date include OM/OS outcomes.

Research on yoga and breath-type intervention on varying adult populations is greater and strengthens the body of research on the efficacy of yoga in clinical treatment. Like Saxena & Saxena (2009), Sharma et al (2014) investigated effect of different pranayama types. Sharma et al (2014) found benefit to parasympathetic tone and visual motor skills though also did not connect benefits to dietary factors specifically. Bhalla et al (2019) explored an orofacial disorder that may be a physical cause of a feeding disorder and found that yoga, when combined with pharmacologic therapies, may offer improved symptom management.

The reviewed research suggests that breathing or yoga-type interventions may be advantageous for associated physiologic, psychologic, and behavioral challenges in children with and without DDs (Birdee et al., 2009; Chambers et al., 2006; Foletto et al., 2016; Garg et al., 2013; Manno et al., 2005; Narasingaro et al., 2017; Radhakrishna et al., 2010; Sotoodeh et al., 2017). Both directly and indirectly, aligning research has revealed improvements in respiratory ability, motor/sensory difficulties, and disordered eating symptoms with breath-based exercises and yoga poses. Notably, no studies to date use a pediatric cohort with a diagnosed OMD. This is a significant gap in the body of available research. Further research is necessary to comprehensively investigate breath-based interventions for increased food acceptance in feeding disorder patients with and without DDs or OMDs. To fill the gap in literature, future studies should evaluate dietary and OM/OS outcomes and target interventions accordingly.

Chapter 3: Methodology

Yoga practice is a known adjunct treatment for many physical and psychological ailments. For children with autism spectrum disorder (ASD), yoga has been shown to benefit a variety of challenges that present with the diagnosis (Garg et al., 2013; Narasingarao et al., 2017; Radhakrishna et al., 2010; Sotoodeh et al., 2017). Multiple treatment modalities exit for managing elements of ASD. Sensory and motor challenges may be addressed by working with an occupational therapist (OT), whilst anxiety is treated by a therapist or psychiatrist. Some challenges, however, can manifest into nutrition concerns which can be addressed in collaboration with a registered dietitian (RD).

Presently, we know that yoga is a feasible intervention in child populations and that yoga may benefit sensory difficulties, anxiety as well as physical ailments. In theory, because yoga with pranayama supports physical structure, reduces stress, and promotes mindfulness, this study hypothesizes that yoga may support improved food acceptance and subsequently nutrition status in children with ASD and a secondary feeding disorder. At this time, there is no research that assesses if yoga practice with pranayama can influence dietary choices. This chapter will discuss proposed methodology for the presented study to explore this relationship.

Research Protocol

Research Question 1

Can yoga practice with pranayama breathing influence the variety of food groups accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number food groups accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food groups by children with ASD and a co-occurring feeding disorder as compared to baseline.

Research Question 2

Can yoga practice with pranayama breathing influence the number of food colors accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number of food colors accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food colors accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

Research Question 3

Can yoga practice with pranayama breathing influence the number of food textures accepted by children with ASD and a co-occurring feeding disorder?

Hypothesis

H₀: After six months of yoga-based intervention there is no significant difference in the number food textures accepted by children with ASD and a co-occurring feeding disorder as compared to baseline.

H_a: After six months of yoga-based intervention there is a significant increase in the number of food textures accepted by children with ASD and a co-occurring feeding as compared to baseline.

Research Question 4

Can yoga practice with pranayama breathing influence the number of calories consumed by children with ASD and a co-occurring feeding disorder?

Hypothesis

 H_0 : After six months of yoga-based intervention there is no significant difference in the number of calories consumed by children with ASD and a co-occurring feeding disorder as compared to baseline.

Ha: After six months of yoga-based intervention there is a significant increase in the

number of calories consumed by children with ASD and a co-occurring feeding disorder as compared to baseline.

Independent/dependent variable and confounding variables for each research question are presented in Table 1.

Table 1

Independent/Dependent Variable and Confounding Variables for Each Research Question

| Research Question | Independent Variable | Confounding Variable | |
|--|--|-----------------------------------|---|
| Can yoga practice with pranayama breathing influence the <i>variety of</i> <i>food groups</i> accepted in children with autism spectrum disorder and a co-occurring feeding disorder? | Sensory-based yoga with pranayama intervention | Number of food groups accepted | Baseline nutrition status Co-occurring treatment interventions Medications Family mealtime routine Eating environment Socioeconomic factors Development patterns Peer/sibling influence Parent underreporting or overreporting food intake Parents ability to provide a variety of foods Diversity of cultural cuisines amongst participants |
| Can yoga practice with pranayama breathing influence the <i>variety of</i> <i>food colors</i> accepted in children with autism spectrum disorder and a | Sensory-based yoga with pranayama intervention | Number of food colors accepted | Baseline nutrition status Co-occurring treatment interventions Medications Family mealtime routine Eating environment Socioeconomic factors |

| co-occurring feeding disorder? | | | Development patterns Peer/sibling influence Parent underreporting or overreporting food intake Parents ability to provide a variety of foods Diversity of cultural cuisines amongst participants |
|--|--|--|---|
| Can yoga practice with pranayama breathing influence the <i>variety of</i> <i>food textures</i> accepted in children with autism spectrum disorder and a co-occurring feeding disorder? | Sensory-based yoga with pranayama intervention | Number of food textures accepted | Baseline nutrition status Co-occurring treatment interventions Medications Family mealtime routine Eating environment Socioeconomic factors Development patterns Peer/sibling influence Parent underreporting or overreporting food intake Parents ability to provide a variety of foods Diversity of cultural cuisines amongst participants |
| Can yoga practice with pranayama breathing influence the <i>number of</i> <i>calories</i> consumed by children with autism spectrum disorder and a co-occurring feeding disorder? | Sensory-based yoga with pranayama intervention | Average number of calories consumed | Baseline nutrition status Co-occurring treatment interventions Medications Family mealtime routine Meal environment Socioeconomic factors Development patterns Peer/sibling influence Parent underreporting or overreporting food intake Parents ability to provide a variety of foods |

| Diversity of cultural |
|-----------------------|
| cuisines amongst |
| participants |
| |

Study Design

The proposed study is a quasi-experimental single-group study with a longitudinal design. The longitudinal design will use measures and observations of the dependent variable before, during, and after the yoga with pranayama intervention. Participant baseline measures will serve as the control to reduce the natural variation among participants and maximize the treatment sample size. This also minimizes the influence of confounding variables as it compares the intervention within the same sample of participants. This design is appropriate as it allows for a practical procedure with the population of interest and permits measuring changes in behavior and outcomes over time.

Setting and Sample

Population

Participants for this study will include elementary-aged children 6-12 years old with a diagnosis of autism spectrum disorder (ASD) and a co-occurring diagnosed feeding disorder. Children with ASD were chosen due to the known co-occurring food selectivity and/or diagnosed feeding disorder. A feeding disorder was chosen as it encompasses suboptimal nutrition intake in the setting of psychosocial, medical, and/or feeding skill challenges (Feeding Matters, 2022).

Sample Size

The sample sizes identified in all studies in the review of the literature was averaged to attain a sample size of sixty-two participants. The determined sample size was estimated using

the Raosoft calculator (Raosoft, 2004). A 5% margin error and a 95% confidence interval were selected. Per the Raosoft calculator, the recommended minimum sample size for this study would be 54 participants. Assuming an attrition rate of 30%, the final sample size for the proposed study should be a minimum of 75 participants to the maintain a sufficiently powered sample.

Recruitment

Participants will be recruited via pediatric health clinics in Milwaukee County, Wisconsin over a 6-month period. If the sample size of 75 participants is not achieved, recruitment will be repeated for another 3-6-month period or until achieved. Healthcare professionals at these clinics, including physicians, psychiatrists, psychologists, nurse practitioners, occupational therapists, registered dietitians, and ASD specialists, will be provided information on the study. Providers will be encouraged to recruit participants by sharing the study with patients that meet the inclusion criteria. This would occur verbally and with a written handout about the study (see Appendix A). The intervention and study will be advertised via handouts and posters in local pediatric health clinics with agreement from clinic administrators (see Appendix B). All prospective individuals that demonstrate interest in the study must be cleared by their primary care provider to be eligible to participate in the study.

Inclusion criteria:

I. Children aged 6-12 years old who have at least one parent or caregiver willing to participate.

- II. Individuals with a DSM-IV diagnosis of autism spectrum disorder with or without accompanying intellectual impairment or language impairment *and* a co-occurring diagnosis of a feeding disorder.
- III. Individuals who are independently ambulatory.
- IV. Both participant and participating parent(s) or caregiver(s) must be English speaking as a primary language.

Exclusion criteria:

- I. Individuals with characteristics of food selectivity without a formal diagnosis of a feeding disorder.
- II. Children with diagnosed *eating* disorders (anorexia nervosa or bulimia nervosa).
- III. Individuals with physiologic limitations requiring adaptive equipment.
- IV. Individuals who meet inclusion criteria but are not cleared to participate in the intervention by their primary care provider.

Those who express interest in the study will be screened via survey (see Appendix C) by the Principal Investigator. All participants who meet the inclusion criteria via survey will then be asked to meet with their primary care provider to review the study parameters and approve participation if the intervention is appropriate for the child. It is the responsibility of the provider to offer clearance for the child to be able to engage in the physical yoga movements as well as the breathing exercises. If a child meets inclusion criteria, but the provider indicates that the intervention would not be safe or appropriate at that time, the child will not be eligible to participate in the study. If the child meets inclusion criteria, and the provider approves the intervention to be safe at that time, the child will be eligible to participate in the study. All costs accrued for the screening by the primary care provide will be funded by the study. Participants will not be compensated or rewarded for their participation in the study, though they may experience physical and/or psychological and knowledge benefits from the intervention itself.

Intervention

Yoga Intervention

The yoga with pranayama intervention will be derived from the book *Sensory Yoga for Kids: Therapeutic Movement for Children of All Abilities* (Collins, 2015). The book is written by a pediatric occupational therapist and provides yoga poses (asanas) and pranayama exercises appropriate for the target population. Study participants will engage in two in-person 1-hour sessions of yoga each week over five consecutive months for a total of 40 yoga sessions. The first 15 minutes of the hour will be for quiet time before the class and the remaining 45 minutes will be for yoga practice. Yoga classes will be taught by a yoga instructor trained to work with children with ASD. Sessions will be held in a local yoga studio and offered five days per week to minimize crowing and allow for smaller class sizes as well and be flexible for family schedules. Parents will be able to select two days/week that work for their schedule, with a maximum of 15 children per class and 15 accompanying parents. Parents will be required to attend all yoga sessions and actively participate as needed to facilitate imitation learning. Parents will be provided with a home curriculum (see Appendix D) that complements the in-person yoga sessions at the start of each week of classes. The curriculum will be given as a physical handout and will include three poses and pranayama breathing exercises. Parents will be responsible to practice the home curriculum with their child at least once per week throughout the treatment period. The anticipated time to complete the home curriculum will be 15-20 minutes. Parents will also be encouraged to reference the pranayama breathing exercises when their child is experiencing a heightened sense of mealtime food anxiety or defiance in response to the served meals and snacks. Parents will be expected to track home yoga sessions on a provided log (see Appendix E).

Home Nutrition Procedure

Prior to the yoga with pranayama breathing intervention, and two weeks prior to measures taken at baseline, at least one parent or caregiver from each household will be required to attend a nutrition education lesson taught by a registered dietitian. The lesson will outline food groups, food colors, and food textures (see Appendix F). Parents and caregivers will be instructed to offer a variety of food groups, food colors, and food textures each day. They will also receive an orientation on how to track and measure portions for the food record (Appendix G). Lunch data will be omitted from the study as parental reporting may not be feasible due to greater variability in lunchtime dynamics and locations. Parents will be encouraged to incorporate these constructs into meals and snacks throughout the intervention period and will also keep a food record as described below.

Instrumentation

Lab Nutrition Assessment

An in-lab food acceptance assessment will be conducted pre-, mid-, and post intervention. The assessment will occur at lunch time (between 11:00 am and 12:00 pm CST) and parents or caregivers may be present with their child during the assessment (see Appendix H). During the lab nutrition assessment participants will be presented with foods from each category: food groups, food colors, and food textures to determine baseline food acceptance. There will be at least 1 food items from each category (for example: grains – bread and pasta; red– red bell pepper and strawberry; firm/hard – steamed beet and almond). Individual food items may overlap categories. The foods will be presented in the form of a meal. The same foods, presented as the same meal, will be given pre-intervention, midpoint (3 months), and post intervention (6 months). Lab food acceptance based on the number of food groups accepted, number of food colors accepted, and number of food textures accepted as well as the number of calories consumed will be assessed by the researchers.

Collection of data from the lab assessment will occur based on a plate waste assessment after the lab meal period is complete. Any amount of a food item will be considered "accepted" if it is observed to no longer be on the plate. This will be recorded as a percentage of what was consumed. For example, a bite of toast could be considered approximately 10% of the toast consumed. This data will then be compared to each participant's baseline, midpoint, and post intervention lab nutrition assessment. Though, because this study is assessing the *diversity* of food accepted based on number of foods in each category eaten, any amount of a food consumed will be considered "accepted." If a food goes untouched, it will be considered "not accepted." The percentages obtained will be used to calculate the number of calories consumed.

Home Food Record

Parents will be responsible for logging food intake. Parents will log food intake for three consecutive days prior to the yoga intervention, but after the dietitian-led home nutrition education lesson and food record orientation, to assess baseline intake (see Appendix I). The home food record will prompt parents to document what food and how much of each food was served and how much of each food was consumed as well as provide any comments about the mealtime relating to disruptions and behaviors. Parents will also submit a 3-day food record to researchers at midpoint (3 months), and post intervention (6 months). As with the lab nutrition assessment, food consumed will be recorded as percentages. Researchers will review the food record for clarity and completeness and will perform a nutrient analysis. The nutrient analysis will assess the number of food groups, amount of each food consumed and associate with the number of food colors, number of food textures, and number of calories consumed.

Nutrient Analysis of Lab Nutrition Assessment and Home Food Record

Data collected from the lab nutrition assessment and food record will undergo a nutrient analysis by a registered dietitian. The food-related dependent variables were chosen to encompass elements of food diversity – a diet that represents a variety of food groups, food colors, and food textures. The food groups referenced in this study are adapted from the USDA and include fruits, vegetables, grains, protein foods, and dairy/dairy-like foods (United States Department of Agriculture [USDA], 2021). The food colors measured in this study are described as the variety of colors that naturally occur in foods. This includes red, orange/yellow, purple/blue, green, white, brown/black. The food textures measured in this study are described as properties of food that can be felt with the fingers, tongue, palate, and teeth. This includes firm/hard, crispy/crunchy, grainy, chunky, smooth, soft, slimy, and chewy. Each food-related dependent variable will be assessed using the following databases and resources in Table 2.

Table 2

| Dependent Variable | Nutrient Analysis Tool |
|--|---|
| Food Groups | Adapted from the USDA MyPlate food groups (fruits, vegetables, grains, protein foods, and dairy/dairy-like foods) |
| Calories (estimated from serving size) | Nutritionist Pro software |
| Food Textures | Determined by researcher |
| Food Colors | Determined by researcher |

Dependent Variables and Analysis Tools Used

Data Analysis Plan

The proposed study consists of one independent variable and four dependent variables (Table 3). A repeated measures analysis of variance (ANOVA) will be applied using the quantitative data from the dependent variables and the yoga with pranayama intervention before the intervention, at the intervention midpoint (3 months), and post intervention (6 months). This test will detect any overall differences between means at each period of measurement over the three time points and each time-point of the independent variable. The repeated measures ANOVA removes the variability due to the individual differences between subjects.

Table 3

Description of Variables

| Variable | Variable Type | Variable Source | Potential | Level of |
|------------------------------------|---------------|---|--|-------------|
| | | | Response | Measurement |
| Variety of food groups accepted | Dependent | Food Record/Lab Nutrition Assessment | Number of food groups accepted (Five categories - fruits, vegetables, grains, protein | Ratio |

| | | | foods, and dairy/dairy-like foods) | |
|---|-----------|---|---|-------|
| Variety of food colors accepted | Dependent | Food Record/Lab Nutrition Assessment | Number of food colors consumed (Six categories - categories include red, orange/yellow, purple/blue, green, white, brown/black) | Ratio |
| Variety of food textures accepted | Dependent | Food Record/Lab Nutrition Assessment | Number of food textures consumed (eight categories - categories include firm/hard, crispy/crunchy, grainy, chunky, smooth, soft, slimy, and chewy) | Ratio |
| Average number of calories consumed | Dependent | Food Record/Lab Nutrition Assessment | Number of calories consumed (0- 10000) | Ratio |

Threats to Validity

The combined lab nutrition assessment and constant food diary logging will serve to offer both objective and subjective perspectives respectively. Despite this, much data of the to be collected is provided by parents and therefore it is reasonable to assume that there could be errors in consistent reporting, which is a primary threat to validity. Another threat to validity is the Hawthorne effect which may influence participant nutrition behaviors as well as parent reporting. Additionally, some families may be able to offer a greater variety of foods which may impact acceptance. Furthermore, due to the length of the intervention attrition rates can pose a threat to validity. This may lead to bias and result in a smaller sample as well as a sample that demonstrates a lesser subset of characteristics among the autism spectrum disorders. Another threat is that because classes will be offered on 5 separate occasions/week there may be variances in teaching. Lastly, the proposed study lacks randomization which lessens internal validity. However, participants will serve as their own control which reduces error variance and maximizes data collected from the sample size.

Ethical Procedures

To keep information confidential, data will be collected by researchers and stored in protected electronic folders. Any paper documents will be stored in a locked filing cabinet and only accessible to researchers then disposed of once put into electronic format. To protect the identity of participants and health care professionals involved in the study, each will be assigned a reference number. The reference numbers will be used in place of names to organize data involving each individual. All computers utilized for study purposes will be required to be password protected. The proposed study will also require an Institutional Review Board (IRB) application as well as consent and assent documents due to the age of participants (see Appendix J).

Summary

The proposed study will utilize a quasi-experimental single-group study with an interrupted time series design. The study will assess the effects of a yoga-based intervention with pranayama breathing on increased food acceptance for children with ASD and a co-occurring feeding disorder. Food acceptance will be based on food diversity as measured by number of

food groups, food colors, food textures, calories consumed. Threats to validity exist as data is to be collected in a lab setting and by way of parent reporting. A repeated measures analysis of variance ANOVA will be used to measure the influence of the one independent variable on the five dependent variables before the intervention, at midpoint (3 months), and post intervention (6 months). All data and personal information will be secured to maintain confidentiality.

Chapter 4: Anticipated Results

Characterization of the Study Population

A total of 75 participants will be recruited through pediatric health clinics over a 6-month period. All participants will be involved in the intervention as there will be no randomization. The participants will engage in a yoga with pranayama. Based on the lower end of reported attrition rates for longitudinal studies, it is estimated that a total of 30% participants may drop out of the study (Gustavson et al., 2012) Their data will still be used to complete the study as an Intention to Treat analysis will be used. Overall, if 21 total participants drop put during the complete duration of this study, then a sample size of 54 participants will complete the study.

Baseline Characteristics

Given the diversity of features seen with ASD, it is anticipated that there may be significant differences between individual participants. Anticipated baseline characteristics of participants are presented in Table 4.

Table 4

Baseline Characteristics of the Study Population

Characteristics

Intervention Group SD N=75

| Female, % | 30 | | | | |
|-----------------------------------|-------|-----|--|--|--|
| Male, % | 24 | | | | |
| Age | 9 | 1.4 | | | |
| Weight-for-Length Z- | -0.30 | 0.6 | | | |
| Score | | | | | |
| Underweight, % | 36 | 0.4 | | | |
| Overweight/Obese, % | 4 | 2.8 | | | |
| Diagnosed Stunting | 0 | | | | |
| Extreme food selectivity | 70 | 0.8 | | | |
| Ritualistic eating | 42 | 1.5 | | | |
| behaviors | | | | | |
| Lab Nutrition Assessment Outcomes | | | | | |

For the lab nutrition assessment, intake of food group, food colors, food textures, and calories consumed will be based on average servings consumed. Means are based on the average consumed at the one-meal lab assessment. A serving is represented by the amount served to the participant by the researcher and will not be determined by the nutrition label of a food item or recommended amount.

A repeated measures ANOVA will be performed to compare the effect of the yoga with pranayama interventions on intake of food group, food colors, food textures, and calories consumed in a laboratory setting. It is anticipated that there will be a statistically significant difference in intake of food group, food colors, food textures, and calories consume between baseline, at midpoint (3 months), and at the end of the intervention (6 months). Table 5-8 summarizes anticipated results.

Table 5

Food Groups – Lab Nutrition Assessment Outcomes

| Outcome | Mean Servin | Mean Servings Consumed | | | | | |
|--------------------|--------------|------------------------|-----|--------|---------|----------|--|
| Food Groups | Baseline | | 3 N | Ionths | 6 Montl | ns | |
| Fruits | 2 | | 3 | | 4 | | |
| Vegetables | 1 | | 1 | | 2 | | |
| Grains | 3 | | 4 | | 4 | | |
| Protein | 2 | | 3 | | 3 | | |
| Dairy/Dairy-like | 1 | | 2 | | 3 | | |
| Foods | | | | | | | |
| One-Way Repeated M | leasures ANO | VA | | | | | |
| Source | SS | df | | MS | F | Р | |
| Between measure | 4.9333 | 2 | | 2.4667 | F=18.5 | P=0.0010 | |
| Within measure | 10.8 | 159 | | 0.9 | | | |
| Error | 1.0667 | 106 | | 0.1333 | | | |

*p<0.5 indicates statistical significance

Table 6

| Food Colors | - Lab Nut | trition Asse | ssment Outcor | nes |
|-------------|-----------|--------------|---------------|-----|

| Outcome | Mean Servings Consumed | | | | | |
|---|------------------------|-----------------------|-----------------------|--|--|--|
| Food Colors | Baseline | 3 Months | 6 Months | | | |
| Red Orange/Yellow Green Blue/Purple White | 1 2 1 1 3 | 2 3 2 2 3 | 4 3 3 3 4 | | | |

| One-Way Repeated Measures ANOVA | |
|---------------------------------------|----------------|
| Source SS df MS F | Р |
| Between measure 6.4 2 3.2 F=1. | 1.294 P=.00468 |
| Within measure 5.2 159 0.4333 periods | |
| Error 2.2667 106 0.2833 | |

Table 7

Food Textures – Lab Nutrition Assessment Outcomes

| Outcome | Mean Servings Consumed | | | | | |
|---|------------------------|-----|-----------------------|--------|-----------------------|----------|
| Food Textures | Baseline | | 3 Months | | 6 Months | |
| Firm Crispy/Crunchy Smooth Soft Chewy | 2 1 3 2 1 | | 3 2 3 3 2 | | 3 3 4 3 3 | |
| One-Way Repeated M | easures ANOV | Ά | | | | |
| Source | SS | df | | MS | F | Р |
| Between measure periods | 4.9333 | 2 | | 2.4667 | F=18.5 | P=0.0010 |
| Within measure periods | 4.8 | 159 | | 0.4 | | |
| Error | 1.0667 | 106 | | 0.1333 | | |

Table 8

Calories Consumed – Lab Nutrition Assessment Outcomes

Summary of Data

Intervention Periods

| | Baseline | 3 Months | 6 Months | Total |
|-----------|----------|----------|----------|---------|
| Ν | 54 | 54 | 54 | 162 |
| $\sum X$ | 11355 | 11855 | 12355 | 35565 |
| Mean | 210.278 | 219.537 | 228.7963 | 219.537 |
| $\sum X2$ | 2525227 | 2758227 | 3002627 | 8286081 |
| SD | 50.9389 | 54.2 | 57.6012 | 54.5021 |

| Source | SS | df | MS | F | Р |
|-------------------------|-----------|-----|----------|----------|----------|
| Between measure periods | 9259.26 | 2 | 4629.62 | F=4.4214 | P=0.0142 |
| Within measure | 468987.01 | 159 | 2949.6 | | |
| Error | 110740.7 | 106 | 1044.724 | | |

One-Way Repeated Measures ANOVA

Home Food Record Assessment Outcomes

For the home food record nutrition assessment, intake of food group, food colors, food textures, and calories consumed will be based on parent reporting from 3-day food records. Means are based on average intake each day. A serving is represented by the amount of food a parent serves to their child by and will not be determined by the nutrition label of a food item or recommended amount.

A repeated measures ANOVA will be performed to compare the effect of the yoga with pranayama interventions on intake of food group, food colors, food textures, and calories consumed in a home setting. It is anticipated that there will be a statistically significant difference in intake of food group, food colors, food textures, and calories consume between baseline, at midpoint (3 months), and at the end of the intervention (6 months). Table 9-12 summarizes anticipated results.

Table 9

| Outcome | Mean Servings Consumed | | | | |
|---------------------------|------------------------|----------|----------|--|--|
| Food Groups | Baseline | 3 Months | 6 Months | | |
| Fruits Vegetables | 3 | 4 | 5 4 | | |
| Grains | 4 | 5 | 6 | | |
| Protein | 4 | 4 | 5 | | |
| Dairy/Dairy-like Foods | 3 | 4 | 4 | | |

Food Groups – Home Food Record Assessment Outcomes

One-Way Repeated Measures ANOVA

| Source | SS | df | MS | F | Р |
|---------------------------|---------|-----|--------|----------|----------|
| Between measure periods | 10.1333 | 2 | 5.0667 | F=10.482 | P=0.0058 |
| Within measure periods | 29.6 | 159 | 2.4667 | | |
| Error | 3.8667 | 106 | 0.4833 | | |

Table 10

Food Colors – Home Food Record Assessment Outcomes

| Outcome | Mean Servings Consumed | | | | | |
|---------------------------|------------------------|-----|----------|------|----------|--|
| Food Colors | Baseline | 3 1 | 3 Months | | 6 Months | |
| Red | 2 | 3 | | 4 | | |
| Orange/Yellow | 1 | 3 | | 4 | | |
| Green | 2 | 3 | | 4 | | |
| Blue/Purple | 1 | 2 | | 3 | | |
| White | 5 | 6 | | 7 | | |
| Brown/Black | 5 | 5 | | 6 | | |
| One-Way Repeated M | leasures ANO | VA | | | | |
| Source | SS | df | MS | F | Р | |
| Between measure periods | 12 | 2 | 6 | F=45 | P=0.0001 | |
| Within measure periods | 40 | 159 | 2.667 | | | |
| Error | 1.3336 | 106 | 0.133 | | | |

Table 11

Food Textures – Home Food Record Assessment Outcomes

| Outcome | Mean Servings Consumed | | | | | |
|---|------------------------|-----------------------|-----------------------|--|--|--|
| Food Textures | Baseline | 3 Months | 6 Months | | | |
| Firm Crispy/Crunchy Smooth Soft Chewy | 3 3 5 2 1 | 4 4 5 2 2 | 5 5 5 3 2 | | | |

| One-Way Repeated Measures ANOVA | | | | | | | |
|---------------------------------|-------|-----|--------|----------|----------|--|--|
| Source | SS | df | MS | F | Р | | |
| Between measure periods | 3.6 | 2 | 1.8 | F=8.3070 | P=0.0116 | | |
| Within measure periods | 24 | 159 | 2 | | | | |
| Error | 1.733 | 106 | 0.2167 | | | | |

Table 12

Calories Consumed – Home Food Record Assessment Outcomes

Summary of Data

Intervention Periods

| N ∑X Mean ∑X2 SD One-Way Repea | Baseli 54 10175 188.42 21392 64.726 | ne 259 77 53 easures AN | 3 M 54 1133 209. 2580 61.8 | onths 30 .8148 0202 .885 A | 6 Months 54 11750 217.5926 2779402 64.8204 | Total 162 33255 205.278 7498881 64.6235 | | |
|---|--|-------------------------------------|---|---|---|--|----|---------|
| Source | | SS | | df | MS | F | Р | |
| Between measur | e | 24636.11 | | 2 | 12318.0556 | F=5.427 | P= | =0.0057 |
| Within measure | | 647732.39 | 9 | 159 | 4073.7886 | | | |
| Error | | 240580.50 | 6 | 106 | 2269.6279 | | | |

Chapter 5: Discussion

Feeding challenges exist for children with ASD and increase their risk for nutritional deficiency, impaired growth, and malnutrition. As the field of complementary and alternative medicine has become more widespread so does its influence on pediatric populations, including children with ASD. Though, a lack of evidence exists among all populations whether yoga with pranayama breathing has any direct effect on nutrition intake outcomes, including increased food acceptance. Feeding disorders are common for those with ASD, and yoga *and* breathing exercises have been shown to benefit both physiologic and psychologic symptoms across many populations, so, exploring the application of a yoga with pranayama breathing intervention may present data to fill the gap in literature concerning yoga directing influencing nutrition intake.

The proposed 6-month quasi-experimental single-group study with an interrupted time series design will investigate the influence of yoga with pranayama breathing on increased food acceptance in children with ASD and a co-occurring pediatric feeding disorder. If yoga with pranayama breathing can be shown to be a feasible and effective intervention to aid the nutrition status of children with ASD, it may offer value to not only children and families but also clinicians seeking alternative treatment methods. This chapter will discuss the anticipated results of the proposed study as compared to related studies, the strengths and limitations, and suggestions for future studies.

Interpretation of Results

Using multiple repeated measures and observations of the dependent variable before, during, and after the yoga with pranayama intervention, it is anticipated that all the null hypotheses will be rejected, and the alternative hypotheses will be accepted. The expected outcomes are increased number of foods in each food groups accepted, number of food colors accepted, number of food textures accepted, and number of total calories consumed as compared to participant baseline measures.

Given the novelty of the proposed study topic it is difficult to compare anticipated outcomes with previous research. Anticipated results demonstrate positive outcomes in general, which is consistent with studies on yoga interventions in pediatric ASD populations. Of the literature reviewed, outcomes may align with Radhakrishna et al (2010) study where participants engaged in imitation skills and significant changes were noted in imitating gross motor action, oral facial movements, and breath exercises. Parental involvement and prompting of behavioral was also observed. While not measured in the proposed study, demonstrated imitation of yoga skills and parental support are anticipated.

Although related studies do not assess nutrition outcomes directly, there is literature that supports the efficacy of yoga among ASD populations. It is anticipated that the proposed intervention will be realistic for children with ASD, which is an outcome similar to Radhakrishna et al and Sotoodeh et al (2017) studies. Both of these studies suggest that yogatype studies may be feasible interventions for the target demographic, which is anticipated outcome of the proposed study. In Narasingaro, Pradhan, & Navaneetham (2017) study, data collection was dependent on subjective parental reporting. Researchers used parent questionnaires pre and post yoga intervention, which is similar the proposed study as part of the data will be based on parent reporting.

Overall, current literature on yoga-type interventions demonstrates a variety of positive outcomes, though further research is needed to connect the benefits with improvements in dietary intake specifically. This makes comparing outcomes of the proposed intervention challenging. However, permits the proposed study to fill a gap in literature concerning yoga practice and effects on nutrition intake.

Food Group Outcomes

It is anticipated that by 3 months, the number of food groups accepted will be greater than baseline nutrition outcome but statistically significant for either the lab nutrition assessment or the home nutrition assessment. It is anticipated that there will be a statistically significant increase in the number of food groups accepted between the baseline lab nutrition assessment outcome and 6-month lab nutrition assessment outcomes. It is anticipated that there will be a statistically significant increase in the number food groups accepted between the baseline home nutrition assessment outcome and 6-month home nutrition assessment outcomes.

Food Color Outcomes

It is anticipated that there will be a statistically significant increase in food colors accepted between the baseline lab nutrition assessment outcome and 3-month lab nutrition assessment outcomes and the 6-month lab nutrition assessment outcomes. It is anticipated that there will be a statistically significant increase in food colors accepted between the baseline home nutrition assessment outcome and 3-month home nutrition assessment outcomes and the 6month lab nutrition assessment outcomes.

Food Texture Outcomes

It is anticipated that there will be a statistically significant increase in food textures accepted between the baseline lab nutrition assessment outcome and 3-month lab nutrition assessment outcomes and the 6-month lab nutrition assessment outcomes. It is anticipated that there will be a statistically significant increase in food textures accepted between the baseline home nutrition assessment outcome and 3-month home nutrition assessment outcomes and the 6-month lab nutrition assessment outcomes and the 6-month home nutrition assessment outcomes.

Calories Consumed Outcome

It is anticipated that by 3 months, the number of calories accepted will be greater than baseline nutrition outcome but not statistically significant for either the lab nutrition assessment or the home nutrition assessment. It is anticipated that there will be a statistically significant increase in calories consumed between the baseline lab nutrition assessment outcome and 6month lab nutrition assessment outcomes. It is anticipated that there will be a statistically significant increase in the number of calories consumed between the baseline home nutrition assessment outcome and 6-month home nutrition assessment outcomes.

Strengths and Limitations

There are strengths to the proposed study. First, the intervention itself is intended to offer a treatment for the participants. This may affect attrition as families may have increased adherence to the intervention due to knowing it is at a benefit to them. Another benefit is that both the lab-based and home-based measures allow for data to be looked at in two ways, a lab setting and usual home setting. This allows the researchers to realize two sets of data on food acceptance and present a more specific reference for data collection style in future related studies.

There are also limitations to the proposed study. Firstly, the nature of the quasiexperimental design lacks randomization and will not show causation in study outcomes. This then will only demonstrate an association but will be unable to determine if the proposed intervention was the cause of the outcomes. Second, the intervention is limited to a small, specific population and cannot be generalized to other populations. Third, although parents of participants will be provided home nutrition education and food record keeping instruction, it will be difficult to assume if families are accurately reporting.

Suggestions for Future Studies

The application of complementary and alternative medicine practices presents opportunities for clinicians to expand treatment modalities. Care for children with ASD may require a variety of interventions due to the varying characteristics present within the diagnosis. For children with ASD and a co-occurring pediatric feeding disorder, nutrition management may be complicated by some of these characteristics. Yoga with pranayama breathing has been shown to benefits some behaviors that may exist in ADS. Given the noninvasive nature of yoga practice, it may be an advantageous intervention for this population.

In future studies, it may also be valuable to liberalize the inclusion criteria to include children without ASD to generalize the findings. Future studies should continue with a longitudinal design as randomization would not be feasible with this type of intervention and continued monitoring over a long period of time allows for determining sustained effects. Should comparison to another treatment be desired, it would be interesting to investigate a yoga with pranayama intervention as compared to another type of physical activity (such as daily walk/runs or cardio-type exercises that increase respiratory effort). It may also be useful to compare a yoga with pranayama breathing intervention to standard nutrition education, child cooking classes, and/or involvement in other food-related activities such as grocery shopping or gardening.

Conclusion

A yoga-based study for children with ASD and co-occurring feeding disorders will provide data on addressing eating challenges from a whole-health perspective. The complexities of ASD diagnoses warrant a variety of interventions to accommodate the diversity of needs. A yoga with pranayama breathing practice can be adapted for each child to meet their individual abilities and also encourage parents to implement some constructs, such as specific types of breathing exercises, should difficulty with food intake at mealtimes present. The proposed study may offer data to support a complementary and alternative medicine approach for feeding difficulties in children with ASD and lend to the growing body of literature concerning holistic adjunct treatments for feeding disorders.
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Appendix A Clinic Trifold Pamphlet Advertisement



Your Child About the Potential May Study **Benefits Qualify If: Improved Nutrition Status** connection between yoga and • Aged 6-12 years old what have at least one parent or caregiver willing to participate. caregiver will participate in a 2-day per week yoga class for 6-months. • Your child has a DSM-IV diagnosis of autism spectrum disorder with or Lessons will be taught by an without accompanying intellectual Decreased Anxiety impairment or language impairment and a co-occurring diagnosis of a feeding disorder. and breathing exercises. • Your child is independently <u>س</u>ر ambulatory. At 3 points throughout the study Your child and participating parent(s) or caregiver(s) are English speaking as a primary language. Learning a New Skill • Your child is cleared to participate in the study by your primary care if yoga can help children with autism who also struggle with eating accept provider. a grater variety of foods.

Appendix B

Clinic Poster Advertisement

Volunteers Needed for Research Study on Nutrition and Yoga.

Do you have a child with autism and a diagnosed feeding disorder? You may be eligible to participate in a 6-month study that could improve their nutrition status.

You May Qualify If

- Your child is 6-12 years old and have at least one parent or caregiver willing to participate.
- Your child has a DSM-IV diagnosis of autism spectrum disorder wand a co-occurring diagnosis of a feeding disorder.
- Your child is independently ambulatory.
- Your child and participating parent(s) or caregiver(s) are English speaking as a primary language.
- Your child is cleared to participate in the study by your primary care provider.

Participation Involves

- 6-months of sensory-based yoga classes, twice per week with accompanying home exercises.
- Lessons taught by an instructor trained in working with children and ASD.
- 3 total measures of nutrition intake documented by parents/guardians and researchers.
- One dietitian-led nutrition class.

Potential Benefits

- Acceptance of a grater variety of foods
- Decreased mealtime anxiety
- Learning a new skill
- Practice with imitation skills
- Socialization

Talk to your child's primary care provider to see if they qualify!

Appendix C

Participant Screening Survey

Please complete the following questions with your child's primary care provider:

What is your child's age?

Does your child have a DSM-IV diagnosis of autism spectrum disorder?

 \Box Yes \Box No

Does your child have a diagnosed feeding disorder?

 \Box Yes \Box No

Does your child have a diagnosis of anorexia nervosa or bulimia nervosa?

 \Box Yes \Box No

If your child independently ambulatory?

 \Box Yes \Box No

Is your child and the participating parent(s) or caregiver(s) primarily English speaking?

 \Box Yes \Box No

Does your child have physiologic limitations requiring adaptive equipment?

 \Box Yes \Box No

FOR CLINIC USE ONLY

Select one of the following:

□ YES, this child may participate in a yoga with pranayama breathing research study.

□ NO, this child may NOT participate in a yoga with pranayama breathing research study.

This child has been assessed and cleared to participate in the intervention by their primary care provider.

Signature of primary care provider

Date

Appendix D Home Curriculum Template

Home Yoga Curriculum

Date:____ Expected Time: 15-20 minutes

Pose 1:

Pose 2:

Pose 3:

Pranayama:

Appendix E Home Yoga Tracking Log

| WEEK | COMPLETED HOME YOGA CURRICULUM THIS WEEK |
|---------|--|
| Week 1 | |
| Week 4 | |
| Week 3 | |
| Week 4 | |
| Week 4 | |
| Week 6 | |
| Week 7 | |
| Week 8 | |
| Week 9 | |
| Week 10 | |
| Week 11 | |
| Week 12 | |
| Week 13 | |
| Week 14 | |
| Week 15 | |
| Week 16 | |
| Week 17 | |
| Week 18 | |
| Week 19 | |
| Week 20 | |
| Week 21 | |
| Week 22 | |
| Week 23 | |
| Week 24 | |

Appendix F

Dietitian-Led Nutrition Lesson Outline

LESSON PLAN

Title: Nutrition lesson for parents participating in yoga with pranayama breathing study

Length: 2 hours

Objectives:

- 1. Parents will learn about food diversity: food groups, food colors, and food textures.
- 2. Parents will learn about food record keeping
- 3. Parents will demonstrate learned information in example meals.

Overview:

Review of the following:

- 1. Food diversity
- 2. Food groups (fruits, vegetables, grains, protein foods, and dairy/dairy-like foods)
- 3. Food colors consumed (red, orange/yellow, purple/blue, green, white, brown/black)
- 4. Food textures consumed (firm/hard, crispy/crunchy, grainy, chunky, smooth, soft, slimy, and chewy)

The lesson will begin with discussion about different food groups. This will include the function of each of these food groups. Examples of foods from each food group will be discussed. Next, food colors will be discussed. This will include the general groups of food colors that naturally occur, and the general nutrients found in each color category (phytonutrients). Examples of foods from each color group will be discussed. Next, food textures will be discussed. This will include general groups of food textures, including raw and cooked foods. Discission will include how cooking can alter the taste and texture of food foods. Examples of foods from each texture group will be discussed. The RD will *not* review pairing food groups together or considering food colors and food textures as this could skew data.

Following this, the RD will review food record keeping (Appendix G).

The RD will then give instruction to build a meal. Next, the parents will be guided to demonstrate understanding of keeping a food log by creating examples of breakfast and lunch/dinner meals then documenting.

Materials:

1. RD-created PowerPoint

HOW TO KEEP A FOOD RECORD

A food record, or food journal, is a tool that can be used to keep track of what is eaten during a specific period. You will be instructed to keep a 3-day food record of the foods your child eats at 3 periods, as instructed, during this study. Use the food record log provided and follow the instructions below.

What to Document

What foods were served

- Include amount (such as in cups, oz, number of packages (ex. 1 string cheese), number of items (ex. 5 almonds), etc.
- Include brand name if serving a prepackaged item such as a single serve yogurt cup, granola bar, cracker pouch, etc.
- If the food item is a mixed dish (such as soup, casserole, chili, etc.), please note visible ingredients representing different food groups, food colors, and food textures in the "What Was Served" category of the food record.

The percentage consumed of each food item served

Examples:

- Child was served 1 cup of cereal with 4 oz whole milk. Use your judgement to estimate based off the remaining food in the bowl. If the child ate 5 large bites with minimal cereal left but all the milk still in the bowl, you could document that the child ate ~75% of the cereal and 0% of the milk. If the child ate 5 small bites with milk and much of the cereal was remaining in the bowl, you could document that the child at 25% of the cereal and 25% of the milk.
- Child was served 1 string cheese and one whole apple (not sliced). Document based on the food remaining. If the child ate half of the string cheese document as 50%, if the child ate one bite of the apple you could document as 10% apple consumed. If the child ate most of the apple skin and top layer of flesh but did not eat to the core, you could document somewhere between 50-90% consumed based on what was remaining on the apple.
- Child was served a bowl of chicken noodle soup, ~1 cup. Child ate all the chucks of chicken and all the carrots but did not eat any peas, broth, or noodles. Document as 100% chicken, 100% carrots, 0% peas, 0% broth, 0% noodles.

Tips for keeping a food record:

- As able, log right away after a meal is consumed
- Write down everything, including small nibbles
- Be specific about the foods consumed

Appendix H

Lab Nutrition Assessment Protocol

LAB NUTRITION ASSESSMENT PROTOCOL

Menu:

Menu foods for the lab nutrition assessment will be determined based on availability at the time of the study. A minimum of at least one food item from each category will be selected for the assessment. Food items may overlap categories (example: a whole wheat cracker can be considered both a brown food and a crispy/crunchy food; a banana can be considered both a yellow food and a slimy food; a slice of cheese can be considered both a white food and a smooth food; a cooked steamed carrot can be considered both an orange food and a soft food). An alike food will be substituted for any child with an allergy to a food item on the menu. This same food substitution will be used at each lab nutrition assessment.

Protocol:

- 2. The lab nutrition assessment will occur on an individual basis and no other participants will be present during each assessment. Researchers may be assessing participants at the same time, but each participant will be in a separate room.
- 3. The assessment will occur at lunch time (between 11:00 am and 12:00 pm CST) and parents or caregivers must be present with their child during the assessment.
- 4. Participants will sit at a table and be served a variety of foods presented in the form of a meal. The same foods, presented as the same meal, will be given pre-intervention, midpoint (3 months), and post intervention (6 months).
- 5. Participants will have 30 minutes to complete the meal. Researchers will not be present during the time of the meal. Researchers are to return after the 30 minutes and excuse the participant and accompanying caregiver.

Data Collection:

Collection of data from the lab assessment will occur based on a plate waste assessment after the lab meal period is complete.

Any amount of a food item will be considered "accepted" if it is observed to no longer be on the plate.

Any food consumed will be recorded as a percentage of what was served. This it only to calculate the number of calories consumed.

A registered dietitian will perform a nutrient analysis of the foods consumed to assess intake. All data collected will be documented electronically.

Appendix I Three-Day Home Food Record

| | | What was served | % Consumed | Comments |
|-----|-----------|-----------------|------------|----------|
| y 1 | Breakfast | | | |
| Day | Dinner | | | |
| | | | | |
| | Breakfast | | | |
| y 2 | | | | |
| Day | Dinner | | | |
| | | | | |
| | Breakfast | | | |
| 13 | | | | |
| Day | Dinner | | | |

Appendix J

IRB Application, Consent, and Assent Documents



Mount Mary University Institutional Review Board (IRB) for the Protection of Human Subjects

Application for IRB Review

DATA COLLECTION CANNOT BEGIN UNTIL THE IRB HAS APPROVED THIS PROJECT

Directions:

- Faculty and student researchers, as well as student research advisors, should <u>read all relevant</u> information on the University IRB page in My Mount Mary before initiating an application. This includes full knowledge of the US Department of Health and Human Services Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
- All applicants must verify completion of Human Subjects Training. See http://www.citiprogram.org.
- The IRB application must be filed and approved by the IRB prior to any Mount Mary University faculty, staff, or student (undergraduate or graduate), initiating a research project/study.
- If there is a cooperating institution, attach a copy of their IRB approval.
- In the case of a student research project, the student may complete the IRB application but the student's research advisor must sign and submit the application to the IRB for approval. It is the responsibility of the faculty research advisor to ensure that student applications and all attachments (e.g., informed consent forms and survey instruments) are in their final edited form. Even though a student research project may qualify as exempt from full IRB review, the research advisor may request the student to complete and submit a full IRB application.
- Complete this application using your word processing program (e.g. Word), then send it on or print it out and obtain signatures from all investigators and advisors. (Handwritten applications will not be accepted.) For your benefit, save the completed application on your computer in case it needs to be revised and resubmitted.
- This is a professional document; please check spelling, grammar and punctuation.
- Submit an electronic copy, via email, of the completed application with required signatures and attachments, in a single pdf, to Tammy Scheidegger, IRB Chair, <u>scheidet@mtmary.edu</u>. You will receive an email verifying receipt of the application.
- Allow a minimum of 30 working days to process your application. Make sure this timeframe is accounted for when considering initiation of data collection and due dates for student projects. Please be aware that if, upon completion of the application, you find that no exemptions apply to your research, your application will need to go through a full IRB Committee review which can take as many as 60 days to be completed.
- For class projects you must submit IRB applications to the IRB Chair by October 31st of the fall semester and March 31st for the spring semester. For summer classes, please consult with the IRB Chair.
- Upon receipt of the IRB letter of approval, data collection may begin.

I. <u>Required Documentation</u> - No action will be taken without these attachments.

Are the following attached to the IRB application?

| Informed Consent Document | ✔ Yes | Informed Consent Documents should include an explanation of procedures, risk, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, signature and date. See Appendix A and use the MMU Informed Consent Template to avoid delays in the process. |
|---|-------|--|
| Survey/Interview Instrument(s) | ₽ Yes | If a survey is being administered in any written format (e.g., Google Forms, Survey Monkey, Qualtrics), a copy of that survey must accompany this application. If a survey/interview is being conducted verbally, a copy of the introductory protocol/comments and survey questions being asked must be attached to this application. If survey/interview includes focus group questions, a complete list of the question must be attached. For research using a published/purchased instrument, a photocopy of the instrument will suffice. |
| Verification of Human Subjects Training | 🖌 Yes | Copy of transcript, certificate or other evidence that ALL members of the research team have completed the required training. |
| Copy of cooperating institution's IRB approval. | 🖌 Yes | Not required if there is no cooperating institution. |

| II. Investigator(s): |
|---|
| Name: Bree Phillips Phone: |
| Affiliation with Mount Mary University (e.g. faculty, student, etc.): Student |
| Signature: Date: 11/12/2022 |
| Name: Phone: |
| Affiliation with Mount Mary University: Email: |
| Signature: Date: |
| If student, list Research Advisor and complete the application. Research Advisor must provide requested information and verify. |
| Research Advisor's Name: Dr. Dana Scheunemann Department: Dietetics Email: Phone: |
| Research Advisor: Have you completed Human Subject's Training? Yes No |
| Research advisor's signature indicates responsibility for student compliance with all IRB requirements. |
| Signature: Date: Date: Research Advisor |

Individuals who participate in research play an important and active role in the advancement of knowledge. In recognition of their important contributions to research, humans will be referred to as "participants" rather than "subjects."

III. Project Description - Required by all applicants

Instructions: Briefly describe the proposed project including the sample and methodology (e.g. human subjects, data collection, data analysis and instruments).

1) Objectives (purpose of project):

The purpose of this study is to evaluate if yoga with pranayama breathing can influence food acceptance in children with autism spectrum disorder (ASD) and a diagnosed feeding disorder. and a diagnosed feeding disorder. This includes number of food groups, food colors, food textures, and calories consumed.

2) Relevance to practice/body of knowledge:

Yoga and general wellness, including nutrition, are often connected. Though, there is a lack of research demonstrating yoga to have any effect on nutrition status. There is also no research concerning yoga and/or pranayama breathing for feeding disorders or related to overall food acceptance. Additionally, the efficacy of yoga with pranayama breathing for children with a diagnosed feeding disorder has not been studied. More research is necessary to explore the influence of yoga and breathing exercises on food acceptance in

children with ASD and a diagnosed feeding disorder. If this study successfully demonstrates positive outcomes, it will offer data to support a complementary and alternative medicine approach for feeding difficulties in children with ASD and lend to the growing body of literature concerning holistic adjunct treatments for feeding disorders.

3) Describe the research design (e.g., subject/participant selection and assignment, design, intervention, data analysis):

The proposed study is a quasi-experimental single-group study with an interrupted time series design. It will assess the influence of a yoga with pranayama breathing intervention on acceptance of food diversity as measured by food groups, food colors, food textures, and calories consumed. Study participants will be recruited through pediatric health clinics in Milwaukee County, Wisconsin over a 6-month period. The sample will be comprised of children aged 6-12 years old with a diagnosis of autism spectrum disorder (ASD) and a co-occurring diagnosed feeding disorder. The target sample size will be 75 participants. Participants will be screened and must be cleared for participation by their primary care provider. All costs accrued for the screening by the primary care provide will be funded by the study.

Study participants will engage in two in-person 1-hour sessions of yoga each week over five consecutive months for a total of 40 yoga sessions. The first 15 minutes of the hour will be for quiet time before the class and the remaining 45 minutes will be for yoga practice. Yoga classes will be taught by a yoga instructor trained to work with children with ASD. Sessions will be held in a local yoga studio and offered 5 days/week to minimize crowing and allow for smaller class sizes as well and be flexible for family schedules. Parents will be provided with a home curriculum that complements the in-person yoga sessions at the start of each week of classes. The curriculum will be given as a physical handout and will include three poses and pranayama breathing exercises. Parents will be responsible to practice the home curriculum with their child at least once per week throughout the treatment period. Prior to the yoga with pranayama breathing intervention, and prior to any measures taken at baseline, at least one parent or caregiver from each household will be required to attend a nutrition education lesson taught by a registered dietitian.

Nutrition status will be measured in two ways at three points during the intervention period (baseline, 3months, 6-months). Measurement will include a lab nutrition assessment and a home food record. Data collected from the lab nutrition assessment and food record will undergo a nutrient analysis by a registered dietitian. A repeated measures analysis of variance (ANOVA) will be applied using the quantitative data from the dependent variables and the yoga with pranayama intervention at the data collection points.

4) What measurement/data collection tools are being used?

Food record, Nutritionist Pro software, categories of food colors/food textures determined by researchers

V. Additional Project Information – Required by all applicants

1) What human subjects training has the researcher completed (e.g., course work, online certification)?

Nutrient analysis will be completed by a registered dietitian. The yoga with pranayama classes will be taught by a certified yoga institutor trained to work with children who have ASD.

2) What process is used for obtaining informed consent?

See below for consent application.

3) Does the research include special populations?

- Minors under 18 years of age?
- Persons legally incompetent?
- Prisoners?
- Pregnant women, if affected by research?
- Persons institutionalized?
- Persons mentally incapacitated?

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If <u>YES</u>, describe additional precautions included in the research procedures.
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A parent/caregiver will be required to accompany the child during the intervention and lab data collection points. See Assent Form below.

4) Does the research involve any of the following procedures?

- False or misleading information to subjects?
- Withholds information such that their informed consent might be questioned?
- Uses procedures designed to modify the thinking, attitudes, feelings, or other aspects of the behavior of the subjects?

If <u>YES</u>, describe the rationale for using procedures, how the human subjects will be protected and what debriefing procedures are used.

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| ✔ Yes | □No |
|-------|-----|
| ☐ Yes | ✓No |
| 🗌 Yes | ☑No |
| ☐ Yes | ✓No |
| Yes | ✓No |
| Yes | ☑No |

□Yes ☑No

□Yes 🗹 No

5) Does the research involve measurement in any of the following areas?

- Sexual behaviors?
- Drug use?
- Illegal conduct?
- Use of alcohol?

If YES, describe additional precautions included in the research procedures.

| 🗌 Yes | ✓No |
|-------|-----|
| 🗌 Yes | ✓No |
| 🗌 Yes | ✓No |
| T Yes | No |

| 6) Are any portions of the research being conducted online? | |
|--|----------------|
| • Survey posted on a website? | 🗌 Yes 🗹 No |
| • URL for survey includes information that could identify participants? | 🗌 Yes 🗹 No |
| • Invitation to participate sent by email? | 🗌 Yes 🗹 No |
| • Items use drop-down box? | 🗌 Yes 🗹 No |
| If yes, assure that items allow choice of "no response" | |
| • Will you be recording virtual interviews? | 🗌 Yes 🗹 No |
| Audio only Video only Audio & Video | |
| If video recording is being used, assure anonymity by only recording audio unles | s the research |
| necessitates visual recording. | |

If <u>YES</u>, to any of the above items, describe additional procedures.

7) Describe the methods used to ensure confidentiality of data obtained.

To keep information confidential, data will be collected by researchers and stored in protected electronic folders. Any paper documents will be stored in a locked filing cabinet and only accessible to researchers then disposed of once put into electronic format. To protect the identity of participants and health care professionals involved in the study, each will be assigned a reference number. The reference numbers will be used in place of names to organize data involving each participant. All computers utilized for study purposes will be required to be password protected.

Risks and Benefits

1) Describe risks to the subjects and the precautions that will be taken to minimize them. (Risk includes any potential or actual physical risk of discomfort, harassment, invasion of privacy, risk of physical activity, risk to dignity and self-respect, and psychological, emotional or behavioral risk.)

There is physical activity involved in this study involving various yoga poses. There are also breathing exercises that may be deter from typical breathing patterns. Steps will be continually taken to ensure research ethics are followed. All yoga poses and pranayama breathing will be adapted to be appropriate for the target population and study subjects will not be put at any risk or harm. The participants may excuse themselves from the yoga lessons and/or the study at any time.

2) Describe the benefits to subjects and/or society. (These will be balanced against risk.)

This proposed study will help determine if a yoga with pranayama breathing can influence improved acceptance of food diversity in children with ASD and a co-occurring feeding disorder. These outcomes could include increased acceptance of food groups, food colors, food textures, and calories, indicating improvement in overall nutrition habits among the study population. The study subjects may also may experience physical and/or psychological and knowledge benefits from the intervention itself.

V. <u>Is the proposed project "research" as defined by Institutional Review Board requirements? -</u> <u>Required by all applicants</u>

Per 45 CRF 46.102: "Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes."

Per HHS.gov and the Office for Human Subjects Research (<u>https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html#:~:text=For%20purposes%20of%20the%202018,by%20a%20public%20health%20aut hority), the following activities are deemed <u>not</u> to be research:</u>

• Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

• Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

• Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

• Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A human subject is defined as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information. In social science research, human subjects may be referred to as research subjects or research participants.

Does the research involve human subjects/participants or official records about human subjects/participants?

If "no", STOP here, and submit application.

If the results will be available in the library, presented at a professional conference (includes any presentation to group(s) outside of the classroom), or published, please check the Yes box:

☐ Yes ☑ No If "yes", proceed to SECTION VI. If "no, STOP here, and submit application.

VI. <u>Exemptions - Required by all applicants</u>

Are you requesting exemption from IRB review in one of the federally approved categories?

Yes No If yes, please reference OHRP website <u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html</u> and continue with application.

1) Does the research meet the criteria for exempt category 1 (education)? [45 CFR 46.104(d)(1)]? Is the research conducted in established or commonly accepted educational settings (e.g. schools, Universities, or other sites where educational activities regularly occur)?

□Yes □No

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Research Participant Information and Consent Form Mount Mary University

Title of Study: A Quasi Experimental Study to Determine the Effects of a Yoga with Pranayama Breathing Intervention for Increased Food Acceptance in Children with Autism Spectrum Disorder and a Co-Occurring Feeding Disorder

Invitation to Participate and Purpose of the Research

You are invited to participate in a research study that seeks to explore if there is a connection between yoga and increased food acceptance. Participants will be asked to participate in two yoga classes each week and at home one day per week with a parent. Participants will be asked to try some foods with the researchers every three months for the next six months. Parents will also keep track of what their child eats every three months for the next six months. Data will be de-identified and analyzed by researchers. Participants must be 6-12 years of age.

Benefits and Risks

This research is designed to benefit the dietetics profession and the field of complementary and alternative medicine. By assessing the effects of a yoga-based intervention with pranayama breathing on dietary choices of children with ASD and a co-occurring feeding disorder this study aims to explore outcomes of a no-risk exercise-based adjunct treatment. Participants may benefit personally from being in this research study and findings generated by this research may add new knowledge to the nutrition, autism, and pediatric fields in general. There will be no monetary compensation. There are no known potential risks associated with participating in this study and participants will be medically cleared by their primary care physician prior to participation. Participants will also be encouraged to discontinue the yoga practice if any pose is uncomfortable. Please address any questions or issues of concern to the researchers using the contact information provided below.

Confidentiality

All information obtained will be kept confidential by the researchers who will be the only people with access to the data. Information obtained will be stored electronically and will be password protected. Per the U.S. Office of Human Research Protections (code §46.115), all data will be destroyed 3 years after the end of data collection. Paper files will be shredded, and electronic files will be deleted. Individual participants will not be identified in any report or publication about this study.

Contact Information (An explanation of whom to contact for answers to questions about the research. When a Mount Mary student is the principal investigator, the name and phone number of a supervising faculty member is

required. Also include an explanation of whom to contact for concerns about the participant's privacy and rights, which for Mount Mary University is its IRB Chair.)

If you have questions about this research study, your rights as a research subject, or would like to know the outcome of the research, please contact Dr. Dana Scheunemann, 414-930-3000, scheuned@mtmary.edu and Bree Phillips, 808-652-9127, phillipb@mtmary.edu. If you have any questions regarding your rights or privacy as a participant in this study, please contact Dr. Tammy Scheidegger, Mount Mary University Institutional Review Board Chair, 2900 North Menomonee River Parkway, Milwaukee, Wisconsin, 53222-4597, telephone (414) 930-3434 or email scheidet@mtmary.edu.

Consent

By signing below, you are indicating that you have read this consent form, have been given the opportunity to ask questions, and have agreed to voluntarily participate. You may withdraw from participation at any time, or refuse to answer any question herein, without penalty or loss of benefits to which other participants are entitled.

You may request a copy of this page for your records. Thank you for your participation.

| Signature of participant | Date |
|--------------------------|----------|
| | |

Other Possible Elements Needed

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. For research involving more than minimal risk, a statement describing any compensation for injuries and contact information. (Minimal risk is a risk of harm to the participant that is no greater than the risk encountered in normal, day-to-day activities or during routine physical or psychological examinations.) If the participant is a patient or client receiving medical, psychological, counseling, or other treatment services, there should be a statement that withdrawal from the study will not jeopardize or otherwise affect any treatment or services the participant is currently receiving or may receive in the future. Participants also should be told whether their data will be destroyed should they withdraw from the study. If a survey instrument or interview questions are used and some questions deal with sensitive issues, the participants should be told they may refuse to answer individual questions.

ASSENT TO BE IN A RESEARCH STUDY

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when a researcher/research group collects a lot of information to learn more about something. Researchers are doing a study to learn more about children with autism spectrum disorder and a co-occurring feeding disorder. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

We want to find out if an exercise caller yoga, and some breathing exercises, can increase the types of foods you are willing to eat. So, we are getting information from lots of kids like you.

What will happen to you if you are in this study?

Only if you agree, three things will happen:

- 6. You will be required to participate in two yoga classes each week. This is a type of exercise that includes different movements and breathing. You will also do this at home one day per week with a parent.
- 7. You will be asked to try some foods with the researchers every three months for the next six months. This is to see if the yoga has influenced your food choices.
- 8. Your parents will also keep track of what you eat for three days, every three months, for the next six months. This is to see if the yoga has influenced your food choices.

Will this study hurt?

Yoga should not hurt. If you feel uncomfortable with any of the exercises, you do not have to participate in that movement. We ask that you listen to your body and stop if any exercise hurts.

Will you get better if you are in this study?

This study may be helpful for some of your symptoms but is not a replacement for your current medical care. However, the researchers might find out something that will help other children like you later.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me, or you can talk to someone else.

Do you have to be in this study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And remember, you can say yes now and change your mind later. It's up to you.

If you DO NOT want to be in this study, just tell us.

If you DO want to be in this study, just tell us.

The researchers will give you a copy of this form to keep.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to ______ (*print name of child here*) in language they can understand, and the child has agreed to be in the study.

Signature of Person Conducting Assent Discussion

Date

Name of Person Conducting Assent Discussion (print)

*Template for assent form adapted from UCSF Benioff Children's Hospital Assent #1 Template