IRB Protocol Version 4

IRB # 23-0342

4/16/2024

Protocol for Using a Weighted Blanket to Treat Anxiety Related to Trying New Foods in the Pediatric Population

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IRB Protocol Version 1

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The signature below constitutes the approval of this protocol and the attachments and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Site Investigator:*
Signed: Date:

(name and title)

1.0 Background

Exploring and eating food is one of the most critical occupations for children. However, some children experience challenges impacting their ability to interact with food in a healthy way. Feeding challenges can negatively impact a child's quality of life and health (Cunliffe et al., 2022).

There are many reasons that children do not eat the variety and amount of foods required for optimum health. Some children have structural, neurological, or medical challenges impacting their ability to tolerate foods (Kamarudin et al., 2023). For optimal outcomes, these areas must be addressed and treated. However, following treatment, sometimes difficulty accepting food remains.

Food Avoidance

Food avoidance can occur within nonclinical and clinical populations (Cunliffe et al., 2022; Chao, 2018). Diagnoses or terms used to describe children who have challenges eating a variety of foods and trying new foods include picky eaters, children with food neophobia, and avoidant/restrictive food intake disorder (ARFID). A child presents with picky eating (PE) when they eat a limited variety of foods, have rigidity around the sensory qualities of food, and demonstrate difficulty trying new foods (Barnhart et al., 2021). PE is not a medically defined term but describes restrictive food intake behavior common among children (Chao, 2018).

Taylor and Emmett (2019) discuss the prevalence of PE among toddlers and state that food-related behavior in infants under 12 months should not be considered PE or neophobia due to their lack of experience with food. Cardona Cano et al. (2015) completed a study including 4,018 participants examining the trajectory of PE in childhood. At age 1.5 years, 26.5% of children were reported to have PE behavior, and at age 3, parents reported a slight increase to

27.6%. However, at age 6, only 13.2% of children had reported PE behavior. The authors cautiously speculated that PE behaviors at age 6 suggest risk factors for worse health outcomes than children without a history of PE. While transient PE may be part of typical development in the toddler and preschool years, persistent and severe PE will likely lead to poor health outcomes. It is estimated that PE is common and ranges from 25% to 53%, with statistics differing by country (Kamarudin et al., 2023).

Food neophobia relates to the fear and avoidance of novel foods and can relate to visual attention bias toward the food (Maiz & Balluerka, 2018). Hazley et al. (2022) completed a study and found that food neophobia peaked at approximately age 6. The prevalence of food neophobia is not widely understood due to no universal way of measuring and defining food neophobia (Białek-Dratwa et al., 2022).

According to the Diagnostic and Statistical Manual of Mental Disorders 5th edition (2022), the diagnosis of ARFID captures a wide variety of feeding disturbances and leads to inference with psychosocial functioning and failure to meet nutritional and energy needs. Dinkler et al. (2022) found that children at risk for ARFID began to demonstrate more food-avoidant behaviors than their peers during toddlerhood. Sanchez Cerezo et al. (2022) completed a systematic review to understand the epidemiology of ARFID. They found that most studies reported a prevalence rate between 5%-22.5%. Anxiety disorders were found to be common within the population of children and adolescents diagnosed with ARFID studied, ranging from 9.1%-72%.

Impact of Feeding and Eating Challenges

Anxiety surrounding food can be debilitating for a child. Difficulties tolerating a variety of foods due to anxiety can negatively impact many areas of a child's life, including nutrition,

energy, self-esteem, self-regulation, and social interactions (Maiz & Balluerka, 2018). Selfregulation's definition can vary based on the theoretical framework as noted within cognitive learning and sensory integration theories (Martini et al., 2016). Kuypers (2013) defined selfregulation as obtaining and maintaining an optimal level of alertness to function. Kuypers also included the ability to manage emotions and sensory needs to participate in occupations such as schoolwork and activities of daily living as part of self-regulation.

Shree and Murthy (2021) completed a study and concluded that there is a significant association between scholastic performance and nutritional status. Zickgraf and Elkins (2018) discussed how PE is problematic from both a psychosocial and nutritional standpoint. Maiz & Balluerka (2018) found that children with food neophobia scored lower on the social and family dimensions of self-concept than their peers.

In addition, parents of children who experience anxiety surrounding food report increased stress (Cunliffe et al., 2022). Zickgraf and Elkins (2018) stated that parents of children with PE experience anxiety, stress, and family conflict. Kim et al. (2021) completed a study examining parent strategies for expanding food variety and perceptions of helpfulness as reported by adults with symptoms of ARFID. The study found that while strategies to increase the pleasure of the eating experience could make a positive change, forceful strategies were not perceived as helpful.

Children's feeding difficulties and food avoidance are significant concerns for parents and healthcare providers. Food avoidance can impact a child's growth, physical well-being, and health later in life (Zickgraf & Elkins, 2018). Grey et al. (2021) completed a systematic review to understand the effects of famine and food restriction on children as they grew to adulthood. They

found a consistent association between significant childhood malnutrition with adult increased risk for cardiovascular disease, metabolic syndrome, and hypertension. While children with food avoidance behavior do not have forced food restrictions, such as children experiencing a famine, malnutrition due to poor intake of vegetables and proteins limits their nutritional health and micronutrient intake (Kamarudin et al., 2023). In addition, Padhani et al. (2022) discussed how malnutrition can contribute to a weakened immune system.

Anxiety and Picky Eating

Anxiety appears to contribute to challenges with food tolerance for children with food neophobia, ARFID and PE. Zickgraf and Elkins (2018) completed a study to understand the relationship between anxiety, sensory sensitivity, and PE. They found that children who had identified anxiety demonstrated increased sensitivity to sensory input. Increased sensory sensitivity is predictive of PE behavior. The researchers linked anxiety to both state and trait sensory sensitivity. It is unclear, per the study completed by Zickgraf and Elkins, if anxiety causes sensory sensitivity. Therefore, best practice requires the treatment of both anxiety and sensory sensitivity.

Most research supports the concept that children with food avoidance also have anxiety and challenges with regulation. Maiz and Balluerka (2018) found that children with food neophobia scored higher on trait anxiety. State anxiety refers to a natural anxiety response to danger. This type of anxiety is experienced only when danger is present and is not related to an underlying anxiety condition. Trait anxiety describes someone who experiences anxiety most of the time as part of their personality, not only when presented with a trigger. Santos et al. (2022) completed a study suggesting that children's emotion regulation predicted healthy food consumption. These studies support the hypothesis that treatment for children who are picky

eaters supporting regulation and decreasing anxiety would improve healthy eating habits. IronSegev et al. (2020) generated research that showed more emotional disturbances occur in children with ARFID compared to the control group. In contrast, this study showed no significant difference between the control group and the group with an ARFID diagnosis on anxiety outcome measures.

Researched Interventions

Interventions that have been proven effective in helping children with neophobia tolerate foods include cognitive behavioral therapy, routine following, food exposure, sensory play, and tactile food exploration (Kamarudin et al., 2023; Thomas et al., 2020; Merritt & Caldwell, 2020; Garcia et al., 2020; Nekitsing et al., 2019; Karagiannaki et al., 2021). Beyond sensory play, limited recent studies exist regarding sensory strategies to calm during feeding. One article contained a randomized controlled trial and studied the use of mindful breathing techniques and mindful eating when trying new food. This study found that children ages 10-12 years old who used mindfulness techniques increased their intake of novel fruit but did not decrease their anxiety or food neophobia, as shown by outcome measures of the Food Situations Questionnaire and Spence Children's Anxiety Scale Teddy Picture Rating Scale (Bennett et al., 2020). However, this was the only article on this subject, and it had many limitations, including a small number of participants. Using breathing techniques to calm children with food neophobia appears to lack research and warrants future study.

Weighted Blankets

Weighted blankets have increased in availability and popularity in recent years. A systematic review study found that weighted blankets reduce anxiety (Eron et al., 2020). Occupational therapy practitioners (OTP) use deep pressure techniques such as weighted

blankets during treatment to improve a client's ability to self-regulate and calm. A study including functional magnetic resonance imaging and a compression sleeve to provide deep pressure without human touch completed by Case et al. (2021) found that deep pressure was calming to the nervous system. Reynolds et al. (2015) completed a study examining deep pressure applied with an inflatable vest and found that participants who were stressed by a challenge experienced a decreased arousal level following the deep pressure. Lane et al. (2012) had previously completed a study that positively correlated anxiety in children ages 6-10 years with sympathetic measures of arousal level. Lönn et al. (2023) found weighted blankets to improve sleep efficiency in children diagnosed with attention-deficit/hyperactivity disorder with a mean age of 9 years using a randomized controlled crossover trial. The children reported increased satisfaction with the weighted blanket compared to the control blanket. Meth et al. (2022) found that melatonin was secreted in young adults when provided with a weighted blanket at bedtime. Vinson et al. (2020) found that anxiety was reduced in people receiving chemotherapy who used a weighted blanket. Dickson et al. (2021) completed a small study where the participants in a psychiatric ward reported decreased anger and anxiety in their posttest scores. Becklund et al. (2021) produced a study that showed statistically significant decreases in anxiety in adults at an inpatient psychiatric facility who utilized a weighted blanket. Bolic Baric et al. (2021) examined the effectiveness of weighted blanket use on sleep and activities of daily living among participants with diagnoses of autism spectrum disorder and attention deficit hyperactivity disorder. They found that weighted blankets improved sleep at night and relaxation during the day. These studies further support the use of deep pressure as a treatment strategy for calming and regulation. Improved self-regulation can allow for improved participation in occupations such as eating.

While no studies were found supporting the use of weighted blankets with children with anxiety-related food avoidance, the findings from the pilot randomized controlled trial completed by Ohene et al. (2022) found that weighted blankets combined with traditional occupational therapy (OT) may benefit adults diagnosed with anorexia nervosa and AFRID. The use of weighted blankets to calm children who experience food avoidance appears to be an area requiring study.

2.0 Rationale and Specific Aims

Contribution to Occupational Therapy

Many children experience anxiety-related food avoidance, and there is a dearth of research on sensory strategies to address these difficulties. Researchers must explore intervention options to provide individualized and appropriate care for children with eating challenges related to anxiety. The fourth edition of the *Occupational Therapy Practice Framework: Domain and Process* describes well-being, health, and occupational engagement as central concepts of OT (American Occupational Therapy Association [AOTA], 2020). AOTA (2017) clarifies the role of the OTP within the occupation of eating, including providing environmental modifications. My aim for my capstone is to produce scholarly work and research to support these core OT values in pediatric feeding and expand on environmental modification treatment options. While Ohene et al. (2022) completed a pilot study examining the sensory strategy of weighted blankets with adults with ARFD and anorexia nervosa, no research has been published to understand if weighted blankets might be helpful for children with feeding issues. Completing research in pediatric food avoidance and treatment strategies provides additional evidence-based treatment options for OTPs to help children within this population.

AOTA (2016) describes the importance of scholarship and creating new knowledge to contribute to the profession and society. Boyer (1990) describes the *scholarship of discovery* as a disciplined and structured investigation to gain understanding. I intend to research this topic without bias to provide novel information using a studied treatment strategy in an innovative way, thus participating in the scholarship of discovery. Furthermore, the OT *Standards for Continuing Competence* generated by AOTA (2015) demands that OTPs use evidence-based knowledge and critical reasoning skills to provide best-practice therapy. Therefore, the profession of OT must continue to provide cutting-edge research and add to the body of existing knowledge.

Proposed Pilot Study

This small experimental pilot study addresses the knowledge gap related to the use of weighted blankets for children with anxiety related to food and eating. My plan includes recruiting a minimum of seven children who receive OT treatment at the clinic where I work and clinics in the surrounding area. However, I would like permission to recruit twelve children due to concerns with attrition. The design of the study will include a control period prior to the treatment period. This study will seek to understand if children improve their ability to self regulate and calm with the use of a weighted blanket when trying new foods. It will also attempt to research whether children improve novel food consumption using a weighted blanket.

3.0 Inclusion/Exclusion Criteria

Subjects must meet all inclusion criteria to be eligible to participate in the study.

Inclusion criteria are:

1. Subject and guardian has provided informed consent in a manner approved by the IRB and is willing and able to comply with the trial procedures.

2. Subject is receiving occupational therapy to treat identified feeding challenges

3. Subject has anxiety related to food as reported by caregiver

4. Subject is between the ages of 8-12

5. Subject has good reading abilities

6. Subject weighs 30 pounds or more

Subjects meeting any of the exclusion criteria at baseline will be excluded from study participation.

Exclusion Criteria are:

1. Any medical condition that, in the opinion of the investigator, would place the subject at increased risk for participation due to the inability to remove the blanket safely. Examples of diagnoses that would exclude a participant include spinal cord injury, cerebral palsy, and muscular dystrophy.
2. Concurrent participation on another research study

3. Participants outside of the ages 8-12

4. Participants refuse to use the weighted blanket

5. If the use of a weighted blanket is contraindicated for any reason

6. Participants lacking the reading ability to complete a questionnaire

7. Participants who weigh under 30 pounds per parent report and cannot use a commercially available weighted blanket as the minimum weight of a weighted blanket is 3 pounds will be excluded but this exclusion is unlikely due to the inclusion age range

8. Participant is not currently receiving occupational therapy to address feeding difficulties

4.0 Enrollment/Consenting Process

Children receiving occupational therapy services at Capital Area Speech and Occupational Therapy to address feeding who have anxiety related to food will be offered enrollment via flyers and word of mouth. The first level of recruitment will include potential participants that have a patient relationship with the principal investigator or are receiving occupational therapy services from another occupational therapist at Capital Area Speech and Occupational Therapy. If 12 participants meeting the inclusion criteria cannot be recruited from Capital Area Speech and Occupational Therapy, the second level of recruitment will occur including other clinics in the Austin, Texas area who have given permission for flyers to be left in their waiting rooms. During the second level of recruitment, potential participants will contact the principal investigator for additional information regarding the study. A flyer will be available to potential participants with information about the study and principal investigator's contact information so that caregivers can ask questions. Potential study participants will only be provided additional information upon request regarding the study.

Recruitment will take place for 2 months and is anticipated to start April 2024 following IRB approval with researchers determining eligibility for the study based on inclusion and exclusion criteria. Participants and at least one guardian of each participant will be required to sign a consent form to affirm that they understand the purpose of this study, risks, and

requirements. To respect potential participant privacy, no information will be collected for research purposes prior to consent form completion. Also, no information of participants who withdraw from this study will be used. To consent to this study, potential participants will be provided with a consent form to review via email prior to signing it. Potential participants will be given an opportunity to speak with the investigator prior to signing the consent form.

No randomization will take place. There will be a control period consisting of usual care occupational therapy lasting 1 month prior to the treatment period lasting 1 month.

5.0 Study Procedures

1. Recruitment

2. Consent
3. Enrollment of participants based on inclusion and exclusion criteria.

4. Guardians of enrolled participants will complete the baseline outcome measure Food Neophobia Scale for Children (FNSC) questionnaire consisting of 10 questions (Pliner, 1994). Guardians of participants will also complete an initial food list on the initial food log form including all foods that the participant currently tolerates. Included on the initial food log form will be a place for the caregiver to record the age and weight of the child. The weight of the child will be used to calculate the appropriate weight of the weighted blanket. The weighted blanket will not exceed 10% of the child's body weight. Weighted blankets are commercially available through the company yescool for children in weights of ten pounds, seven pounds, five pounds, and three pounds. Each participant will receive a weighted blanket that is approximately 10% of their body

weight but does not exceed 10% of their body weight. For example, if a child weighs 55 pounds, they will receive a five-pound weighted blanket. The initial food log form including the initial food list and weight of the child will be scanned and returned to the caregiver prior to the control period. The FNSC will be collected.

5. Participants will receive occupational therapy services treatment as usual without use of a weighted blanket for 1 month. During this period, participants will complete the S-Anxiety scale of the State-Trait Anxiety Inventory for Children (STAIC) three times per week upon sitting at the table prior to a meal (Spielberger, 1973). The S-Anxiety scale questionnaire will take about 8-12 minutes for a child to complete the first time and 5-8 minutes for repeated administrations. All forms and scales necessary for the control period will be provided to the caregivers prior to the control period of the study.

6. After the 1-month control period, caregivers will complete the FNSC and complete the second food list adding any new foods to the initial food log (Pliner, 1994). The principal investigator will collect the FNSC and the initial food log form at this time.

7. Following the 1-month control period, participants and their guardians will receive a weighted blanket with verbal and written instructions for use and safety. The participants will continue usual care occupational therapy treatment during the treatment period. The caregivers will be provided with copies of the S-Anxiety scale of the STAIC, new food log, and a copy of the initial food log for reference (Spielberger, 1973). Participants will be instructed to use the weighted blanket for at least 5 minutes and no more than 15 minutes while participating in a quiet enjoyable activity prior to a meal with guardian supervision. Guardians will be responsible to keep the weighted blanket when not in use. Due to busy family schedules, it may not be possible to use

the blanket daily, therefore, the family will be asked to offer use of the blanket a minimum of 3 meals a week. On the days that the weighted blanket was used, the participant will complete the S-Anxiety scale of the STAIC at the table where they will consume the meal, following using the blanket and before eating the food (Spielberger, 1973). The guardians will be asked to record any new foods tried during the meal on the new food log along with the date each time the participant uses the weighted blanket.

9. Upon completion of the 1-month treatment period, the guardians will complete the FNSC (Pliner, 1994). The principal investigator will collect the FNSC, new food log, and S-Anxiety scale of the STAIC at this time either through HIPAA protected email or in-person (Spielberger, 1973).

10. Once the study is completed the guardians will be gifted the weighted blanket to use as they deem appropriate

6.0 Sources of Research Material

Data for this study will be gathered by caregiver report via the Food Neophobia Scale for Children (FNSC) questionnaire consisting of 10 questions and parent interview to gather information about the age and weight of the child (Pliner, 1994). Participants will complete the State-Trait Anxiety Inventory for Children (STAIC) S-Anxiety scale consisting of 20 questions (Spielberger, 1973). The guardians will also complete a food log. All data collected from the assessments will be used for research purposes. No data from records will be reviewed for this study. In addition, any protocol deviations or unanticipated problems will be monitored.

6.0 Study Product Description

A weighted blanket 10% or less of the participant's body weight will be used under parent or therapist supervision as a calming strategy prior to introduction to new food paired with a preferred stationary task such as watching a video or reading a book.

Weighted blankets are commercially available for children in weights of ten pounds, seven pounds, five pounds, and three pounds through the company yescool (yescool, n.d.). The blankets are made from glass beads and breathable polyester microfiber fabric according to the Amazon website. The glass beads are enclosed in five inch by 5 inch square compartments and stitched by high-density 15000 stitches to secure the glass beads within the blanket. Each participant will receive a weighted blanket that is approximately 10% of their body weight but does not exceed 10% of their body weight. For example, if a child weighs 55 pounds, they will receive a five-pound weighted blanket.

7.0 Potential Risks

Risks for this program are limited, but some potential risks are possible.

- Loss of confidentiality.
- Risk of mild to moderate discomfort due to having to reflect upon things that may make them feel uncomfortable such as anxiety level and food
- Risk of discomfort using the weighted blanket

8.0 Subject Safety

This study controls for risk as all use of weighted blanket will be under adult supervision and not during sleep. In addition, the participant can refuse the use of the weighted blanket at any

time during the study limiting any psychological risk or adverse events. Any adverse events will be reported immediately.

Prior to the start of the study, researcher will discuss best practices for weighted blanket use and guardians will be provided with a handout detailing the protocol and safety guidelines. The guardian will have the blanket in their possession and will only offer the blanket during times detailed in the protocol. All subjects will be given the opportunity to exit the program and withdraw consent at any time if they determine that they are no longer able to participate. The researcher will be available via HIPAA compliant email throughout the study to answer any questions that may arise and offer support. In person meetings will also be available upon request. All data collected throughout the program will be maintained on password protected emails and computers to reduce the risk for breach of privacy.

Dr. Claudia Hilton will provide supervision as the faculty sponsor through a weekly check-in via email, phone or zoom meeting with the principal investigator. The principal investigator will notify the faculty sponsor immediately via email with any questions or concerns. The principal investigator will include the faculty sponsor on any emails with the participants to ensure appropriate monitoring. All information pertaining to this study will be available to Dr. Hilton.

9.0 Data Monitoring and Participant Confidentiality

Data from questionnaires and food logs will be kept on password protected computers to ensure protection of participants confidentiality. No discussion of participants' information will be discussed in public settings and all data analysis will be performed in private settings.

10.0 Potential Benefits

By participating in this program, participants are expected to gain a better understanding of their own anxiety related to food and if a weighted blanket is beneficial to help them feel calmer and more regulated. The program aims to improve the everyday living experience of participants as it relates to mealtime. Participants will be provided with a weighted blanket for continued use as needed.

11.0 Study Withdrawal/Discontinuation

Possible reasons for withdrawal from this study:

1. Time commitment
2. Participant no longer wants to use the weighted blanket
3. Use of weighted blanket becomes contraindicated
4. Discontinuation from occupational therapy services

Handling withdrawals:

Withdrawal from the study will be accepted and an interview regarding reasons for withdrawal will be completed.

Termination of this study will occur if there are no participants willing and able to participate.

12.0 Biostatics and Subsidies

A statistical analysis using IBM SPSS Statistics (Version 28) predictive analytics software will be completed. The STAIC S-Anxiety scale mean score during the treatment period will be compared to the control period mean score using paired-samples t-tests (Spielberger,

1973). The control period mean score will be compared to the baseline. Similarly, the raw score from the FNSC during the treatment period and the raw control period score will be compared using paired-samples t-tests to understand if the children demonstrated a statistically significant change in food neophobia (Pliner, 1994). The control period raw score will be compared to baseline raw score using paired-samples t-tests. Nonparametric analysis will be used as necessary.

The average number of foods tried during the control period will be compared to baseline and the average number of new foods tried during the control period will be compared to the average number of new foods tried in the treatment period to understand if more foods were tried when using the weighted blanket. A paired-sample t-test will be completed to compare the control period to the treatment period. Nonparametric analysis will be used as necessary.

A weighted blanket will be provided to each of the participants of this study for their use following the study at no cost to the participant. The weighted blankets will be purchased by the principal investigator. This study is not funded by grants or subsidies.

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