Feasibility of Anxiety Assessment for Children with Minimally-Verbal Autism

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ABSTRACT

While it is estimated that 30% of the total Autism Spectrum Disorder (ASD) population acquire very little or no language (Davis et al., 2011), few studies look at ASD treatment from a mental or emotional health perspective for this minimally verbal (MV) population (Tager-Flusberg & Kasari, 2013). It is well documented that there is a need for anxiety assessment and treatment for children with ASD (White, Oswald, Ollendick & Scahill, 2009). This study examined the feasibility of implementing an observational anxiety assessment and concurrent physiological data collection for children with MV-ASD. It was hypothesized that this measure would demonstrate adequate demand, acceptability, and feasibility to merit further study of the measure. Participants consisted of 12 children with MV-ASD and one parent. Each family visited the clinic for one three-hour visit during which the parent completed several questionnaires to assess the child's eligibility for the study as well as their current functioning. Children completed several clinician-administered assessments and observations. The results of this study suggest that this observational assessment protocol is acceptable and practical per parents self-report and the amount of children able to complete the study protocol, but there may not be enough demand for such a measure based on the number of interested participants. Additionally, the concurrent collection of physiological data was not practical in the current sample due to many children scoring too high on a measure of tactile sensitivity to attempt this data collection. Future studies should more carefully assess demand for this kind of assessment, as well as collect more data on the psychometric properties of such as measure.

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GENERAL AUDIENCES ABSTRACT

Many children with Autism Spectrum Disorder or ASD, also experience a lot of anxiety or even an anxiety disorder. Unfortunately, many children with ASD also have a lot of difficulty learning to talk. When children with ASD can't speak to tell people how they are feeling it can make the diagnosis of anxiety really difficult. This project sought to use physical signs such as heart rate in combination with observing behaviors related to anxiety to see if we could better measure anxiety in children with ASD who can't talk. This was a feasibility study meaning that the goal of this project was just to see if the anxiety assessment process was possible and practical for these children to complete. 12 children with ASD and one of their parents participated in the study. They came to the clinic for three hours and completed some anxiety measures given by a clinician and some questionnaires. Our results suggested that some aspects of the anxiety assessment process are possible and helpful, such as the number of children who were able to complete the assessment process, but others aspects need more work before they are helpful, such as the collection of heart rate.

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Introduction

It is well documented that children with Autism Spectrum Disorder (ASD) experience significant difficulty with anxiety (White, et al. 2009). However, much less work has been done examining the prevalence of anxiety in children with Minimally-Verbal Autism Spectrum Disorder (MV-ASD), in part because objective anxiety measures are not identified in this population. The Generalized Unsafety Theory of Stress (GUTS) model suggests that anxiety disorders are often the result of "generalized unsafety" or lack of the ability to detect safety signals (Brosschot, 2017). Two suggested mechanisms for the formation of generalized unsafety are the lack of generalization of safety cues learned early in life, and social isolation (Brosschot, 2017). There is additional support in the fear conditioning literature to suggest that children with ASD have more difficulty differentiating safe contexts from threatening situations (Lissek et al., 2005; Top et al., 2016). Based on this reasoning for the formation of heightened anxiety it seems likely that children with MV-ASD could have an increased risk for anxiety. Heart Rate (HR) and Heart Rate Variability (HRV) have been used in previous studies of anxiety from the GUTS perspective (Thayer et al., 2009). The current study examined the feasibility of collecting HR and HRV data from children with MV-ASD in combination with an observable measure of anxiety.

Anxiety at the Minimally-Verbal End of the Spectrum

About 1 in 59 children is diagnosed with Autism Spectrum Disorder (Biao et al., 2018). ASD is a developmental disorder which is comprised of deficits in communication and social skills and the presence of restricted interests and repetitive behaviors (APA, 2013). It is estimated that 30% of the total ASD population acquire very little language or never acquire any language at all (Davis et al., 2011). Tager-Flusberg and Kasari, (2013) refer to these children as

the "neglected end of the spectrum" (pg. 1). While there are treatment options for these children, few studies look at treatment from a mental or emotional health perspective (Tager-Flusberg & Kasari, 2013).

About 40% of children with ASD also experience anxiety concerns in the form of a traditional anxiety disorder (Kerns et al., 2014). Additionally, it is reported that between 11% and 84% of children with ASD experience some form anxiety that interferes with their daily life (White et al., 2009). However, these statistics seem to vary throughout the literature and often present an unclear picture of the role that being minimally-verbal may play in a child's risk for elevated anxiety. One study reported findings in which groups with ASD and greater language abilities showed higher anxiety than control groups (Gillott et al., 2001); however, this study only looked at children with no language impairments. Therefore, no conclusions may be drawn about children with language impairment. Still others assert that greater levels of anxiety could potentially be a function of characteristics associated with ASD, including communication deficits such as reduced receptive and expressive language (Wood & Gadow, 2010).

Still another study compared groups of children classified as having either "Autism"- the diagnosis more likely to be associated with reduced receptive and expressive language- or "Asperger's"- the diagnosis associated with no language delay- as per DSM-IV criteria and found no difference in parent reported levels of anxiety between the two groups (Kim et al., 2000). Kerns et al. (2014) found a positive association between anxiety disorder and stronger expressive and receptive language abilities. One study demonstrated that in TD children and in children with Pervasive Developmental Disorder- Not Otherwise Specified (PDD-NOS), poorer expressive language was correlated with increased anxiety (Davis et al., 2011). However, in this same study, poorer communication ability was correlated with decreased anxiety in children

diagnosed with autistic disorder. PDD-NOS is a pervasive developmental disorder listed in the DSM-IV with features of autism that did not meet the full DSM-IV criteria. In the newest iteration of the DSM (i.e, the DSM-5) PDD-NOS has been subsumed into the ASD category (APA, 2013). It is unclear why the findings differ between PDD-NOS and ASD in this study, since PDD-NOS is now encompassed within the diagnosis of ASD in the DSM-5; more research may need to be done in this area. This somewhat contradictory result may be explained by inferring that TD children and children with PDD-NOS in this study were still able to express anxiety in some way despite decreased overall communication ability, while children with the diagnosis of autistic disorder were not. The authors imply more severe communication difficulties in the autistic disorder group, stating that the communication deficits and increased likelihood of alexithymia present in autism may make it difficult in this population to evaluate anxiety symptoms as they are currently defined. It is also possible that some components of anxiety are more recognizable to parents than others (i.e. running away is more recognizable than a child feeling scared).

These variable findings demonstrate that currently the results are mixed as to whether children with MV-ASD experience more, less or the same amount of anxiety as their more verbal peers with ASD. However, considering the documented struggles with increased anxiety this population is known to experience and the challenges that compromise language (whether expressive or receptive) has on ability of clinicians to accurately diagnose anxiety, it seems important that more research be directed towards accurate assessment of anxiety in children with MV-ASD.

One possible explanation for the lack of a consistent narrative in the research is that is difficult to assess these children for mental health concerns. Due to their limited expressive

language, these children are not able to self-report. Parent reports have been shown to be limited, particularly with respect to internalizing symptoms (Jansen et al., 2017). This makes the assessment of anxiety difficult in this population. While difficult, anxiety assessment in this population may be especially important.

Theoretical Relationships Between Anxiety, Physiology and ASD

While anxiety is sometimes discussed as a unitary construct, it is important to acknowledge that there are actually several different components to anxiety including cognitions, behaviors, and physiological responses (Brosschot, 2017). Several models have been proposed that relate these various components of anxiety. One of the most commonly researched models of anxiety is that of fear conditioning (Lissek et al., 2005). Fear conditioning is the process by which a neutral stimulus becomes frightening by being repeatedly associated with a stimulus that evokes fear. Within the fear conditioning literature, it is suggested that individuals who go on to develop anxiety disorders may have a stronger conditioned fear responses and take longer to extinguish learned fear responses than those who do not develop anxiety disorders, or are worse at perceiving "safety cues" or cues that signal when the aversive stimulus is not present. These different possibilities were examined in a meta-analysis which determined that while there is not sufficient research to distinguish between strength of initial acquisition vs. a slower extinction process, the pattern of results reviewed supports the theory that individuals with anxiety disorders have more difficulty in discriminating fear cues from safety cues once fear response has been conditioned (Lissek et al., 2005).

Further in support for the hypothesis that individuals with ASD may have more difficulty differentiating safety cues, one article examined amygdala response to safety versus threat cues in a fear conditioning paradigm with individuals with ASD (Top et al., 2016). This article

showed significantly decreased neural differentiation of threat vs. safety cues in individuals with ASD compared to their neurotypical peers. The article concludes that a deficit in the ability to identify safety contexts may underlie the increased likelihood of anxiety disorders in ASD. Interestingly, another study suggests that the more complex, or multi-sensory, the conditioned stimulus is the less likely individuals with ASD are to learn a conditioned response in comparison to their typically develop peers (Powell et al., 2016). For example, when exposed to a multi-sensory fear stimulus (a puff of air and a loud noise) individuals with ASD demonstrated fewer conditioned fear responses compared to neurotypical peers. While seemingly counterintuitive, this does again suggest that perhaps the reason for the increased prevalence of anxiety in ASD is not that these individuals more easily learn fear responses, or overgeneralize fear responses but rather that they have difficulty learning how to detect when the environment is safe and undergeneralize safety cues.

Another model is the Generalized Unsafety Theory of Stress (GUTS) model (Brosschot, 2017; Brosschot, Verkuil, Thayer, 2016, 2017). The GUTS model suggests that the human default response is that of stress, and that throughout life people learn safety cues to tell when this response is not needed (Brosschot et al., 2016). It is posited that when people fail to explicitly perceive safety, they remain in a state of psychological and physiological stress (as opposed to feeling safe until explicitly perceiving a stressor). When an organism perceives their environment as "generally unsafe" or lacking in information that signals safety, this leads to chronic anxiety or stress, despite the fact that no explicit stressful event may have occurred. According this model, people may develop a sense of Generalized Unsafety (GU) as a result of not perceiving cues that explicitly signal safety. This can lead to a chronic stress response even in a seemingly safe world (i.e., a world where there are no apparent threat cues; Brosschot et al.

[2017]). It is important to note that this is not mutually exclusive with previous models of fear learning such as fear conditioning. Brosschot et al. (2016) point out that there is room for this model within the context of fear conditioning paradigms. Brosschot and colleagues utilize the example from Duits et al. (2015), in which participants with Generalized Anxiety Disorder (GAD) showed a fear response to the conditioned stimulus, to the unconditioned stimulus, as well as to a neutral stimulus that had not been paired with the unconditioned stimulus in comparison to a control group who did not demonstrate a fear reaction to a neutral stimulus. This example demonstrates that, while the participants with GAD did respond to fear conditioning in a way consistent with previous fear conditioning research, they also failed to perceive a cue that signaled safety accurately.

As suggested by Brosschot et al., (2017), GU may result from a failure to learn and generalize safety contingencies in early life. From this perspective, it is not hard to imagine how children with ASD may be vulnerable to chronic anxiety and stress, since it is well documented that children with ASD have difficulty taking information learned in one context and generalizing it to others (Sartini et al., 2017). As such, it is possible that children with ASD may have difficulty learning safety cues in early life and then generalizing them to new contexts. Brosschot and colleagues also argue that loneliness may be one of the mechanisms through which a GU develops. They suggest that social connectedness may be one of the main ways that humans learn to perceive safety. Difficulty forming effective and meaningful social relationships is a hallmark symptom of ASD (APA, 2013). Hence, children with ASD may be vulnerable to chronic anxiety from the perspective of the GUTS model.

While in some ways the well-researched fear conditioning model and the newer GUTS model of anxiety disorders may seem contradictory, in some regards there actually many core

characteristics that they have in common in relation to anxiety as it presents in children with ASD. Namely, both models offer a rationale that suggest individuals with ASD may be worse at perceiving safety cues than their typically developing peers (Broschott et al., 2017; Lissek et al., 2005, Powell et al., 2016). Additionally, both models offer a rationale that suggests that heightened anxiety may result in differential patterns of physiology for children with ASD (Brosschot, Verkuil, Thayer, 2016, 2017; Top et al., 2016)

Measurement of Physiological Responses

The idea that the stress response is suppressed by safety cues rather than activated by stress cues is consistent with some studies of specific physiological measures. For example, Thayer and colleagues (2009) demonstrated that when pre-frontal cortex activity is blocked by administration of sodium amobarbitol, Heart Rate (HR) increased and Heart Rate Variability (HRV) decreased, despite the fact that no stressor was introduced. Autonomic features such as HRV and HR have often been hypothesized to be biomarkers for the presence of anxiety or even of the elevated levels of anxiety present in anxiety disorders (Chalmers et al., 2014; Pittig et al., 2013; Yeragani et al., 1993). It has been shown that compared to controls, people with anxiety disorders have significantly lower baseline HRV (Chalmers et al., 2014; Penninx et al., 2009; Pittig et al., 2013). Increased HR is also indicative of many different heightened emotional states, one of which is anxiety (Watkins et al., 1998). Increased HR is associated both with increased sympathetic and decreased parasympathetic nervous system activity, while HRV is partially vagally-mediated and is sometimes interpreted to reflect overall cardiac vagal activity (Penninx et al., 2009). More specifically, Respiratory Sinus Arrhythmia (RSA) refers to HRV that occurs as a function of respiration and is mediated by the vagus nerve, which is under parasympathetic influence. Many studies that examine the relationship of HRV to anxiety and ASD measure HRV

via RSA. (Beauchaine, 2015; Benevides & Lane, 2015). Moreover, most studies use resting RSA due to the increased influence of the vagus nerve during resting state (Benevides & Lane, 2015). It is also important to note that baseline or resting HR, and HRV are often used in the literature (as opposed to reactive HR or HRV) and have been shown in many cases to be related to anxiety (Benevides & Lane, 2015; Pittig et al., 2013). It is suggested that resting or baseline HR and HRV may be suggestive of more stable or trait-like states of anxiety (Williams et al., 2015).In contrast to some studies that have examined cardiac variables solely in relation to anxiety, Beauchaine (2015) noted relationships to anxiety and ASD as well as several other disorders, and refers to RSA as a transdiagnostic marker of emotional dysregulation. The general finding of reduced baseline HRV also has been shown across several different anxiety disorders including Panic Disorder, Generalized Anxiety Disorder, and Social Phobia (Friedman 2007; Pittig et al., 2013).

This body of research suggests that baseline HRV and HR may be promising biomarkers for anxiety in ASD, and some studies have even gone so far as to claim that results are demonstrative of this promise. For example, one study stated that reduced baseline HRV may be a promising biomarker for the many difficulties that may underlie problems with social approach behaviors, such as impaired stress regulation (Alvares et al., 2013). Another study referred to HRV as "transdiagnostic," but characterized it as a transdiagnostic biomarker of "worry" specifically (Chalmers et al., 2014). In order to make this claim more powerful, however, it seems important to not only examine the literature surrounding anxiety and autonomic biomarkers, but to also look at the literature related to other characteristics of ASD and autonomic activity. For example, some studies have shown that HRV is not specific to anxiety (Neuhaus et al., 2014; Patriquin et al., 2015), and that HRV anomalies, like HR anomalies, may

be present as a feature of ASD itself (Daluwatte, 2013). Additionally, HRV and HR face challenges in terms of a paucity of knowledge with respect to its interactions with language ability. Few studies have been conducted to specifically test whether or not HRV and HR may discriminate between anxiety and other maladaptive states and behaviors.

Measurement of Behavioral Responses

Consistent with the belief that anxiety is a multidimensional construct, it seems important to consider not just the physiological but also the behavioral domain of anxiety. Related to the measurement of observable behaviors, several studies have successfully engaged the use of behavioral coding schemes for children with MV-ASD (Grzadzinski et al., 2016; Lord et al., 2008). Perhaps the most well-known, Lord et al. (2008) developed a behavioral coding scheme for the diagnosis of ASD in children with varying language abilities including completely non-verbal children and children with phrase speech. Additionally, the work that has been done on treating anxiety children with MV-ASD has often made use of behavioral coding paradigms to measure treatment success. For example, Davis et al. (2007) and Ricciardi et al. (2006) are both case studies that utilized collection of behavioral observation data to determine a child's progress in the treatment of a specific phobia. Finally, Mian et al. (2015) recently developed an anxiety coding paradigm, the Anxiety Dimensional Observation Schedule (Anx-DOS) for the detection of anxiety disorders in typically developing preschool age children. Similar to the ADOS, this measure consists of a series of behavioral codes and has shown good inter-rater reliability, internal consistency, and convergent validity (Mian et al., 2015).

Goals of the Current Study: Why a feasibility study?

In 2010 the United Kingdom National Institute for Health Research (NIHR) defined a feasibility study as a piece of research done before a main or larger study of which the purpose is

to answer the question "Can this study be done?" It is known that children with MV-ASD often demonstrate higher rates of disruptive behavior (Baker & Blacher, 2015) and high rates of tactile sensitivity (Mikkelsen et al., 2018). Therefore, it seems reasonable to ask whether a study that requires these children to tolerate some form of physiological data collection as well as a long and demanding assessment procedure can reasonably be completed. The NIHR guidelines suggest reasonable goals of feasibility studies including number of eligible participants that are able to be recruited, rates of responses to questionnaires, and time needed to collect and analyze data. Additionally, it has been suggested that a feasibility study may be especially appropriate when the population may for some empirical reason need unique consideration of the method used in research (Bowen et al., 2009; Eldridge et al., 2016). Bowen et al. (2009) also suggests eight different areas of focus that could be addressed by a feasibility study including acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited-efficacy testing. These domains are further defined and operationalized in the method section below. The current study focused on the domains of "acceptability", "demand", and "practicality". The other domains, while important, are more appropriate to later studies. For example, the domain of "integration" would assess whether the proposed measure could be implemented in a community setting, or the domain of "expansion" which would assess whether a currently working approach can be expanded to include new components.

The goal of the current study was to conduct a feasibility study utilizing Mian et al.'s (2015) Anx-DOS in children with MV-ASD while collecting physiological data in the form of HR and HRV. The study focused on the domains of acceptability, demand, and practicality, as suggested and defined by Bowen et al. (2009), of this potential assessment protocol for anxiety in children with MV-ASD. This study aimed to test hypotheses related to the feasibility of

conducting a later larger study of this measures as well as to conduct exploratory analyses related to the initial convergent and divergent validity of this measure.

Hypotheses

Feasibility

I. Acceptability was defined as the extent to which the proposed measure would be judged as suitable, satisfactory, and "doable" for children with MV-ASD as perceived by their parents. It was hypothesized that the measure would deemed acceptable to the participants.

II. Demand is defined as the extent to which the proposed protocol was likely to be used or participated in. It was hypothesized that the proposed measure would demonstrate sufficient demand to merit consideration for further study.

III. Practicality was defined as whether the measure could be implemented with intended participants using existing means, resources, and circumstances. The goal of measuring practicality was to determine whether these data could be practically collected in the clinic setting. It was hypothesized that the method described below would be able to be practically implemented in the clinic setting.

Exploratory Analyses

I. Based on the GUTS model as well as models of fear conditioning, children with MV-ASD may be more likely to experience anxiety than typically developing children, or perhaps children with ASD and no language impairment. Exploratory analyses were conducted to examine the number of participants above the clinical cut-off on the CBCL and PRAS-ASD.

II. Estimates of overall inter-rater reliability and internal consistency as well item-level statistics of each item's difficulty and discrimination were conducted.

III. Exploratory correlations were conducted between the proposed behavioral measure of anxiety (the Anx-DOS, described below in methods section) and other measures of anxiety including the PRAS-ASD and the CBCL.

IV. Exploratory correlations were conducted between the proposed behavioral measure of anxiety (the Anx-DOS, described below in methods section) and theoretically unrelated measures, including the SRS-2.

V. Exploratory correlations were proposed between the proposed behavioral measure of anxiety (the Anx-DOS, described below in methods section), and physiological data including HR and HRV; however, these analyses were not able to be conducted for several reasons stated below.

Method

Participants

Participants consisted of 12 children with MV-ASD of developmental age 6 or under, and chronological age 2.5-10, as well as at least one parent who could report on their current behavior. Participation was not restricted by gender, previous diagnoses, or intellectual functioning. The final sample was 92% male (n=11) and 83% white/Caucasian (n=10). One child was identified as "Asian" and one child was identified as "Multi-racial." 33% (n=4) of the sample had an active medical condition such as a seizure disorder.33% (n=4) of the sample were taking some kind of medication regularly. 58% (n=7) of the sample had been diagnosed with a psychiatric condition besides ASD. 92% (n=11) received some kind of therapy, with 42% (n=5) of the sample receiving three or more different kinds of therapy (i.e. speech therapy, occupational therapy, applied behavior analysis etc.).

Children who presented with significant psychopathology on any parent report measures were referred for further assessment or treatment services as appropriate. Children who scored high on a measure of tactile sensitivity were able to participate, but did not complete physiological data collection. "Minimally verbal" was defined as a child for whom it was appropriate to administer a Module 1 or 2 Autism Diagnostic Observation Schedule-2nd edition (ADOS-2). The criteria for a Module 1 ADOS-2 administration are that the individual uses no words, single-words, or up to two words together. The criteria for Module 1 or 2 ADOS-2 administration are that the individual uses "phrase speech." Phrase speech is defined in the ADOS-2 manual as non-echoed, three-word utterances. The ADOS-2 was also used to confirm ASD diagnosis. Six participants were administered a Module 1 ADOS-2 and six participants were administered a Module 2 ADOS-2.

Participants were recruited from the Southwest Virginia area. Recruitment made use of several resources. First, flyers were posted at several community locations in the Southwest Virginia area including grocery stores, community centers, and children's museums. Additionally, flyers were mailed to doctors' offices in the area with the request that they post them in their waiting room. Recruitment also made use of the Virginia Tech Autism Clinic & Center for Autism (VTAC/CAR) Research Registry to circulate news of the study to families who have registered as being interested in participating in research. The flyer was also distributed to the VTAC/CAR affiliate listserve which includes several community practitioners who work with children with ASD. Finally, the flyer was distributed to schools in the area (e.g. Blue Ridge Autism and Achievement Center, Minnick School, Rivermont) as well as other Applied Behavior Analysis programs (e.g. ABC's of ABA, Blue Mountain Behavior Therapy) where there was a high likelihood of them being distributed to families of children who are minimally-verbal. The information about the study was also posted to the Virginia Tech Center for Autism Research Facebook page, as well as distributed to the Virginia Tech Autism Clinic Families email list.

The families of 18 children expressed interest in this study. Of these 18, two did not show up for their scheduled appointment, one was not able to complete the study due to changes in schedule with current therapy, one was not able to be scheduled due to restrictions on face-to-face contact resulting from the COVID-19 pandemic, one was over the developmental age of 6, and one did not meet criteria for ASD based on the ADOS-2. Thus, the study had a total of 12 participants whose data were used in final analyses (Figure 1).

Measures

Feasibility design. Bowen et al. (2009) suggest three different stages of measuring feasibility including, 1) Can it work? 2) Does it work?, and 3) Will it work? As noted above, feasibility was assessed via the domains of acceptability, demand, and practicality. Measurement of these constructs is designed in alignment with the goal of measuring "Can it work?" meaning the goal is to provide some evidence that the proposed assessment procedures can be successfully carried out in the clinic setting.

Demand. Demand was measured by the number of participants who enrolled, arrived at the clinic, and consented to be included in the study for the proposed assessment protocol, (regardless of whether or not they completed the protocol in its entirety) relative to how many participants likely had knowledge of the study. A percentage of the number of people who participated divided by roughly how many people have knowledge of the study was calculated by tracking the recruited populations.

Practicality. Practicality was measured via several percentages and qualitative data as listed below:

1. When a family was read the phone screen and declined to participate, they were asked if they could provide a reason for why they had declined.
2. The percentage of participants who signed a consent form for the study who were then able to complete the study protocol in its entirety (behavioral and physiological data collection) was calculated. The percentage of families who were able to complete exclusively behavioral data collection was also calculated. Any time data were not collected due to a participant declining, the participant was asked if they could provide a reason why and this information was coded for common themes.

3. The percentage of physiological data that was able to be successfully cleaned and analyzed was calculated.

Acceptability. Acceptability was measured using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), & Feasibility of Intervention Measure (FIM; Weiner et al., 2017). These are three 4-item measures of outcomes that have been shown to be indicators of intervention or protocol success (Weiner et al, 2017; Proctor et al., 2011). Items are rated on a 5-point Likert scale where 1=completely disagree, 2=disagree, 3= neither agree nor disagree, 4=agree, and 5=completely agree. Scores were calculated summing all responses. Wiener and colleagues (2017) demonstrated that this measure shows promising psychometric properties in that the measure demonstrates content validity, discriminant content validity, reliability, structural validity, structural invariance, known-groups validity, and responsiveness to change. Discriminant and predictive validity of the measure are currently being researched. In the current study, Cronbach's alpha for the AIM was 0.94, demonstrating excellent internal consistency. Cronbach's alpha for the IAM was .95, demonstrating excellent internal consistency. Finally, Cronbach's alpha FIM was 0.69, demonstrating questionable internal consistency.

Demographic Survey. The demographic survey obtained information about the parent (e.g., education level, relation to the child, income), the child (e.g., age, race, education level), the child's current diagnosis, medical information related to the collection of physiological data, and the child's current symptoms.

Anx-DOS (Mian et al., 2015). The Anx-DOS is an observation measure that employs a variety of presses as well as six different codes. Presses are designed to increase the likelihood of observing a variety of clinically relevant behaviors but are especially designed to facilitate

observation of anxiety. Four presses are administered in the following order: 1. Mystery jar: the child is asked to reach into a clear jar to retrieve a prize, 2. Spider: the child is asked to play with a large, realistic spider, 3. Bell: An electronic bell is used to signal the transition to the next task, 4. Separation: the parent separates and leaves the child with the clinician. Each of the six codes are rated along a clinical continuum: 0-no evidence, 1-mild/normative, 2-of concern, and 3-atypical. Scores of 2 or 3 indicate clinically concerning behaviors. Codes include: Fear Arousal, Physical Avoidance, Exaggerated Startle, Proximity Seeking, Latency to Touch, and Separation Distress. This measure has demonstrated good inter-rater reliability and internal consistency, as well as initial convergent validity evidence with a preschool aged sample (Mian et al., 2015). This measure was selected because it is, to our knowledge, the only observational measure of anxiety that has shown some initial validity evidence. Additionally, previous studies have demonstrated that observational assessments (e.g. the ADOS; Lord et al., 2000) have appropriately captured symptomology in children who are minimally-verbal. While other measures are included in the assessment protocol to measure anxiety (i.e. PRAS-ASD, CBCL) one of the goals of this project was to see if another dimension of assessment, besides just parent report, can be accessed for these children. The psychometric properties of the Anx-DOS measure for this study are discussed in the results section.

ADOS-2 (Lord et al., 2000). The ADOS-2 is a semi-structured observation designed to assess the symptomology characteristic of ASD. It has shown strong predictive validity against best estimate diagnoses (Gotham et al., 2007). There are four developmental- and language-level dependent modules. In this project, Module 1, designed for children with no language or single words, and Module 2, designed for children with phrase speech, were be used. In both modules, a protocol of social presses is administered by a clinician. Behaviors relevant to ASD are then

scored on a 4-point scale, with 0 indicating 'no abnormality of type specified' and 3 indicating 'moderate to severe abnormality.' This measure was used to confirm ASD diagnosis with overall cut-off score meeting classification of 'autism spectrum' or 'autism.' Additionally, it was coded using the Anx-DOS (below) coding scheme for potential future analyses on the possibility of coding the ADOS-2 for a measure of anxiety. Cronbach's alpha for the Module 1 ADOS-2 in this study was 0.85, demonstrating good internal consistency. Cronbach's alpha for the Module 2 ADOS-2 was 0.91, demonstrating excellent internal consistency.

Leiter-Revised (Roid et al., 2013). The Leiter-Revised is a non-verbal measure of intellectual functioning. Subscales include Reasoning, Memory, Attention, and Visualization. This measure is norm-referenced and appropriate for children and adults ages 3-75 years old. As reported in the manual, alpha coefficient for Nonverbal IQ in the normed sample ranged from .94 to .98 for five age groupings. The full scale IQ is based only on fluid reasoning and visual processing subtests. The overall FSIQ scores were used to provide descriptive information about the sample. Cronbach's alpha for this measure in the current study was 0.85, demonstrating good internal consistency.

Peabody Picture Vocabulary Test, Third Edition (PPVT-III; Dunn & Dunn, 1997). The PPVT-III measures receptive language skills (understanding and comprehension of spoken words) in a format that is conducive to measuring language skills in children with ASD. The examiner orally presents a stimulus word with a set of pictures, and the participant selected the picture that best represented the words' meaning. The PPVT-III is significantly correlated to the Vocabulary Comprehension Index on the Wechsler Intelligence Scale for Children, Third Edition, $r = 0.75$, $p < .01$ (Tannenbaum, Torgesen, & Wager, 2006). The PPVT-III score was calculated by subtracting the number of errors the child makes from a total ceiling score. The

raw score was converted into a standard score. The standard score (M = 100, SD = 15), which is a measurement of relative standing among chronologically aged peers. The PPVT has been used in experimental studies to assess receptive vocabulary in children with autism (e.g., Badawi, 2006) and has demonstrated good psychometric validation (Williams & Wang, 1997). The age equivalent from this measure was used to determine the child's developmental age and subsequent eligibility for inclusion in the study. The T-score from this measure was also used to provide descriptive information about the sample.

Expressive Vocabulary Test-2 (EVT-2) (Williams, 1997). The EVT is a norm-referenced test that assesses expressive vocabulary and word retrieval for children and adults, ranging from age 2 years 6 months to beyond 90 years of age. In the EVT-2 examinees are shown a picture and asked to provide a single word to label or to provide a single word synonym for the target word. Reliability evidence suggests that coefficient alpha reliabilities are in the .90s across age and grade norm groups. The T-score from this measure was used to provide descriptive information about the sample.

Child Behavior Checklist (CBCL) (Achenbach, & Edelbrock, 1983). The CBCL is a parent-report measure, which measures the behavioral and emotional functioning of children ages 1.5 to 18-years-old. This measure uses a 3-point scale, and is standardized. Parents are asked to rate their agreement with 113 items related to their child's behavior, ranging from 0 = not true to 2 = very true or often true. The measure yields several subscales. On each of these, T-scores less than 65 (i.e., less than 1.5 SD above the mean) are considered to be within the normal range, scores between 65 and 69 (i.e., between 1.5 to 2 SD above the mean) are considered borderline, and scores of 70 and above (i.e., 2 or more SD above the mean) are considered to be clinically significant (Achenbach & Rescorla, 2001). In this study Cronbach's alpha for the

CBCL 1.5-5 was 0.78 indicating acceptable internal consistency. Cronbach's alpha for the CBCL 6-18 could not be calculated due to the number of participants. The behaviorally observable items were taken from this measure to create a composite raw score of observable anxious behaviors or observable anxiety composite. For the CBCL 1.5-5 these items included "clings to adult or too dependent," "doesn't want to sleep alone," "doesn't want to go out of home," and "gets too upset when separated from parent." The Cronbach's alpha for these items was 0.69, demonstrating questionable internal consistency. For the CBCL 6-18 the items in the observable anxiety composite included "clings to adult or too dependent," "cries a lot," "talks about killing self." There were not sufficient participants for Cronbach's alpha to be calculated for these three items.

Social Responsiveness Scale (SRS-2) (Constantino, & Gruber, 2012). The Social Responsiveness Scale (SRS-2) is a 65-item rating scale that measures social difficulty in children and adults over 1.5 years of age. Items are scored to create a raw score and gender-normed T-scores. The overall T-score from this measure was used to provide descriptive information about the sample. For this study, the Social Awareness and Social Cognition subscales were used. The Social Awareness subscale describes a child's awareness of whether various behaviors are socially appropriate. The social cognition subscale evaluates the child's understanding of various social behaviors. These were chosen as subscales least likely to be related to the presence (or lack thereof) of anxiety. Cronbach's alpha for SRS-2 Preschool Version was 0.98 indicating excellent internal consistency. Cronbach's alpha for the SRS-2 School Age Version was 0.90 indicating excellent internal consistency.

Parent Rated Anxiety Scale-ASD (PRAS-ASD) (Scahill et al., 2018). The 25-item Parent-Rated Anxiety Scale for ASD (previously called the Parent Anxiety Checklist-ASD) was

developed with funding from the National Institute of Mental Health (MH099021, L. Scahill, Principal Investigator). The copyright is held by L. Scahill, L. Lecavalier, K. Bearss, M. Aman. The measure consists of 25 item each rated from 0-3 with 0 being "no difficulties" and 3 indicating "severe" difficulties. This measure is still in development and data on its psychometric properties have not yet been published. The total score from this measure was used to provide descriptive information about the sample as well for potential future convergent validity studies. In the current study, Cronbach's alpha for this measure was 0.87 indicating good internal consistency.

Short Sensory Profile (SSP; McIntosh et al.,1999). The Short Sensory Profile is a measure of a child's responses to sensory stimuli in their environment. It is a 38-item parent report measure. The "tactile sensitivity" subscale was used to determine whether the child was eligible to participate in physiological data collection. If the child's score in the "tactile sensitivity" domain was scored as "much more than most people" no physiological data were collected. Items are rated on a scale from 0-4 with "0" indicating a child "always" struggles with that particular sensory experience and "4" indicating the child "never" struggles with that sensory experience. Cronbach's alpha for this measure in the current study was 0.83, indicating good internal consistency.

Physiological Data. Physiological data were collected using MindWare (MindWare, Gahana, OH) data collection equipment. For the collection of HR and HRV, this equipment requires two electrodes placed on the participant's skin, connected to a small battery pack which can be placed in a backpack worn by the child. The placement of these electrodes can be seen in Figure 3. The Brown and black circles in the figure represent the electrodes used. As shown in the figure, the electrodes were placed on either hip, and at the base of the left shoulder. This data

collection method allowed the participant to move freely throughout the room. For the purposes of this study, HR was measured in beats per minute (bpm) and HRV was measured using RSA. RSA is a measure of HRV that takes respiration into account, and there are many metrics for quantifying RSA. While RSA is a good index of parasympathetic regulation of HR, it should be noted that this does not necessarily generalize to all parasympathetically-mediated functions. Data were proposed to be analyzed using CardioBatch software. This is a program that utilizes algorithms, specifically the Porges-Bohrer method, to extract the heart rate variance within the frequencies of spontaneous breathing to determine the amplitude of RSA (Porges,1985; Porges & Bohrer, 1990). For more details of the calculation of RSA refer to Patriquin, Lorenzi, & Scarpa, 2013 and Patriquin, Scarpa, Friedman & Porges, 2013. Several past studies have utilized Porges method which filters out slower vacillations and leaves only the fast frequencies that are considered to be vagal (Applehans & Luecken, 2006). As noted below, ultimately these data were not analyzed due to the location of the analysis software on campus and access to campus being restricted to "essential personnel" due to the COVID-19 pandemic.

Procedure (Figure 2)

This project was approved by the Virginia Tech Institutional Review Board. This project consisted of a one-session visit to the clinic during which participants completed a series of measures of expressive and receptive language, anxiety, and ASD symptomatology. After indicating interest in the project, a clinician or trained research assistant completed the phone screen with the participant and scheduled their visit to the clinic. The child and at least one parent arrived at the clinic and met with the clinician to go over the study procedures and signed consent forms. The parent was also given $20 as a thank you for participating as well as reimbursement for travel to the clinic if they indicated that they wanted it. After consent, the

parent was given the parent report questionnaires to complete while the child was taken to a separate room to complete the PPVT and EVT. The parent completed the SSP and if the child scored in the highest possible bracket for tactile sensitivity no physiological data collection was attempted. After the child completed the PPVT and EVT, the parent came back into the room and clinician put on the electrodes for the physiological data collection. Only electrodes needed for the collection of HR and HRV were used. If it had been determined that no physiological data would be collected, the child proceeded directly from the PPVT and EVT to the ADOS. The child was given ten minutes to acclimate to wearing the electrodes and then watched a neutral video of animals for five minutes to obtain a measure of their baseline HR and HRV. The electrodes were then removed and the child completed the ADOS-2, Anx-DOS, and Leiter with the parent in the room. At the end of the session the child was able to select a small toy to take home with them.

Results

Analyses

Descriptive Statistics (Table 1). Descriptive statistics were conducted to determine the mean and standard deviation of all relevant variables. Bivariate correlations were also conducted between descriptive variables and all variables of interest. Age was negatively correlated with the CBCL Observable Anxiety Composite, r_s=-.58, p=.046, such that older children had lower anxiety scores. Additionally, PPVT score was negatively correlated with the CBCL internalizing scale, r_s=-.51 p=.046, and EVT score was also negatively correlated with the CBCL internalizing scale, r_s=- .75, p=.004. The participants' scores on any of the anxiety measures utilized for this study did not differ based on whether or not the child had an additional psychiatric diagnosis besides ASD. Children with a medical condition had significantly higher scores on the PRAS-ASD , $t(10)$ =2.15, p=.029. Children taking a medication scored significantly lower on the CBCL Anxious/ Depressed subscale, $t(10)$=-1.95, p=.04.

Hypothesis testing.

Acceptability (Table 2): Scores from the acceptability questionnaire were calculated and an overall mean score was determined. All three measures demonstrated that the Anx-DOS was largely acceptable to parents. On all three measures a score of 20 was indicative of the highest possible acceptability, appropriateness, or feasibility. On the Acceptability of Intervention Measure (AIM) parents' mean rating of the Anx-DOS was 18.75 (*SD*=2.6, *Range*=12-20). On this measure the overall lowest rated items was "I like this assessment" (*M*=4.6). On the Intervention Appropriateness Measure (IAM) the mean rating was a 17.83 (*SD*=3.1, *Range*=12-20). The lowest rated item on this measure was "This assessment seems fitting" (*M*=4.50). On

the Feasibility of Intervention Measure the mean rating was 18.75 (*SD*=1.7, *Range*=16-20). The lowest rate item on this measure was "This assessment seems implementable" (*M*=4.50).

Demand: The number of participants who signed a consent form was counted with reference to the study's initial enrollment goal of 30 participants over the course of 1 year, or about 3 participants each month. 80% enrollment was used as the cutoff for determining sufficient demand. Due to the grant funding timeline delaying the start of the project as well as the COVID-19 pandemic causing the study to conclude earlier than planned, the study was only able to actively recruit participants for eight months. Because of this, the target number of participants was reduced to 24, consistent with a goal of 3 participants per month over 8 months. During these eight months, a total of 14 families signed a consent form to participate in the study, resulting in the study successfully recruiting 58% of the original recruitment goal.

Additionally, a percentage of those interested in the study based on how many people were recruited was calculated. This study utilized several recruitment sources including the Virginia Tech Autism Clinic (VTAC) families email list, the Virginia Tech Center for Autism Research (VTCAR) Facebook page, advertisement at outreach presentations, emails to past research participants, and emails to third parties such as teachers and therapy companies. As far as was possible, the total number of families reached was tracked from each source, although some sources could not be tracked (i.e. the number of families reached by third party sources such as teachers and therapists). In total, it was estimated that from the sources we were able to track, information about the study reached about 534 families affected by autism. Using current prevalence rates, it was estimated that 30% of these families may have a child who is minimally verbal. Therefore, it was estimated that information about the study reached about 160 potentially eligible families. Based on the families of 18 children who reached out to express

interest, demand for this measure was estimated to be about 11%. Demand based on each individual recruitment source is shown in the table below (Table 2). Of the recruitment sources utilized the most successful was the VTAC families email list (44% of participants), followed by the VTCAR Facebook page (28%), a teacher or therapist referral (22%), and finally recruitment from a list of past participants (6%) (Figure 4).

Practicality: Three percentages as described in the method section were calculated to determine the practicality of this measure in a clinic setting: 1) Achievement of 80% of the sample being able to tolerate the electrodes. 2) Achievement of usable data in 80% of the sample will be used as the cutoff for determining adequate practicality, 3) Achievement of usable behavioral data from at least 80% of the sample.

In regard to goal 1, of the 12 children in the final sample 16% (n=2) were able to tolerate the electrodes throughout the duration of the study. There were many reasons why the remaining 10 children were not able to complete physiological data collection. 80% of children scored too high on the SSP tactile domain to participate in this data collection (n=8), 10% had a parent refuse to allow this kind of data collection (n=1), and 10% would not tolerate the electrodes (n=1; i.e cried and pulled off). The parents who refused cited their child's high level of anxiety as the reason and explained that he had that kind of data collection attempted before and that it "had not gone well."

In regard to goal 2, due to the COVID-19 pandemic, the analysis software became inaccessible and these analyses could not be run so it is unknown if the physiological data that were collected were usable. Finally, in regard to goal 3, 75% of the sample (n=9) were able to complete behavioral data collection in its entirety. The remaining children were too fatigued to complete behavioral data collection and stopped complying with the examiner's requests to

complete the tasks. All of the children who did not complete the assessment protocol were able to complete all but the last measure administered (the Leiter-R). Each of the children was able to begin this measure and completed from 1-3 of the 4 subtests administered before they stopped complying with the clinician's prompts. This did not seem to be due to the nature of the task but rather the child reaching the end of their tolerance for demands being placed.

Qualitative Observations from Anx-DOS administration and physiological data collection. There were some notable qualitative observations with regard to the administration of the Anx-DOS assessment. The observation, which consists of six tasks (free play, mystery jar, spider, separation from parent, free play, and bell) was relatively quick to administer and took an average of 15-20 minutes to complete. The task children seemed to respond the most consistently to was "mystery jar." Almost all the children insisted on pulling the jar down to look inside before reaching their hand in to retrieve the prize.

Notably, many children did not respond with fear to the spider task, despite giving indications that they understood the stimulus to be a spider. For example, upon being presented with the spider, one participant picked it up immediately. The examiner stated, "oh, I guess it's not real" to which the participant responded, "No. It's real" while continuing to hold and look closely at it. Another participant, upon being presented with the spider, immediately picked it up and walked over to try and scare his mother with the spider by giggling, putting in on her arm and moving it as if it were walking.

There were some instances when the parent(s) in the room endorsed that various stimuli would make their child anxious or fearful and this did not turn out to be the case. For example, when asked to leave the room, one child's mother stated, "okay but get ready for the crying to start." After his mother left the room the child did not demonstrate any indications of fear arousal

and continued to play quietly with toys, even after the examiner called his attention to the fact that his mother had left the room.

Children also had varied qualitative reactions to the attempts to collect physiological data with electrodes. Upon being read the picture consent form, one child pointed to the picture of physiological data collection and commented, “No sticky circles.” However, another child when being presented with the same materials smiled and whispered, “fun today.” One of the children who was actually able to proceed to the collection of physiological data tolerated the electrodes well for several minutes. However, during data collection, he began to become upset and commented, “No more robot” (which is how the examiner had referred to the data collection equipment). The examiner and his mother were able to soothe him, however, and he was able to complete the data collection. Also important to note, many parents whose children scored too high on tactile sensitivity for their child to participate in the physiological data collection expressed continued interest in participating. For example, one mother stated that her daughter was sensitive to tactile stimuli but she had had several medical procedures done and was very used to this kind of equipment. Many parents also responded to the news that physiological data would not be collected with “let’s just try” or “let’s see how it goes.” Although the way the ethical protocol written for this study prohibited attempting data collection for these participants in this study, this may be something to keep in mind for future studies.

Exploratory analyses

Number of Children with Clinically Significant Anxiety. The number of children above what could be considered the “clinical cut-off” on each measure of anxiety was examined. For the CBCL, t-scores above 65 on normed subscales indicate clinical concern. 16% (n=2) of children were above the clinical cut-off on the Anxious/Depressed subscale. 25% (n=3) of

children were above the clinical cut-off on the Anxiety Problems subscale. 42% (n=5) of children were above the clinical cut-off on the overall Internalizing subscale. Although the PRAS-ASD has no clinical cut-off, the original study on the measure reported that in a general sample of children with ASD the mean score was 29.04, while the mean score in a sample of children with ASD with at least mild anxiety was 31 (higher scores indicating greater anxiety; Scahill et al., 2019). These scores are both higher than the mean of 17.42 in the current sample.

Instrument Design. Proposed exploratory analyses, from a classical test theory perspective, included estimates of overall internal consistency as well item-level statistics of each item's "difficulty" (internal consistency), standard deviation, and discrimination for the Anx-DOS coding scheme when used to code the Anx-DOS tasks and the ADOS-2 tasks.

Iner-rater Reliability (Table 3). Each Anx-DOS administration was coded by two independent coders: one graduate student researcher (criterion coder) and one undergraduate research assistant. After coding, the two coders met to discuss their codes and arrived at a consensus code which was used in the final data set. Each ADOS-2 administration was coded with the Anx-DOS coding scheme by either the graduate student researcher or an undergraduate assistant who reached 80% reliability in using the coding scheme with at least three Anx-DOS administrations before coding independently. Cohen's Kappa was calculated between the graduate student researcher and undergraduate assistant for a randomly selected 20% of the Anx-DOS administrations (n=~4). Kappa on these administrations ranged from 0.4-1.0, or from fair-almost perfect.

Test and items level analyses.

Anx-DOS Fear Composite (Table 4). Cronbach's alpha was calculated to determine test-level internal consistency. Cronbach's alpha for the overall test was 0.35, which is an

unacceptable level of internal consistency. Item level analyses were then conducted to examine each item's "difficulty" (internal consistency), standard deviation, and discrimination. All items demonstrated acceptable or greater discrimination with the exception of "proximity seeking" and "exaggerated startle" which demonstrated unacceptable discrimination, suggesting these items are not helpful in discriminating between groups (see Table 4). Cronbach's alpha was re-calculated with these items removed. After removing these items Cronbach's alpha was .67 which is closer to an acceptable level of internal consistency (i.e. 0.7). The Anx-DOS fear composite was therefore calculated without the Proximity Seeking and Exaggerated Startle items.

ADOS-2 Fear Composite (Table 4). Cronbach's alpha was calculated to determine test-level internal consistency when the Anx-DOS coding scheme was used to code the ADOS-2. Cronbach's alphas for the overall test was 0.67, which is an unacceptable level of internal consistency, although approaching acceptable (i.e. 0.7). Item level analyses were then conducted to examine each item's "difficulty" (internal consistency), standard deviation, and discrimination. All items demonstrated acceptable or greater discrimination with the exception of "separation distress" and "exaggerated startle" which demonstrated unacceptable discrimination, suggesting these items are not helpful in discriminating between groups (see Table 4). Cronbach's alpha was re-calculated with these items removed. After removing these items Cronbach's alpha was .79 which is an acceptable level of internal consistency. The ADOS-2 fear composite was therefore calculated without the Separation Distress and Exaggerated Startle items.

Convergent Validity (Table 5). With regard to convergent validity, the Anx-DOS and ADOS-2 fear composite scores were each correlated with CBCL observable anxiety composite

score, the existing CBCL subscales of Anxious/Depressed, Anxiety Problems, and overall Internalizing Symptoms, and the PRAS-ASD.

Fear Composite on Anx-DOS: Convergent validity was measured by correlations between the observable anxiety composite and fear composite on the Anx-DOS. A non-parametric, one-tailed Spearman correlation showed no significant relationship between the Anx-DOS fear composite and CBCL observable anxiety composite, r_s=.21.; p=.25.The Anx-DOS fear composite was significantly, positively correlated with the CBCL Anxiety/Depression subscale, r_s=.72.; p=.004, and significantly, positively correlated to the CBCL Anxiety Problems, r_s=.64.; p=.01. It was not significantly correlated with the CBCL Internalizing subscale, r_s=-.07; p=.42. A non-parametric, one-tailed Spearman correlation also showed no significant relationship between the Anx-DOS fear composite and the PRAS-ASD total, r_s =-.12; p=.36.

Exploratory analyses were also conducted with the Anx-DOS fear composite when calculated with all items included. When all items were included a non-parametric, one-tailed Spearman correlation showed no significant relationship between the Anx-DOS fear composite with all items and CBCL observable anxiety composite, r_s=.31.; p=.16. The Anx-DOS fear composite with all items was significantly, positively correlated with the CBCL Anxiety/Depression subscale, r_s=.53.; p=.037. It was not significantly, correlated to the CBCL Anxiety Problems, r_s=.48; p=.059, nor the CBCL Internalizing subscale, r_s=-.15; p=.32. A non-parametric, one-tailed Spearman correlation also showed no significant relationship between the Anx-DOS fear composite and the PRAS-ASD total, r_s =-.28; p=.19.

Fear Composite on ADOS-2: Additionally, Mian et al.'s original Anx-DOS coding scheme was utilized to code the ADOS-2 and determine an ADOS-2 fear composite. A non-parametric, one-tailed Spearman correlation showed no significant relationship between the

ADOS-2 fear composite and CBCL observable anxiety composite, r_s =.40; p=.11. The ADOS-2 fear composite was also not significantly, positively related to the CBCL Anxiety Problems subscale, r_s=.46; p=.08, the CBCL Anxious/Depressed subscale, r_s=.35; p=.14, nor the CBCL Internalizing subscale, r_s=.-17; p=.31. A non-parametric, one-tailed Spearman correlation also showed no significant relationship between the ADOS-2 fear composite and the PRAS-ASD total, r_s =.01; p=.48.

Exploratory analyses were also conducted with the ADOS-2 fear composite when calculated with all items included. A non-parametric, one-tailed Spearman correlation showed no significant relationship between the ADOS-2 fear composite with all items and CBCL observable anxiety composite, r_s =.34; p=.16. The ADOS-2 fear composite with all items was also not the significantly correlated with the CBCL Anxious/Depressed subscale, r_s=.44; p=.089, nor the CBCL Internalizing subscale, r_s=.-20; p=.27. It as however, significantly, positively correlated with the significantly, positively related to the CBCL Anxiety Problems subscale, r_s=.54; p=.044. A non-parametric, one-tailed Spearman correlation also showed no significant relationship between the ADOS-2 fear composite and the PRAS-ASD total, r_s =.06; p=.44.

Divergent Validity (Table 6). Divergent validity was measured by correlations between the Anx-DOS and ADOS-2 fear composite scores and the social awareness and cognition scales of the SRS-2.

Fear Composite on Anx-DOS: A non-parametric, one-tailed Spearman correlation showed no significant relationship between the Social Awareness subscale and Anx-DOS fear composite, r_s =-.19.; p=.27, nor between the Social Cognition subscale and the Anx-DOS fear composite, r_s =.08.; p=.40.

These calculations were also completed using the Anx-DOS fear composite when all items were included. There remained no significant correlation between the Social Awareness subscale and Anx-DOS fear composite with all items, r_s =-.26.; p=.21, nor between the Social Cognition subscale and the Anx-DOS fear composite with all items r_s =.02; p=.48.

Fear Composite on ADOS-2: A non-parametric, one-tailed Spearman correlation showed no significant relationship between the Social Awareness subscale and ADOS-2 fear composite, r_s =-.44; p=.09, nor between the Social Cognition subscale and the ADOS-2 fear composite, r_s =-.27; p=.21.

These calculations were also completed using the ADOS-2 fear composite when all items were included. There remained no significant correlation between the Social Awareness subscale and ADOS-2 fear composite with all items, r_s =-.41.; p=.11, nor between the Social Cognition subscale and the ADOS-2 fear composite with all items r_s =-.25.; p=.23.

Physiological Data. Additionally, exploratory correlations were proposed between HRV/HR and the Anx-DOS codes scored from the ADOS-2. Due to the lack of data that were able to be collected in this domain as well as the sudden inaccessibility of the analysis software, these analyses were not conducted.

Discussion

Children with ASD may be especially vulnerable to difficulties with anxiety. Children with MV-ASD, however, present a unique challenge to the assessment of anxiety due to their lack of ability to self-report their own experiences. Additionally, there is a notable lack of research on the assessment and treatment of mental health needs in this population. The goal of this study was to determine the feasibility of an assessment method that employs behavioral observation and measurement of physiological variables. This project sought to determine if an observational assessment of anxiety was acceptable, used/demanded, and practical to carry out in a clinic setting.

With regard to the first goal, it seems that the assessment protocol was largely acceptable, feasible, and appropriate to parents based on their ratings on the AIM, FIM, and IAM. With regard to demand, it is unclear whether there is sufficient demand for this measure to merit further consideration. Overall, the study reached about 58% of its proposed recruitment goal and only 11% of potentially eligible families reached out to express interest in the measure. This statistic is not encouraging, and could suggest that there is not sufficient demand for a measure such as this one. However, there are many variables that should be considered prior to making this conclusion. Parents of children with ASD sometimes place a low priority on treatment for anxiety in their children with ASD, choosing instead to address other ASD related concerns first (Mason & Scior, 2004). Therefore, some families may not access certain services for anxiety difficulties, although they are needed. In this sample, 92% of the children were receiving some kind of therapy with 42% receiving three or more different therapies. This is consistent with the literature that families who care for a child with ASD often have many demands placed on their time and these time demands may contribute to lack of participation in a study such as this one,

even if they felt their child could benefit from such as measure. Additionally, it should be acknowledged that this measure was only piloted in a single community and there may be many aspects unique to this community (i.e. rurality, proximity to a university) that could limit demand for a measure such as this one. Future studies should examine demand for this measure in a variety of communities and populations. Another consideration with regard to demand could be to examine exactly who might demand a measure such as this one. For example, many families present to community clinics with concerns about their child but with little knowledge of what assessments may or may not be needed. Future studies should examine clinician "demand" or whether clinicians experience a need for a measure such as this one when selecting assessment protocols for their minimally-verbal clients.

Finally, with regard to practicality it seems that certain aspects of this assessment protocol may be more practical than others. Behavioral data collection was largely practical in that most (75%) of children were able to successfully complete the assessment protocol in a single visit to the clinic and no appointment went over the allotted three hour time slot. The 25% of children who were not able to complete the behavioral data collection were not able to do so because of fatigue. It is possible that if the session were broken into two 1.5 hour visits to the clinic the remaining children would be able to complete the assessment protocol. However, future studies should be mindful of the effect this additional time may have on increased burden for the families as this would require families to make two separate trips to the clinic. The collection of physiological data in this study was largely not practical. The majority of children (83%) scored too high on tactile sensitivity on the SSP to make the attempt of physiological data collection practical. Therefore, future studies may wish to consider physiological measures that can be collected without placing any electrodes on the child's skin. It is also notable that,

qualitatively, many parents continued to express interest in attempting physiological data collection and future researchers could also consider making exceptions to ruling participants out based on tactile sensitivity based on the parent and child's reported comfort with the data collection procedure.

Several exploratory analyses were also conducted to examine the prevalence of anxiety in this sample, the initial psychometric properties of the measure, and the initial convergent and divergent validity. Important to note, some of the measures utilized in this study (besides the Anx-DOS and ADOS-2 fear composites) demonstrated questionable internal consistency or internal consistency was not able to be examined due to the sample size. The FIM and the CBCL 1.5-5 OAC demonstrated questionable internal consistency, while the CBCL 6-18 and CBCL OAC 6-18 Cronbach's alpha could not be calculated due to the sample size. As such, the results relating to these measures should be interpreted with caution.

When the sample was examined for the presence of anxiety symptoms per the results on the CBCL the majority of the sample did not present with clinically significant anxiety. This could be explained by the fact that the CBCL is not specifically designed to assess anxiety in a sample of children with MV-ASD. These results are more puzzling, however, when noting that the mean of the PRAS-ASD, a measure specifically designed to be used across the entire spectrum of ASD, is significantly lower in this sample than in Scahill et al.'s 2019 sample of children with ASD. Scahill et al. examined the properties of this measure in children with a range of IQ's but not specifically in a sample of children with language impairment. The current sample consists of children who, like Scahill et al.'s sample, have a range of IQ, but who all have language impairment and it is possible that this affected the overall mean. Although the current small sample size should be interpreted with caution, these results suggest that perhaps children

with MV-ASD do experience less anxiety than their more verbal peers. This is consistent with some qualitative observations from the measure, such as children demonstrating that they understood the stimulus was a spider, and still expressing little fear. Future studies should continue to explore this possibility as well as the theoretical reasons why this finding could be the case. One possibility could be that more verbal children with ASD may experience social stressors or instances of bullying that are not experienced by minimally-verbal children. Additionally, it may be worth exploring in the future the nuance inherent in some of the tasks on the observation measure. For example, it could be examined whether the tasks truly capture anxiety (the anticipation of a negative event) or if some of the tasks more appropriately capture fear (the experience of present threat). Additionally, it is worth acknowledging that anxiety is common in children with ASD but it is not a core feature. Thus, this sample may reflect that there are some children with ASD who do not experience clinically significant anxiety.

Psychometric properties were examined for the Anx-DOS coding scheme when used to code both the Anx-DOS tasks and the when the same coding scheme was used to code the ADOS-2. When the coding scheme was used to code the Anx-DOS, the items “Exaggerated Startle” and “Proximity Seeking” had insufficient discrimination to differentiate between groups. There may be several reasons these items did not perform as well as other items. Mian’s initial 2015 paper makes the suggestion that “proximity seeking” may be capturing a style of coping rather than anxiety per se, and thus that it may load on a different factor than other items. Although this sample was too small to consider a factor analysis this is something future studies may wish to examine. Additionally, it is possible that although this measure is meant to capture anxiety, “exaggerated startle” may be capturing a construct more like fear, or an initial reaction

to a present stimulus, rather than the concern about something that may or may not happen as we would expect to see in anxiety.

After problematic items were removed the measure was approaching an appropriate level of internal consistency. The fear composite on the Anx-DOS showed some initial convergent validity with the CBCL Anxious/Depressed and Anxiety Problems subscales but not with the CBCL Observable Anxiety Composite, nor with the PRAS-ASD. This is surprising given that the PRAS-ASD as well as the Observable Anxiety Composite were designed to be more likely to capture anxiety in a minimally-verbal sample. Children with a medical condition had significantly higher scores on the PRAS-ASD, so it is possible that the PRAS-ASD may be capturing a construct other than anxiety (e.g. chronic discomfort) and this may explain the lack of correlation. It should not be ignored, however, that having a medical condition could simply result in higher levels of anxiety in a child. The lack of correlation with the PRAS-ASD and Observable Anxiety Composite, but positive correlation with other anxiety measures suggest that this measure has some promise, but more research is needed to determine what exactly is being captured by the measure as well as on initial convergent validity. With regard to divergent validity, as expected, the measure was not correlated with social cognition nor social awareness as measured by the SRS-2. Given the small sample size this should be interpreted with caution but it does suggest some initial divergent validity.

The same coding scheme was used to code the ADOS-2. When the coding scheme was used to code the ADOS-2 the items “exaggerated startle” and “separation distress” had insufficient discrimination. After these items were removed, the measure had acceptable internal consistency. Again, it is possible that these items are capturing different constructs than the other items. Namely, exaggerated startle may be more reflective of “fear” than anxiety and it would

make sense that “separation distress” may load on to a similar “coping” factor as “proximity seeking.” Later studies may wish to use a Confirmatory Factor Analysis to assess the possibility of a three factor structure for this measure when these items are included (i.e. anxiety, fear, and coping).

When these codes were assessed for their initial convergent validity, they were not correlated with any other measures of anxiety, suggesting that the Anx-DOS coding scheme may not be an appropriate measure of anxiety when used to code the ADOS-2. The anxiety codes on the ADOS-2 did not correlate with the social awareness or cognition scales of the SRS-2, suggesting no current concerns that the measure is capturing an unintended construct.

Of note, exploratory correlations were conducted both when the fear composite excluded these items and when they were included in the final fear composite calculation. There were largely no differences in the patterns that emerged, with the exception of the CBCL Anxiety Problems and Anxious/Depressed subscales. As explained above, when the problematic items were excluded the Anx-DOS fear composite was significantly correlated to both CBCL Anxiety Problems and Anxious/Depressed subscales while the ADOS-2 fear composite was not significantly related to either. When all items were included, the Anx-DOS fear composite was significantly correlated to the Anxious/Depressed subscale while the ADOS-2 fear composite was significantly correlated to the Anxiety Problems subscale. While this is an interesting observation, more confidence is placed in the analyses conducted using the measure with excluded items, and thus a higher alpha.

Limitations and Future Directions

Taken together, the results of this initial feasibility study are somewhat mixed. First, it should be acknowledged that the primary limitation of this study was the small sample size, which limits the strength of the conclusions that can be drawn from many aspects of the study, but particularly of the exploratory analyses. In addition to being a small sample, this was also a medically and psychiatrically complex sample and the small sample size made it difficult, if not impossible to control for some of this complexity. Finally, as with many studies in children with ASD, this study faces the limitation of the sample being primarily white and male. Additionally, this sample had a very large range in annual family income and, while typical of area in which the study took place, it is unclear whether this could have a role in how families report symptoms. Future studies should strive to continue to examine the questions posed in this study with a larger sample, with more gender and racial diversity.

With regard to the feasibility of a measure such as this, the behavioral aspects of the measure seem to be acceptable and practical. The collection of HR and HRV using electrodes was not practical for this sample. Although the assessment protocol piloted here seems to be acceptable and feasible (with the exception of physiological data), it is unclear whether there is sufficient demand for a measure such as this based on both the demand measures and the comparatively few numbers of children with clinical levels of anxiety symptomology. Future studies may wish to make use of different recruitment sources in different communities to ascertain a fuller picture of whether or not a measure such as this is something wanted by minimally-verbal children and their families. Additionally, the feasibility of capturing usable data on those who were able to tolerate the electrodes, could not be assessed due to sudden

inaccessibility of the scoring software because of the COVID-19 order restricting access to campus and this is a significant limitation.

Initial psychometric properties again provide a somewhat complex picture of this assessment protocol, and more specifically the Anx-DOS, as a potential measure of anxiety. Taking these exploratory analyses at face value, the initial convergent and divergent validity suggests that it may be worth continuing to explore the Anx-DOS coding scheme and behavioral paradigm as a potential measure of anxiety in this population. Future studies may wish to continue to examine this convergent validity with a larger sample. Additionally, studies may wish to utilize a larger sample to conduct a confirmatory factor analysis testing the hypothesis that the measure in its form including the exaggerated startle, proximity seeking, and separation distress may load on three different factors. Some studies have also suggested that Restricted and Repetitive Behaviors maybe indicative of anxiety in children with ASD. For example, one study suggests that self-injurious behaviors may be related to negative affect in children with ASD (Muskett et al., 2019). Future iterations of this measure may wish to examine the utility of including new codes such as “Self-injurious Behavior” specifically for children with ASD. Finally, although physiological data collection was not practical in this study, future studies should continue to examine innovative ways it may be possible to collect these data that will not place a sensory burden on children with MV-ASD.

Conclusion

The objective of the current study was to examine initial feasibility of an observational measure of anxiety in a population of children with MV-ASD. Results presented should be interpreted cautiously in light of substantial limitations such as the small sample size, as well as lack of physiological data. This study provides some initial support to suggest that this measure is feasible and acceptable and that it is correlated with some empirically validated extant measures of anxiety. However, future studies should continue to examine whether there is demand in the community for a measure such as this, and by extension, whether or not anxiety is a prevalent problem in children with MV-ASD. Future studies should also continue to examine the items on a measure such as this one and determine whether items should be added or removed in future iterations of the measure. Finally, the lack of physiological data is a significant limitation of this study and future studies should explore alternative methods for the collection of physiological data or alternative criteria for which children can participate in this kind of data collection.

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Table 1: Participant Characteristics

	M	*SD*	Range
Age	5.08	2.43	2-10
IQ	78	26.5	40-117
Family Income	$87,833	55,331	$25,000-$200,000
ADOS Comparison Score	7.41	2.07	4-10
PPVT-III	61.8	21.8	40-94
EVT-2	63	26.1	40-120
Tactile Sensitivity	23.79	3.77	17-29
Anx-DOS FC	1.83	1.80	0-6
ADOS-2 FC	2.82	3.12	0-10
CBCL OAC	2.58	2.35	0-7
CBCL Int.	62.00	7.00	49-71
CBCL Anx/Dep	56.5	7.39	50-74
CBCL Anx Prob	58.58	9.67	50-81
PRAS-ASD	17.42	9.63	7-35
SRS-2 Awr	71.83	13.44	40-90
SRS-2 Cog	71.42	14.04	40-90

ADOS=Autism Diagnostic Observation Schedule, PPVT=Peabody Picture Vocabulary Test, EVT=Expressive Vocabulary Test, Anx-DOS FC=Anxiety Dimensional Observation Schedule Fear Composite, ADOS FC= Autism Diagnostic Observation Schedule Fear Composite, CBCL=Child Behavior Checklist, OAC=Observable Anxiety Composite, Int.=Internalizing, Anx/Dep=Anxious/Depressed, Anx Prob= Anxiety Problems, PRAS-ASD=Parent Rated Anxiety Scale for Autism Spectrum Disorder, SRS-2=Social Responsiveness Scale-2, Awr=Social Awareness, Cog=Social Cognition

Table 2: Acceptability of Assessment

	M
Acceptability of Intervention Measure	
1. This assessment meets my approval	4.75
2. This assessment is appealing to me	4.75
3. I like this assessment	4.58
4. I welcome this assessment	4.67
Intervention Appropriateness Measure	
1. This assessment seems fitting	4.50
2. This assessment sems suitable	4.67
3. This assessment seems applicable	4.58
4. This assessment seems like a good match	4.67
Feasibility of Intervention Measure	
1. This assessment seems implementable	4.50
2. This assessment seems possible	4.83
3. This assessment seems doable	4.75
4. This assessment seems easy to use	4.67

Table 3: Demand

Source	Number Available	Corrected for 30%	Number Recruited	%
VTAC Clinic Families Email List	454	136.2	8	6%
VTCAR Facebook Page	48	14.4	5	35%
Community Outreach Presentation	22	6.6	0	0%
Email to past research participants	10	Not applicable	1	10%
3rd party (therapist, teacher)	Not able to be determined	Not able to be determined	4	Unknown
Total	534	160	18	11%

Table 4: Inter-rater Reliability on Anx-DOS Coding Scheme

Participant ID	K	p
AC02	0.4	0.20
AC05	1.0	0.01
AC07	1.0	0.01
AC09	0.6	0.03

Table 5: Test and Item-Level Statistics

	Anx-DOS			ADOS-2		
	α	α after items removed		α	α after items removed	
	0.37	0.67		.67	.78[1]	
	Difficulty	SD	Discrimination	Difficulty	SD	Discrimination
FA	0.17	0.40	0.58	0.72	1.10	0.91
PA	0.33	0.65	0.45	0.91	1.22	0.84
PS	0.25	0.45	0.00[2]	0.73	1.01	0.80
SD	0.17	0.39	0.58	0.09	0.30	-0.54[2]
ES	0.50	0.90	-0.23[2]	0.09	0.30	0.02[2]
LTT	0.17	0.94	0.20	0.45	0.52	0.27

[1] indicates acceptable overall internal consistency (α), [2] indicates an unacceptable level of item difficulty or discrimination

Anx-DOS= Anxiety Dimensional Observation Scale, ADOS=Autism Diagnostic Observation Scale, SD=Standard Deviation; FA=Fear Arousal, PA=Physical Avoidance, PS=Proximity Seeking, SD= Separation Distress, ES=Exaggerated Startle, LTT=Latency to Touch

Table 6: Convergent Validity

	r_s			
	Anx-DOS Fear Composite	ADOS-2 Fear Composite	Anx-DOS Fear Composite (All Items)	ADOS-2 Fear Composite (All Items)
CBCL OAC	0.21	0.40	0.31	0.34
CBCL Anx/Dep	0.72*	0.35	0.53*	0.44
CBCL Anx Prob	0.64*	0.46	0.48	0.54*
CBCL Intern	-0.07	-0.17	-0.15	-0.20
PRAS-ASD	-0.12	0.01	-0.28	0.06

*indicates significant correlation

Anx-DOS=Anxiety Dimensional Observation Schedule, ADOS-2=Autism Diagnostic Observation Schedule-2nd Edition, CBCL=Child Behavior Checklist, OAC=Observable Anxiety Composite, Anx/Dep=Anxious/Depressed Subscale; Anx Prob=Anxiety Problems Subscale, Intern=Internalizing Problems Subscale, PRAS-ASD=Parent Rated Anxiety Scale-Autism Spectrum Disorder

Table 7: Divergent Validity

	r_s			
	Anx-DOS Fear Composite	ADOS-2 Fear Composite	Anx-DOS Fear Composite (All Items)	ADOS-2 Fear Composite (All Items)
SRS-2 Awr	-0.19	-0.44	-0.26	-0.41
SRS-2 Cog	0.08	-0.27	0.02	-0.25

*indicates significant correlation

Anx-DOS=Anxiety Dimensional Observation Schedule, ADOS-2=Autism Diagnostic Observation Schedule-2nd Edition, SRS-2=Social Responsiveness Scale-2nd Edition, Awr=Awareness, Cog=Cognition

Figure 1: Participant Inclusion

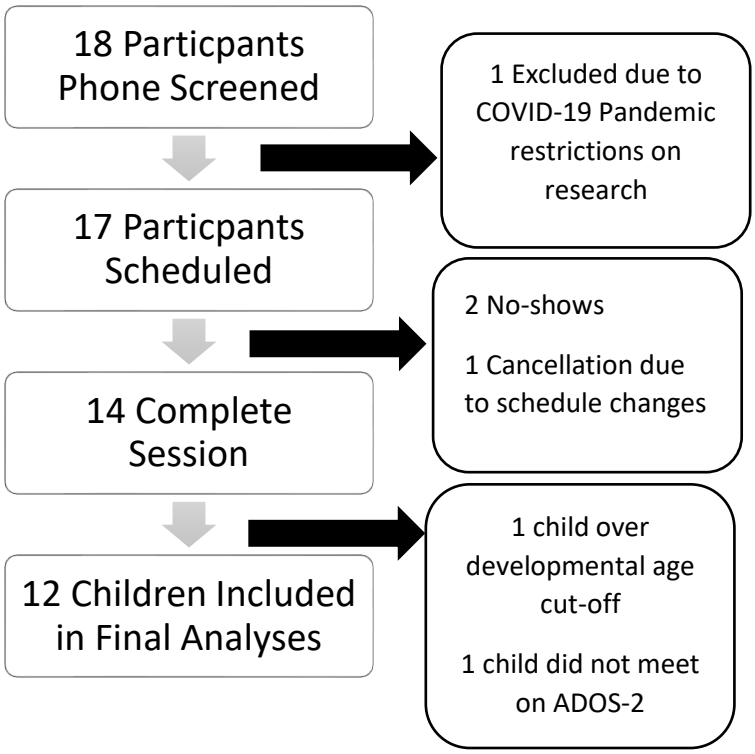


Figure 2: Session Flowchart

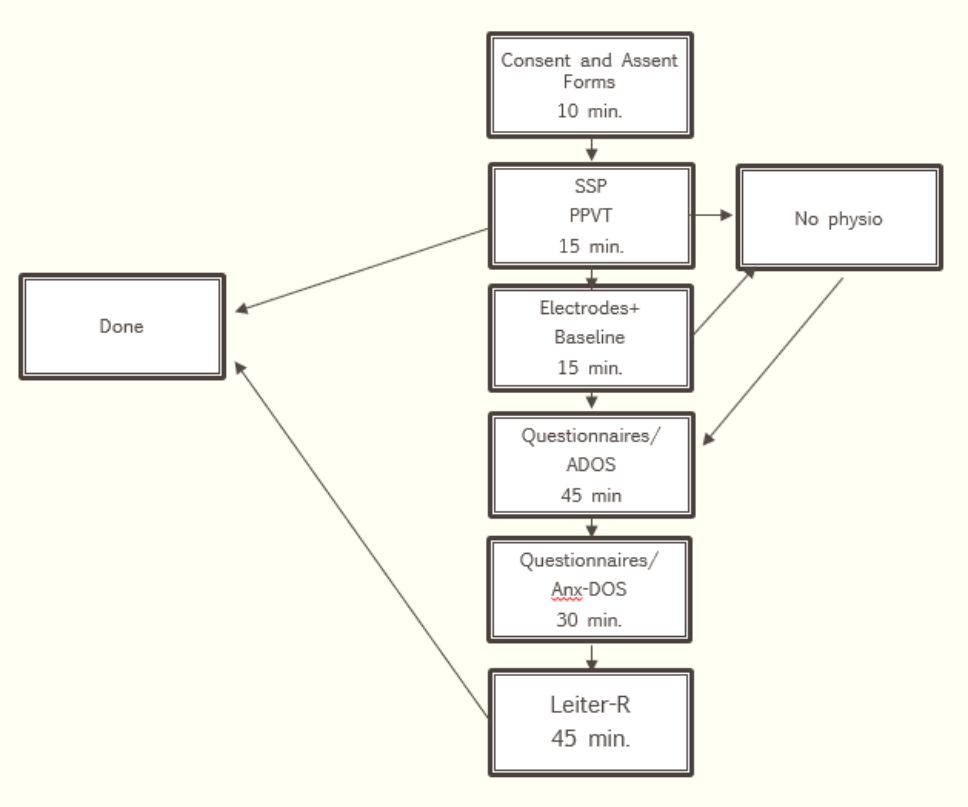
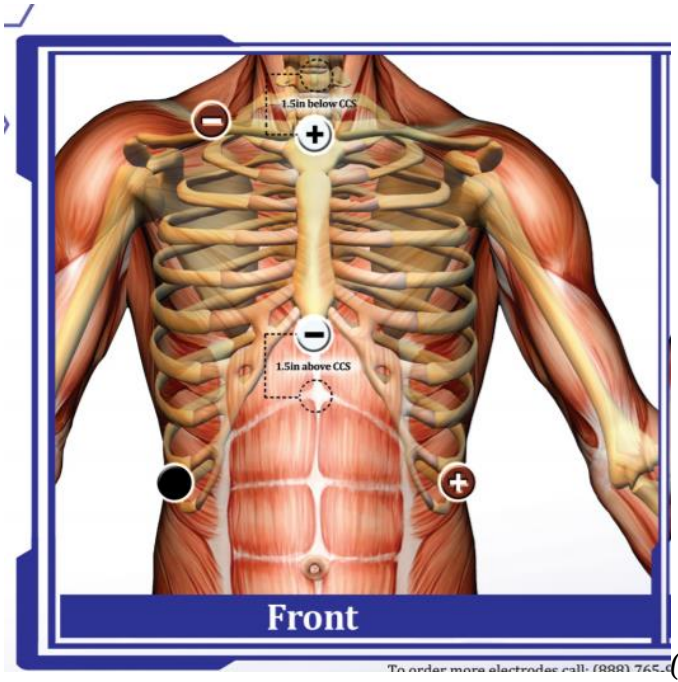


Figure 3: Placement of Electrodes. The brown and black electrodes will be utilized.



(From MindWare)

Figure 4: Success of Various Recruitment Resources