FLUOXETINE FOR THE TREATMENT OF SELECTIVE MUTISM WITH ELEVATED SOCIAL ANXIETY SYMPTOMS: A NONCONCURRENT MULTIPLE BASELINE DESIGN ACROSS FIVE CASES

By

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ABSTRACT

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Selective mutism is a debilitating disorder with academic and social consequences, yet little research is available regarding psychopharmacological interventions (Carlson et al., 2008). This dissertation study examined the utility of fluoxetine (Prozac) for the treatment of five children, ages 5 to 14, diagnosed with selective mutism, who also demonstrated elevated levels of social anxiety symptomology. A non-concurrent multiple-baseline design with a single-blind placebo-controlled procedure was used to examine treatment outcomes. Effectiveness was evaluated by a multi-gate analysis process, including: a) visual analysis (Kratochwill et al., 2010); b) the Wampold and Worsham (1986) randomization test; and c) the Kendall's Tau + Mann-Whitney U (Tau-U; Parker, Vannest, Davis, & Sauber, 2011) effect size calculation. Multiple methods of assessment including Direct Behavior Ratings (DBR; Chafouleas, Riley-Tillman, & Christ, 2009) and standardized measures [e.g., the Multidimensional Anxiety Scale for Children – Second Edition (MASC-2; March, 2012)] were used. Information regarding adverse effects with an emphasis on behavioral disinhibition and ratings of parental acceptance of the intervention were also gathered. Visual analysis of all five cases indicated fluoxetine did not demonstrate utility for the reduction of social anxiety symptoms and was ineffective in increasing spontaneous speech. However, as predicted a significant increase in responsive speech with unfamiliar adults ($p = .03$; Tau-U: .44, $p < .01$) was noted. Two of the five children experienced some acute occurrences of minor behavioral disinhibition, but did not experience

any other side effects during the course of treatment. Behavioral disinhibition did not correspond to changes in social anxiety symptoms, responsive speech, or spontaneous speech. Parents found the use of fluoxetine for the treatment of selective mutism highly acceptable.

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CHAPTER 1

INTRODUCTION

Selective mutism is a rare childhood disorder, affecting less than 1% of children (APA, 2013). The disorder is typically diagnosed before age five and is characterized by the withholding of verbal communication in specific situations (e.g., school, playground, grocery store) while displaying developmentally appropriate speech abilities in other more comfortable settings, such as at home with family members (APA, 2013). Selective mutism has a negative impact on a child's social and academic functioning (Bergman, Piacenti, & McCracken, 2002). Children with selective mutism are especially at-risk for current and future difficulties with social anxiety (Keeton & Budinger, 2012), and typically display a lack of age-appropriate social skills (Carbone et al., 2010). In addition, children's academic performance may suffer, as group work, oral presentations, and contributing to class discussion may be impaired. Withholding speech may also prevent teachers from monitoring the child's academic progress (Bergman et al., 2002; Giddan, Ross, Sechler, & Becker, 1997). Children with selective mutism are more likely to experience a psychiatric disorder as an adult and are at heightened risk for phobic disorders (Steinhausen et al., 2006). Untreated, selective mutism may set a child on a negative developmental trajectory with educational and psychological ramifications throughout the lifespan.

Given the importance of treating selective mutism, consideration of effective treatments is necessary. Selective mutism is particularly difficult to treat as mute behaviors are often reinforced in the environment and become entrenched (Kolvin & Fundudis, 1981). The American Academy of Child and Adolescent Psychiatry (2009) stressed that in cases where the child is not responding to behavioral treatment and the disorder is having a significantly negative

impact on the child's life, it may be appropriate for practitioners to weigh the pros and cons of a pharmacological treatment. However, due to a lack of clinical trial data and the rarity of the selective mutism, it is not likely that the Food and Drug Administration (FDA) will ever approve a medication indicated for this purpose.

In the recently outdated Diagnostic and Statistical Manual of Mental Disorders – 4th Edition, Text Revision (DSM-IV-TR; APA, 2000), selective mutism was classified as a Disorder Usually First Diagnosed in Infancy, Childhood, or Adolescence. Despite this categorization, selective mutism has often been conceptualized as an anxiety disorder (Carlson, Mitchell, & Segool, 2008). In fact, the association between these two disorders has been so prominent throughout the literature that selective mutism was re-categorized as an anxiety disorder in the recently published Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition (DSM-5; APA, 2013). Selective mutism and social phobia have many features in common, such as fear of speaking with others, fear of humiliation, fear of judgment from others, and fear of new situations and people (Westenberg, 1998). Conceptualizing selective mutism as an anxiety disorder is empirically justified considering the shared etiological factors between selective mutism and social anxiety, more generally speaking. Chavira and colleagues (2007) pinpoint the familial (i.e., genetic) link between selective mutism and other anxiety-related conditions. Specifically, this evidence indicates parents of children with selective mutism demonstrate high rates of comorbidity with social phobia or avoidant personality disorder. Serotonin has been connected to the development and etiology of anxiety, and more specifically, the etiology of social anxiety disorder (Nutt, Bell, & Malizia, 1998; Tancer, 1993). Since social anxiety has been associated with a dysfunction in the serotonergic system, Selective Serotonin Reuptake

Inhibitors (SSRIs) make sense as an appropriate approach for treatment resistant cases (Akimova, Lanzenberger, & Kasper, 2009).

A majority of research studies on psychopharmacological interventions with children diagnosed with selective mutism used unstructured case studies, severely diminishing the potential of generalization and providing no definite conclusion about the mechanism of change (Carlson et al., 2008). Despite this, psychopharmacological treatments show promise for inclusion within a comprehensive treatment approach to chronic and severe cases (e.g., Bork & Snyder, 2013; Dummit et al., 1997). The most common psychopharmacological interventions for selective mutism are SSRI medications, with fluoxetine having the most data supporting effectiveness (Carlson et al., 2008). Although not approved by the FDA for the treatment of social anxiety disorder, previous research highlights the efficacy of fluoxetine for the treatment of social anxiety disorder in children. In a randomized control trial, Birmaher and colleagues (2003) found fluoxetine at 20 mg/day for 12 weeks was more efficacious than a placebo in the reduction of anxiety symptoms for children diagnosed with general anxiety disorder, social anxiety disorder, and separation anxiety disorder. A few studies have been completed examining the use of fluoxetine for the treatment of selective mutism in children. One randomized control trial with a small sample (n=15; i.e., Black & Uhde, 1994) found fluoxetine at 12 to 27 mg/day for 12 weeks was superior to placebo for improvements in teacher perceived anxiety and parent perceived symptoms of selective mutism. In an open label study (n=21), Dummit, Lein, Tancer, Asche, & Martin (1997) found that fluoxetine at 20 to 60 mg/day for 9 weeks successfully reduced anxiety symptoms while increasing speech in unfamiliar settings in 76% of participants. Several case studies examining the use of fluoxetine have also shown improvements in mutism symptomology and social anxiety symptoms (e.g., Bork & Snyder, 2013; Milne, 1998).

Previous research identifies the potential of fluoxetine; however, these studies possessed several weaknesses, including: a) lack of standardization of data collection in case studies; b) lack of placebo conditions, and c) small samples for the employed statistical analyses. This study contributes by examining the effects of fluoxetine on symptoms of selective mutism and related behaviors (i.e., social anxiety symptoms) in five children through the use of a placebo – controlled, single- blind, nonconcurrent multiple-baseline single-case design. This methodology provides experimental control while allowing the factors in each case to be examined closely through the collection of data at multiple time points (Riley-Tillman & Maggin, 2008), allowing for a direct comparison between the placebo and fluoxetine treatment. Data were analyzed through the use of visual analysis (Kratochwill et al., 2010). If visual analysis indicated improvement, the Wampold and Worsham (1986) multiple-baseline design randomization test was utilized to identify statistical significance. The Wampold and Worsham (1986) approach is superior to newer randomization approaches (i.e., Koehler & Levin, 1998) for data analysis with psychopharmacological interventions. Due to the delayed onset of fluoxetine effects, the Koehler and Levin approach may provide false negative results, because it does not allow for the inclusion of an acquisition period in data analysis. If significant results were identified, the Kendall's Tau + Mann-Whitney U (Tau-U; Parker et al., 2011) was used to quantify effect size. These methods have not been used concurrently in prior studies to quantify improvements in core symptoms of selective mutism. Because children are randomly assigned to a treatment schedule with varying start points, the use of a multiple-baseline approach provides external validity (Christ, 2007). Furthermore, this study sought to identify adverse events that commonly occur with the use of fluoxetine in children (e.g., behavioral disinhibition) and medication compliance. This study provides preliminary yet needed information to assist practitioners and

parents who are weighing the use of fluoxetine for cases of selective mutism. Additionally, study findings may result in identifying the need for and focus of future group and single-case design studies examining the use of SSRIs for the treatment of selective mutism with comorbid social anxiety symptoms.

CHAPTER 2

LITERATURE REVIEW

In order to inform the research questions and methodology of this study the following areas serve as a foundation and are discussed in detail: (a) the characteristics, associated features, developmental outcomes and prevalence of selective mutism, (b) issues pertaining to pediatric psychopharmacology, (c) an overview of selective serotonin reuptake inhibitors and their mechanism of action, (d) the current evidence-base for effective selective mutism treatments, and (e) an overview of the importance and value of using single-case research design within pediatric psychopharmacology.

Selective Mutism

Diagnostic criteria of selective mutism. The Diagnostic and Statistical Manual of Mental Disorders – 5th Edition (DSM-5; APA, 2013) has provided a clear description of diagnostic criteria for selective mutism that can aid practitioners and researchers in the accurate assessment and linking of effective treatments to the disorder (see Table 1). Selective mutism is characterized by a consistent lack of speech in certain social situations when speech is necessary and expected (e.g., school), while speech occurs freely in other situations, such as at home in the presence of parents and siblings. The reluctance to speak must negatively impact the individual in the areas of educational achievement, occupational achievement, or social communication. For example, an academic impairment may result when a child fails to ask a teacher for clarification when he or she does not understand class content or course expectations (Pionek Stone et al., 2002). Mutism behaviors are typically first observed prior to age five. The presence of symptoms must persist longer than a month. Children who do not speak during the first month of school should not be diagnosed with selective mutism, because this novel social situation may result in

heightened shyness that may spontaneously resolve as the school year progresses and children become more acclimated to their new social situation (Stein, Rapin, & Yapko, 2001). Practitioners need to distinguish typical shyness or avoidant behaviors associated with beginning a new school year from severe mutism lasting for an extended period of time that significantly detracts from optimal development.

Table 1

DSM-5 Criteria for Selective Mutism

A.	Consistent failure to speak in specific social settings in which there is an expectation for speaking, (e.g., at school) despite speaking in other situations.
B.	The disturbance interferes with educational or occupational achievement or with social communication.
C.	The duration of the disturbance is at least 1 month (not limited to the first month of school).
D.	The failure to speak is not attributable to a lack of knowledge of, or comfort with, the spoken language required in the social situation.
E.	The disturbance is not better accounted for by a Communication Disorder (e.g., stuttering) and does not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder.

Adapted from APA (2013 p.127).

Associated features. Children with selective mutism experience disruptions in their lives in personal, social, and academic domains. In order to develop effective interventions, it is imperative to be aware of these associated features. In children with selective mutism, high levels of social anxiety result in avoidant and shy behaviors such as hiding, fleeing, or attempting to minimize attention from others (APA; 2013; Ford, Sladeczek, Carlson, & Kratochwill, 1998). New experiences and situations, such as going to a new preschool or daycare, getting a new babysitter, or playing with a new friend, are difficult and distressing tasks (Ford et al., 1998). Mute behaviors typically occur in social situations, such as being around unfamiliar peers

(Kolvin & Fundudis, 1981; Steinhausen & Juzzi, 1996). These behaviors become even more apparent in social situations with unfamiliar adults (Bergman et al., 2002). Children with this diagnosis display lower levels of social competence, exhibit internalizing symptoms in social situations, and appear to display lower levels of social assertion, self-control, and social skills (Carbone et al., 2010). This lack of social skills may lead to problems forming friendships. When individuals with selective mutism do engage in speaking behaviors, speech occurs infrequently in the form of a whisper or a quiet voice, includes little spontaneity, and takes the form of brief responses to questions or prompts (Ford et al., 1998).

Children with selective mutism frequently have secondary speech and motor difficulties (APA, 2013). Between 19% (Ford et al., 1998) and 38% (Steinhausen & Juzzi, 1996) of children with selective mutism experience speech and language problems. Developmental delays and toilet training problems are common in this population (Steinhausen & Juzzi, 1996). In regards to developmental history, parents of children with selective mutism report a noteworthy prevalence of pregnancy, labor, and neonatal difficulties. As the children progress through infancy and the preschool years, they often experience relationship problems, separation anxiety, sleep disorders, and eating disorders (Steinhausen & Juzzi).

Children with selective mutism frequently experience difficulty with academic coursework (APA, 2013). However, there are mixed data regarding the degree of impact. Ford and colleagues (1998) found that individuals with selective mutism and parents of children with selective mutism reported very few academic problems associated with the mute behavior. However, Bergman and colleagues (2002) argue the impact of selective mutism on classroom performance is often underestimated. Behavioral inhibition experienced by children with selective mutism may cause them to withdraw from others in the context of the classroom and

preclude them from obtaining key social and academic experiences provided during the preschool and early elementary years (Pionek Stone et al., 2002).

Historically, it has been suggested children with selective mutism engage in mute behaviors because they are oppositional, inattentive, or depressed (Elson, Pearson, Jones, & Schumacher, 1965; Ford et al., 1998). Research has not substantiated these claims (Ford et al., 1998). An alternative explanation may be oppositional behaviors occur when children are forced to speak, and are a manifestation of anxiety surrounding the expectation to speak (Dummit et al., 1997). This is essential to consider when selecting and creating interventions for children with selective mutism, as treating the refusal to speak as an oppositional behavior will be ineffective and possibly lead to worse behaviors. In addition, individuals with selective mutism report they do not have difficulty maintaining attention and typically describe their mood as pleasant or neutral when not being forced to speak.

Differential diagnosis. The main diagnostic criteria of selective mutism is having the capability to speak, but withholding speech in unfamiliar situations. Since several disorders, such as neurodevelopmental disorders, communication disorders, mental retardation, and psychotic disorders, lead to a lack of speech, it is essential to differentiate between selective mutism and these other conditions when considering a diagnosis and treatment approach (APA, 2013). Selective mutism is currently listed as an Anxiety Disorder in the DSM-5 (APA, 2013), and almost always presents comorbidly with social anxiety disorder, suggesting these disorders are etiologically related. Most studies examining comorbidity rates of selective mutism and social anxiety disorder found co-occurrence to be greater than 95% (Black & Uhde, 1995; Dummit et al., 1997). Additionally, in a study that examined the types of psychopathology commonly experienced in children with selective mutism, a significant level of social anxiety was the only

consistent abnormal behavioral feature identified throughout the sample (Black & Uhde, 1992). The notion that selective mutism and social anxiety disorder may be different points along the same biopsychosocial continuum is not surprising as many of the diagnostic criteria of selective mutism and social anxiety disorder overlap. These criteria include: experiencing fear during social or performance situations, avoiding social situations to minimize the feelings of anxiety, and a lack of fear or anxiety symptoms when at home (Sharp, Sherman, & Gross, 2007). Although researchers mostly agree social anxiety is a component of selective mutism, there may be unique etiological factors that lead to the withholding of speech in children with selective mutism in contrast to those with social anxiety disorder who mainly avoid social situations, but still speak if necessary (Yeganeh et al., 2003; Yegeneh, Beidel, & Turner, 2006). Mannasis and colleagues (2003) found there was no significant difference in levels of anxiety between children diagnosed with social anxiety disorder and children diagnosed with selective mutism, suggesting selective mutism is not an extreme form of social anxiety. However, both groups presented similarly with high levels of anxiety on a standardized measure. Therefore, Mannasis and colleagues (2003) suggest selective mutism and social phobia may have the same etiological factors, but children with selective mutism choose to cope with the anxiety by not speaking, while children with social anxiety choose to cope with the anxiety by avoiding social situations altogether. Interestingly, the researchers found children with selective mutism are more likely to present with communication and speech problems. Children with selective mutism were significantly more likely to score lower on a standardized measure targeted at assessing children's ability to discriminate between speech sounds. Manassis and colleagues (2003) suggest mild language impairment may make children with social anxiety refrain from speaking in order to avoid experiencing the anxiety. However, an alternative explanation offered by the

authors suggests children with selective mutism may refrain from speaking, preventing them from making speech gains commensurate with same-aged peers.

Prevalence rates. Due to the rarity of the disorder, potential differential diagnoses, varying diagnostic criteria (e.g., DSM-III), and the varying level of expertise of those identifying children with selective mutism, examining the prevalence rate of the disorder has proved challenging as shown in the wide range of rates reported throughout the literature. Prevalence rates in the school setting have ranged from .03% (Krakaya et al., 2008) to 2% (Kumpulainen, Rasanen, Rasska, & Somnpi, 1998); however, 2% is likely an overestimate due to the use of DSM-III criteria, which does not take impairment of the symptomology into account. Rates of selective mutism are also rare in clinical settings. Selective mutism was reported to account for .11% of new patients for psychiatrists (Carlson, Kratochwill, & Johnston, 1994) and less than 1% of individuals treated in mental health settings (APA, 2013). The information found in clinical prevalence studies suggest that although selective mutism is rare in comparison to other disorders such as depression or generalized anxiety disorder; selective mutism is still a disorder many practitioners will encounter throughout their career.

Demographic characteristics. Research suggests selective mutism is somewhat more common in females than males (APA, 2000), with ratios of females to males ranging from 2.3:1 (Black & Uhde, 1995) to 1.5:1 (Kopp & Gilberg, 1997). The finding that selective mutism is more prominent in females is congruent with the conceptualization of selective mutism as an anxiety disorder, as anxiety disorders are typically more prevalent in females (APA, 2000). Previous research indicates the prevalence of selective mutism in immigrant populations may be higher than the prevalence in non-immigrant populations (Bradley & Sloman, 1975). This higher prevalence rate may be the result of the increased stress and social anxiety experienced by

immigrant children when interacting with native adults, because of the differences in language and cultural understanding (Elizur and Perendik, 2003).

Prognosis. Children with selective mutism typically display clinically significant non-speaking behavior for three to five years (Ford et al., 1998). Steinhausen and colleagues (2006) identified two predominant courses throughout childhood. The more prevalent course, which accounts for a little more than half of children, is defined by a slow decline in the intensity of symptoms across childhood. The less prevalent course is characterized by persistent symptomology across childhood. Regardless of the course, a majority of those in the Steinhausen and colleagues study reported improvement with a 58% remission rate. Only 18% of those surveyed reported slight or mild improvements, while the remainder endorsed at least moderate improvement. Although symptoms typically resolve by age 10, individuals who no longer meet criteria still experience higher levels of psychopathology than those not previously diagnosed with any type of mental health disorder, suggesting that untreated selective mutism may place them on a trajectory for future psychological difficulties. More specifically, those diagnosed with selective mutism as children have higher prevalence rates of phobic disorders and social phobia, and continue to feel uncomfortable during social gatherings (Ford et al.).

Etiology of selective mutism.

A joint biopsychosocial framework of selective mutism and social anxiety disorder.

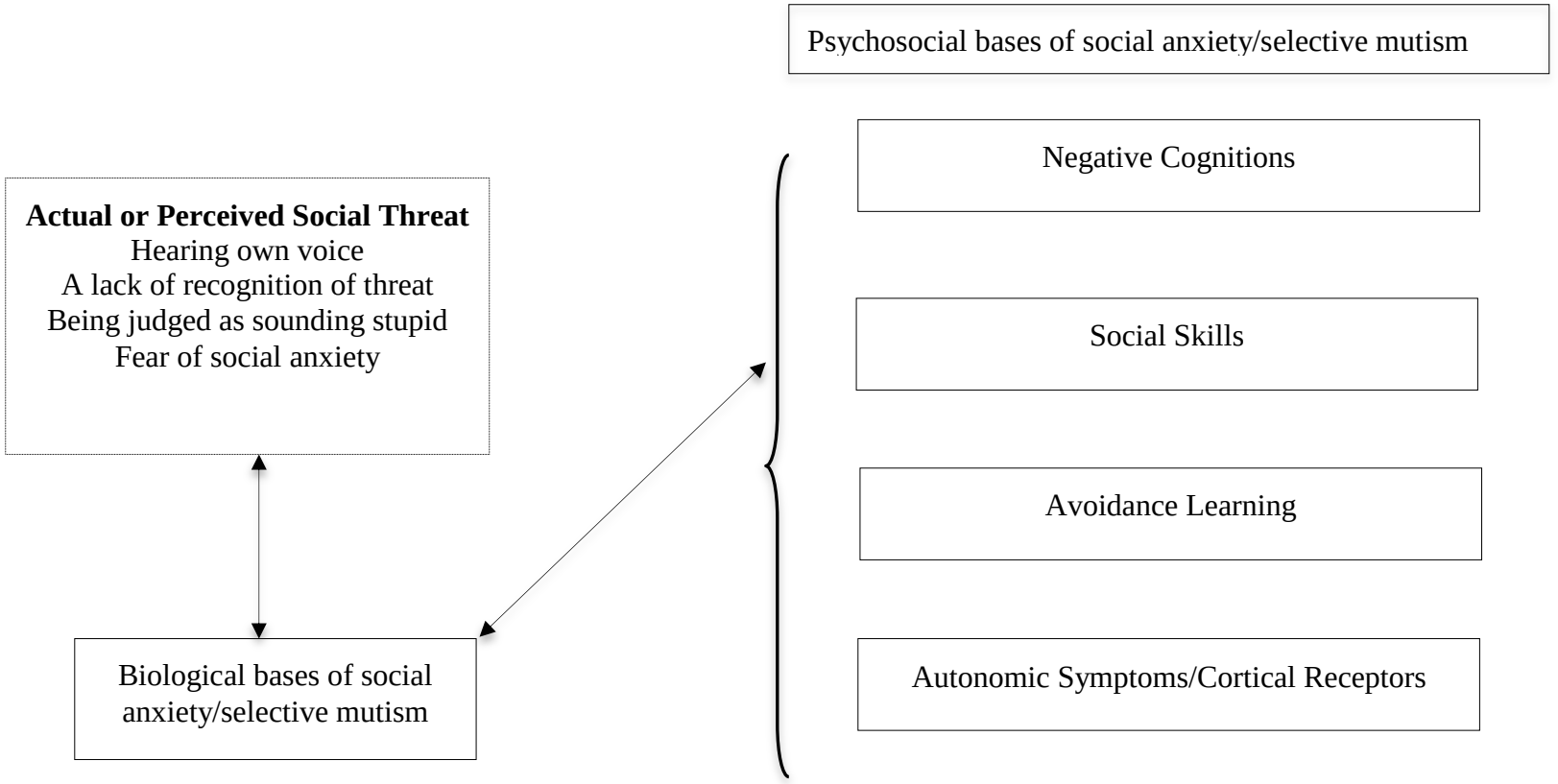
Research has demonstrated both biological and psychosocial factors play a role in the development and display of selective mutism and social anxiety disorder. Therefore, it is essential to use a model that accounts for all of these factors when conceptualizing the disorder and selecting an effective treatment. According to Nutt and colleagues (1998), the innate anxiety circuit within the brain impacts several factors that may lead to the development of social

anxiety, including: autonomic symptoms, avoidance learning, cortical receptors, and negative cognitions. In addition, Shear and Beidel (1998) discussed psychosocial factors impacted by various forms of psychotherapy leading to the reduction of social anxiety, which include: the physiological effects of social anxiety, negative evaluations and expectations regarding social situations, and the avoidance of social situations. Carlson and colleagues (2008) combined the biological model for the development of social anxiety disorder developed by Nutt and colleagues (1998) and the psychosocial model developed by Shear and Beidel (see Figure 1; 1998) in order to create one model of selective mutism and social anxiety disorder.

Biological factors of selective mutism and social anxiety. Research has demonstrated selective mutism and social anxiety are linked biologically, and there are several parallels between the etiological underpinnings of anxiety disorders and selective mutism. First, biological and genetic factors, such as temperament characterized by behavioral inhibition, are similar between children with anxiety disorders and children with selective mutism (Astendig, 1999; Beiderman et al., 2001). In families who have a child diagnosed with selective mutism, there is a higher prevalence of family members with selective mutism, a higher prevalence of family members with social anxiety, and higher prevalence levels of other associated features of selective mutism, such as shy behavior and depression (Black & Uhde, 1995; Chavira et al., 2007; Steinhausen & Ademek, 1997). Black and Uhde (1995) found that 70% of families with a first degree relative with selective mutism displayed high levels of social anxiety and 37% of these families had another member with selective mutism. Chavira and colleagues (2007) found that high scores on scales of social phobia and avoidant personality disorder were 3 to 4 times

Figure 1

Conceptual Framework Adapted from Models of the Biopsychosocial Framework of Selective Mutism and Social Anxiety Developed by Carlson and Colleagues (2008), Nut, Bell, and Malizia (1998), and Shear and Beidel (1998).



more common in parents of children with selective mutism when compared to control parents who did not have a child with the disorder. This genetic link has also been displayed in more distant relatives. For example, Steinhausen and Ademek (1997) found that reserved behavior is more prevalent in the first degree, second degree, and third degree relatives of children with selective mutism when compared to the relatives of children without selective mutism. This finding suggests a genetic component related to social anxiety and selective mutism may play a significant role in the development of both disorders (Steinhausen & Adamek, 1997).

The neurocorrelates of social anxiety and selective mutism have also been discussed in the literature. For example, Lorberbaum and colleagues (2004) conducted an fMRI study examining the differences in brain activity between individuals with social phobia and those without social phobia when preparing to give a speech in front of others. All children in the social phobic group were diagnosed with social anxiety disorder, with one child diagnosed with social anxiety disorder and co-morbid selective mutism. The authors found those with social phobia demonstrated more activity in the subcortical system, the limbic system, specifically the amygdala, and the lateral anterior paralimbic belt. The authors explain these findings are commensurate with the current understanding of the functions of these structures, as these areas are more likely to be involved in automatic emotions.

Psychosocial factors of selective mutism and social anxiety. In addition to biological factors, selective mutism and social anxiety disorder have similar psychosocial etiological underpinnings. First, both those with social anxiety or selective mutism have difficulty with social skills (Astendig, 1999; Voncken & Bogels, 2008). Second, fear of negative evaluation is a primary characteristic of both selective mutism and social anxiety disorder (APA, 2000). Finally,

both children with selective mutism and children with social anxiety disorder are likely to avoid social situations (Dummit et al., 1997; Mesa, Beidel, & Bunnell, 2014).

Pediatric Psychopharmacology and Selective Mutism

Psychopharmacological treatments have been used for a significant amount of time to treat the biological components of behavioral disorders in children, including selective mutism (Carlson et al., 2008), and this practice appears to be increasing (Debar, Lynch, Powell, & Gale, 2003; Olfson, Marcus, Weissman, & Jensen, 2002). In order to provide informed treatment for children diagnosed with selective mutism, it is necessary to understand the context in which this practice began as well as how frequently these psychopharmacological agents are used with children currently diagnosed with mental health disorders.

Research into psychopharmacological agents to change behavior began with Emil Kraepelin in the 1890s. Kraepelin was a student of Wundt and was curious about how drugs might impact psychological constructs in human beings. Kraepelin named the practice of using a medication to alter behaviors "psychopharmacology" (Healey, 2002). The use of psychopharmacological interventions with children began in the late 1930s with the work of Bradley (Popper, 2002). Bradley (1937) reported on the use of Benzedrine to treat children with attention difficulties. Following the reports by Bradley (1937), the use of Benzedrine to treat behavioral and attention difficulties was further examined in the 1930s. Following this research, in 1939, Phenobarbital was studied for the use of behavior disorders in children. After these discoveries, stimulant use and research in children remained relatively the same (Popper, 2002).

In the 1950s, researchers began to explore other classes of drugs. At this time, the biological revolution in psychiatry began, which emphasized the biological basis of disorders in addition or in contrast to the popular psychodynamic conceptualizations prominent throughout

the field (Popper, 2002). The use of antidepressants first began in the mid to late 1950s with the accidental discovery that monoamine oxidase-inhibitors (MAO-Is), which were prescribed as a drug to treat tuberculosis, improved the mood of the patients. Tricyclic antidepressants (TCAs) also came into use during this time (Lieberman, Golden, Stroup, and McEvoy, 2000). Research with both of these drug families continued to demonstrate efficacy in treating depression. However, serious side effects and drug interactions occurred. In the 1980s, SSRIs were developed and had a significantly lower side effect profile compared to the previous gold-standard MAO-Is and TCAs (Judd, 1998). The first research studies examining the use of SSRIs in the treatment of children occurred in the 1990s (Popper, 2002). As time progressed, research on psychopharmacological medications in children and prescription rates continued to expand. Olfson and colleagues (2002) reported an increase in the number of children taking psychotropic medications from 1.4% to 3.9% between the years of 1987 and 1996. Moreover, by 1996, the use of antidepressant medications in adolescents increased to 2.1%, which is 3.5 times higher than the prevalence rate in 1987.

Ethics in pediatric psychopharmacology research and practice. Despite advancements in the field of psychopharmacology and the increase in the use of psychopharmacological agents to treat mental health disorders in children, much still needs to be known about the costs and benefits and the short- and long-term consequences of their use (American Academy of Child and Adolescent Psychiatry, 2009; Fanton & Gleason, 2009). In order to make informed treatment decisions, it is essential to examine the current viewpoints on the ethics of pediatric psychopharmacology. It is clear from the literature that experts have consistently advised psychosocial treatments be the first line approach given the decreased risk associated with these treatments. Despite this, psychopharmacological treatments hold promise

and are recommended in some cases for the treatment of children experiencing severe difficulties, which do not respond to psychosocial treatment (American Academy of Child and Adolescent Psychiatry, 2009; Gleason et al., 2007; Vitiello, 2001).

Psychopharmacological agents are being used to treat children with selective mutism in practice despite a paucity of research supporting this practice (e.g., Harvey & Milne, 1998; Wright, Cuccaro, Leonhardt, Kendall, & Anderson, 1995). In order for a study to be ethical, Vitiello (2001) argues that the possible harm that could occur from using a psychopharmacological agent in research must be smaller than the potential problems of leaving the disorder untreated. To improve this risk benefit relationship, the author suggests there be frequent monitoring of the child for intended outcomes and adverse effects, using standardized behavioral measures. Therefore, single- case design methodologies, especially those that use a multiple baseline approach, are well-suited for the examination of the effectiveness and safety of psychopharmacological agents for rare or unique cases like selective mutism as they include multiple and frequent assessments of the impact of an intervention (Horner et al., 2005).

Selective Serotonin Reuptake Inhibitors

Selective Serotonin Reuptake Inhibitors (SSRIs) are the most commonly used psychopharmacological approach to treat selective mutism in children (Carlson et al., 2008). This makes sense, as the use of SSRIs to treat selective mutism is consistent with the conceptualization of selective mutism as an anxiety disorder (e.g., Black & Uhde, 1995; Dummit et al., 1997). Only a few SSRIs have been approved by the Food and Drug administration for the treatment of anxiety (i.e., obsessive-compulsive disorder) in children (see Table 2). Nonetheless, there is literature to support their efficacy with children and adolescents who experience other anxiety disorders.

Table 2

FDA Approval of SSRIs for Anxiety Disorders in Children and Adolescents

Medication	Anxiety Disorder	Age
Citalopram (Celexa)	Not approved	N/A
Escitalopram (Lexapro)	Not Approved	N/A
Fluoxetine (Prozac)	Obsessive Compulsive Disorder	> 7 years
Fluvoxamine (Luvox)	Obsessive Compulsive Disorder	8-17 years
Paroxetine (Paxil)	Not Approved	N/A
Sertraline (Zoloft)	Obsessive Compulsive Disorder	>6 Years

Derived from ANI Pharmaceuticals (2011), Eli Lilly and Company (2011), and Pfizer (2011)

The FDA has approved fluoxetine up to 20 mg/day to treat 8 to 18 year old children with major depressive disorder and fluoxetine up to 60 mg/day for children between the ages of 7 and 17 for the treatment of obsessive-compulsive disorder. Although not approved for other anxiety disorders, previous research indicates the efficacy of fluoxetine for this indication. Birmaher and colleagues (2003) found fluoxetine at 20 mg/day for 12 weeks was successful in treating a variety of anxiety disorders (e.g., social, generalized) in 37 children, and that this impact was significantly greater than an equivalent placebo group. Moreover, other studies have demonstrated positive outcomes for children with anxiety disorders being treated with sertraline (Compton et al., 2001; Rynn, Siqueland, & Rickels, 2001), citalopram (Baumgartner, Emslie, & Crimson, 2002), fluvoxamine (Walkup, 2001), paroxetine (Stein et al., 1998; Wagner et al., 2004), and escitalopram (Isolan et al., 2007).

In order to have an understanding of the mechanisms of action associated with SSRIs, it is important to discuss the purported role of serotonin in the etiology of anxiety disorders as well as understand the impact that SSRIs have on the serotonergic system. Moreover, in order to determine if SSRIs have their intended effect when treating selective mutism, it is essential to

discuss the mechanism of change and the timing of treatment effects. Finally, it is important to review the possible side-effects that are associated with SSRIs in order to provide patients with an informed understanding of the risks and benefits of treatment as well as to delineate between intended treatment outcomes and side effects that may be similar in appearance, such as an increase in the frequency of speech as a result of decreased anxiety and/or behavioral disinhibition.

The intended effect of SSRIs. Serotonin (5-HT) is a neurotransmitter in the brain that plays a role in the modulation of emotion and mood (Hensler, 2010). Genetic, pharmacological, and neuroimaging studies have demonstrated that the 5-HT1A receptor in the serotonin system, which serotonin (5-HT) binds to, plays a primary role in the neurobiology of anxiety (Akimova, Lanzenberger, & Kasper, 2009). However, the specific mechanism connecting serotonin to anxiety is still not well understood. Research has shown that by modifying levels of serotonin in the brain by implementing a 5-HT1A agonist, such as an SSRI, anxiety can be reduced (Lowry & Hale, 2010). Selective serotonin reuptake inhibitors bind to the 5-HT1A receptor in the brain, and block the re-uptake of serotonin from the synaptic cleft leaving a higher quantity of serotonin in the synaptic cleft, which is then available to stimulate the post-synaptic neuronal receptors which leads to a modification in neuronal functioning (Tschanz & Treiber, 2011). This receptor is located in high densities throughout the brain, including the following areas: the hippocampus, the hypothalamus, the amygdala, the cerebral cortex, the dorsal raphe, and the median raphe (Charney, Krysal, Delgado, & Heninger, 1990).

Modifying the levels of serotonin through the use of an SSRI has been linked to altering the functioning of these various components of the brain. For example, Stahl (1998) suggests that adding a serotonin agonist leads to an increase in serotonin in the parts of the brain responsible

for various psychological disorders, including anxiety disorders, and this increase in serotonin moderates the underlying physiological processes associated with a specific psychological disorder. The mechanism of action in this change has been hypothesized to be the "desensitization of somatodendritic serotonin 1A autoreceptors" (Stahl, 1998 p. 215). Immediately after an SSRI is administered, the serotonin re-uptake pumps are inhibited leaving more serotonin in the synaptic cleft. However, there are several changes within the serotonergic system that take longer to occur. Serotonin autoreceptors, when bound to by 5-HT, function to lower neuronal firing rates when these autoreceptors are chronically stimulated, such as when there is an abundance of 5-HT in the synaptic cleft. Over time, the somatodendritic serotonin 1A autoreceptors become desensitized changing neuronal functioning and leading to more 5-HT within the serotonergic system.

This change in neuronal functioning is what is hypothesized to lead to a delayed treatment impact (Stahl, 1998). Therefore, it is recommended by some in the field that patients be informed that substantial treatment effects may take four to six weeks to occur (Garfield, Francis, & Smith, 2004). However, not all researchers and practitioners in the field of psychopharmacology believe that it takes four to six weeks to see an onset of smaller treatment effects. Some argue there is a rapid onset of treatment effects (e.g., Mitchell, 2006), which does not align with Stahl's (1998) conceptualization. In fact, it has been argued that treatment effects of SSRIs can occur within a week of the onset of the use of SSRIs (Taylor, 2007), and the reported delay in the effect of SSRIs has largely been due to how these effects have historically been measured (Gelenberg & Chelsen, 2000). For example, studies have required the use of a rating of "much improved" on the CGI before calling an antidepressant effective. Therefore, more subtle, clinically meaningful, changes may not be identified. In a meta-analysis, Taylor

(2007) concluded that the initial improvements in functioning that are observed after starting an SSRI treatment are not always placebo effects, but may be the sole impact of the medication. For example, Mitchell (2006) posits that participants can see changes within three days of the onset of treatment, and that 90% of individuals will experience a change in symptoms during the first two weeks. Neuroimaging also supports this notion. Through the use of fMRI technology, researchers demonstrated one dose of an SSRI can change the amygdala's processing of threatening faces (Murphy, Norbury, O'Sullivan, Cowen, & Harmer, 2009).

Side effects associated with SSRIs. SSRIs are an improvement over their predecessors (e.g., tricyclic antidepressants and monoamine oxidase inhibitors), because they are more selective in their binding to neuronal receptors and do not interfere with the functioning of other receptors (e.g., histamine), leading to fewer side effects (Feighner, 1999). Despite these improvements, side effects have been noted. Zuckerman and colleagues (2007) examined the charts of children who had received treatment in a Boston medical facility with a selective serotonin reuptake inhibitor and reported on side effects that were mild, moderate, or severe. The authors defined mild side effects as events that did not interfere with functioning, moderate side effects as events that interfered with functioning but not to an extreme degree, and severe side effects as events leading to difficulty with age-appropriate daily tasks. According to the chart review, no children had to be medically or psychiatrically hospitalized because of the adverse effects of the SSRI during treatment. In addition, the authors found that only 33% of the children who received an SSRI experienced any kind of adverse event and 28% of children who received an SSRI experienced a moderate adverse event (e.g., insomnia, headache). These adverse events occurred within a range of 2 to 144 days since the onset of the medication and for 40% of the

children experiencing an adverse event resolved while still on the medication. Only about 18% of the children that experienced an adverse event discontinued the medication.

The side effects associated with SSRIs include somatic side effects and behavioral side effects. Somatic side effects are commonly reported throughout the literature for children (e.g., Dummit et al., 1996, Carlson et al., 2008), and, include: drowsiness, insomnia, decreased appetite, and nausea (Wilens et al., 2003). A behavioral side effect of SSRIs is behavioral disinhibition and is defined as increased activity that does not include a change in mood or impulse control. A rare behavioral side effect is a manic reaction, which is defined as increased activity accompanied by euphoric feelings and grandiosity (Walkup & Laballarte, 2001). Behavioral side effects appear to be more prevalent in younger children when compared to adolescents. In one study, approximately 10.7% of pre-adolescent children experienced behavioral disinhibition during a trial of an SSRI, while only 2.1% of adolescents in SSRI studies experienced this side effect (Safer & Zito, 2006).

Although significantly safer than their predecessors, SSRIs do have the potential to cause some serious side effects. However, the occurrences of these side effects are rare. First, SSRIs have been linked to an increased risk in suicide in adolescents and young adults causing the FDA to issue a black box warning for adolescents and young adults (FDA, 2007). However, there has been much debate about the link between suicidality and SSRIs and more research needs to be done to illuminate the relationship. For example, Olfson, Shaffer, Marcus, and Greenberg (2003) examined the change in prevalence of antidepressant prescriptions for adolescents and the number of completed suicides in 588 zip codes in the United States. The authors found an increase in antidepressants was negatively correlated to the overall levels of suicides. Although this is the case, no studies have been completed on the likelihood of pre-pubescent children

experiencing suicidal ideation while taking an antidepressant. In addition to the possibility of an increased likelihood of suicide, another serious side effect of SSRIs is serotonin syndrome. Serotonin syndrome occurs when there is a significant excess of serotonin. Symptoms may include: tremor, diarrhea, delirium, rigidness of the muscles, and may be life threatening (Boyer & Shannon, 2005). Although serotonin syndrome is potentially life threatening, the prevalence rate for those taking SSRIs as prescribed is extremely minimal. For example, in an analysis of 200 patients taking fluvoxamine, none of the patients met the criteria for serotonin syndrome (Ebert et al, 1997). Serotonin syndrome usually only occurs when a patient is on multiple medications that impact the serotonin system or when doses are very high.

In addition to short-term adverse events, possible long-term side effects may occur; however, little is known about this topic. The potential for long-term negative side effects should not be an argument for a complete boycott of all psychotropic medications for children, because the impact and negative experiences imposed on the children by a psychological disorder, such as selective mutism in its most serious entrenched form, may result in worse outcomes if not treated (Pine, 2002). A cost-benefit analysis always needs to be conducted when deciding to prescribe psychotropic medications in children (American Academy of Child and Adolescent Psychiatrists, 2009; Gleason et al., 2007).

Intended effects of SSRIs vs. behavioral disinhibition related to selective mutism.

Carlson and colleagues (2008) argue it is essential to examine whether the effects of SSRI treatment are the result of the intended mechanism of action (i.e., reduction in anxiety via modulation of serotonin levels) or due to behavioral disinhibition. Behavioral disinhibition (e.g., increases in activity level, pressured speech) and a decrease in anxiety leading to increased speech production may present similarly to the untrained eye. If increased speech production is

observed without the presence of behavioral disinhibition such as increased risk taking, impulsive behavior, or oppositional behaviors, it is likely the intended effect of treatment is occurring. Since subtle changes in functioning can occur quickly after the onset of the intervention, frequent assessments of functioning during SSRI treatment studies using sensitive measures that examine small changes in functioning are necessary throughout treatment. Single-case design methodology works exceptionally well when examining the treatment effects of SSRIs, because it can examine clinically meaningful aspects of behavior such as frequency in speech behaviors, while simultaneously monitoring symptoms of behavioral disinhibition.

Current Evidence-Base of Selective Mutism Treatments

Psychosocial treatments for selective mutism. Researchers and practitioners have implemented a variety of different interventions based on various conceptual frameworks, including: psychodynamic therapy, family therapy, behavioral and cognitive-behavioral therapy (Cohan, Chavira, & Stein, 2006), psychopharmacological treatments (Carlson et al., 2008), and combinations of these approaches (Eke, 2001; e.g., psychopharmacological and psychosocial). Psychodynamic approaches were the first types of treatments reported on for children with selective mutism (Krysanski, 2003). Currently, behavioral and psychopharmacological treatments appear to be the most common treatments for selective mutism in children, and also appear to have the most evidence supporting their efficacy (Cohan et al., 2006; Pionek Stone et al., 2002).

Behavioral and cognitive-behavioral therapy. Behavioral and cognitive-behavioral approaches operate under the notion that anxiety associated with selective mutism is reinforced by the child's refusal to speak. To treat the anxiety associated with selective mutism using a behavioral approach, children must become desensitized by engaging in anxiety provoking social

tasks that increase in difficulty eventually leading to speaking to unfamiliar individuals. A systematic review of the selective mutism treatment literature conducted by Pionek Stone and colleagues (2002) demonstrated that behaviorally orientated treatments (i.e., systematic desensitization, contingency management, shaping) were more effective than no treatment at all. Research has also demonstrated that cognitive behavioral techniques, which address negative cognitions surrounding speaking to unfamiliar individuals in addition to employing behavioral techniques, are efficacious for the treatment of anxiety disorders (Compton et al., 2004). Given cognitive-behavioral techniques often require verbalizations of negative cognitions to a therapist, this treatment may not always be appropriate for children with selective mutism, who display a primary symptom of withholding speech in front of others.

Selective serotonin reuptake inhibitors for the treatment of selective mutism.

SSRIs that have most commonly been used for the treatment of selective mutism include fluoxetine (Prozac), sertraline (Zoloft), citalopram (Celexa), fluvoxamine (Luvox), and paroxetine (Paxil; Carlson et al., 2008). In order to understand the current evidence-base for these SSRI treatments a review of the available literature is presented.

Fluoxetine. Fluoxetine was the first SSRI to be studied as a treatment for selective mutism and, to date, is the most researched SSRI for this use (Carlson et al., 2008). The first publication on the successful use of fluoxetine at an unspecified dose to treat selective mutism was completed by Boon (1994), regarding the case of a six-year old female who had been experiencing symptoms for two years. Since then, several case studies and two small quasi-experimental studies have been published. However, these studies on the use of fluoxetine were conducted over a decade ago, aside from a case study disseminated by Bork and Snyder (2013).

Quasi-experimental studies. Two quasi-experimental studies have provided valuable information regarding the possible efficacy of fluoxetine for the treatment of selective mutism in children; however, the methodological limitations of these studies leave several questions to be answered. Black and Uhde (1994) were the first to conduct a structured study on the use of an SSRI (i.e., fluoxetine – 12 to 27 mg/day for 12 weeks) to treat selective mutism in children. The authors used a repeated measures analysis of variance to examine the difference in selective mutism behaviors between a control group provided with a placebo (n=9) and an experimental group provided with fluoxetine (n=6). Parent, teacher, and psychiatrist ratings were obtained during week four, eight, and 12 to determine what level of change in functioning was occurring. According to the results, there were no significant differences in teacher ratings and psychiatrist ratings from week four to week 12 between the control and experimental groups. However, there was a significant difference in parent ratings of behavior between the control group and the experimental group. Positive behavior changes included increased speaking behaviors with extended family members, neighbors, and store clerks. The results of the Black & Uhde (1994) study provide mixed results. For instance, only parents reported significant levels of changes. In addition, there were several limitations to the study, which included a small sample size (n=15) for the type of statistical analysis used and differences in baseline scores between the two groups.

The second experimental study to examine the use of fluoxetine in children was completed by Dummit and colleagues (1996). This study included 21 children and adolescents between the ages of five and 14 who were diagnosed with selective mutism. Participants were provided with a daily dose of fluoxetine that was slowly increased as the weeks progressed in order to avoid the development of side effects. During the first week children received a dose of five mg/day, followed by 10 mg/day during the second week, 20 mg/day during week three, 40

mg/day at week six, and 60 mg/day at week eight, if there were not substantial improvements at 40 mg/day. Behavioral changes and side effects were monitored during weekly visits with the study psychiatrist. The effectiveness of fluoxetine was determined by using a number of psychiatrist completed rating scales including the Children's Global Assessment Scale, the Liebowitz Social Anxiety scale, The Liebowitz Social Avoidance Scale, and the Social Behavior Scale (Self and Parent ratings) at pre-treatment (week zero) and post-treatment (week nine). There were significant improvements on all scale scores between week zero and week nine. Some side effects were noted throughout the duration of the study. The most serious side effect experienced was behavioral disinhibition (n=3). Two of these children were removed from the study by the investigators, and one child was removed from the study at week eight by his parents although he was responding better to a reduced dose of fluoxetine. In addition to these two children, 43% of the participants reported that they experienced a potential side effect, however, these side effects did not persist for more than a week in duration. Although the Dummit and colleagues (1996) study provided promising results for the use of fluoxetine to treat children diagnosed with selective mutism, there were several limitations to this study. First, the study did not include a control group. Therefore, it cannot be determined if the reduction in symptoms occurred because of the fluoxetine or because of additional variables. Second, mean pre-test and post-test scores were assessed using t-tests; however, the small sample size makes it difficult to draw conclusions about the findings reported when using this type of analysis.

Case studies. Seven case studies reporting on the use of fluoxetine to treat selective mutism in children have been published in scientific journals. All of these studies report positive outcomes (e.g., speech at school; see Table 3). For example, in a case study completed by Wright and colleagues (1995), a five-year old female prescribed fluoxetine (i.e., four to 8 mg/day) began

Table 3

Published Case Studies on Fluoxetine Treatment for Selective Mutism

First Author (Year)	Participant(s) (Sex; Age)	Fluoxetine Dose	Additional Treatments	Outcomes
Boon (1994)	Female; Six y/o	Unspecified	None	Unspecified improvements
Bork (2013)	Male; Nine y/o	1.5 mg/day to 12 mg/day	Behavioral Intervention	Spontaneous speech in the school settting and community settings
Wright (1995)	Female; Four y/o	Four mg/day to Eight mg/day	Behavioral Intervention	Speech in multiple settings including school; no side effects
Guna-Dumitrescu (1996)	Male; Eight y/o	20 mg/day to 30 mg/day	Behavioral Intervention	No treatment effect after six months; Behavior component was added and speech occurred at school after three weeks
Harvey (1998)	Child One: Female; Five y/o Child Two: Female; Eight y/o	Child One: Two mg/day to four mg/day Child Two: unspecified to six mg/day	Multimodal Psychotherapy	Reduction in anxiety (Child One); Increased speech in unfamiliar settings (Child One); Increased speech at school (Child Two)
RUPP (1999)	Female; Five y/o	Five mg/day to 30 mg/day	Behavioral Intervention; Clonidine 0.025 mg; Haloperidol 0.5 mg	Increase in speech in unfamiliar settings; possible aggression side effect
Silveira (2004)	Female; Six y/o	Unspecified to 20 mg/day; reduced to 15 mg/day due to headaches	Behavioral Intervention; Psychoeducation	Improved social skills; Increased speech in the school and community settings

speaking within 20 days after the onset of treatment without hesitation in several settings, including school. Despite the positive outcomes reported across case studies, it is difficult to determine what other variables may have been involved in influencing outcomes, because of the unstructured approach. For example, some of these studies included a behavioral intervention in addition to the fluoxetine treatment (e.g., Guna-Dumitrescu & Pelletier, 1996). Moreover, Rupp (1999) reported on the use of fluoxetine (i.e., five to 30 mg/day) in combination with two other psychopharmacological agents (i.e., clonidine and haloperidol). Therefore, these studies provide initial evidence of the possible benefits of fluoxetine treatment of selective mutism; yet, more research needs to be conducted before conclusions from these case studies can be drawn.

Critical summary of fluoxetine studies. The available quasi-experimental studies and case studies suggest that fluoxetine from four to 60 mg/day is a promising treatment for selective mutism in children. However, as evidenced by the limitations associated with these two quasi-experimental studies and the lack of a specific measure of outcome variables and lack of scientific rigor in the case studies, it is evident that more work needs to be done to ensure that fluoxetine is indeed successful in treating selective mutism in children. In order to accomplish this, studies that adhere to rigorous experimental designs examining the use of fluoxetine to treat selective mutism should be conducted.

Sertraline. Two single-case design studies have examined the impact of an alternative SSRI (i.e., sertraline) treatment for children with selective mutism. First, Carlson and colleagues (1999) examined the use of sertraline to treat five children ages five to eleven diagnosed with selective mutism using a double-blind placebo procedure with a replicated multiple-baseline across participants design. Participants in the study had been experiencing selective mutism symptoms between two and seven years. All children were provided with a dose of 50 mg/day

for two weeks and 100 mg/day for the rest of the study. Several standardized methods were used to determine the efficacy of the sertraline treatment including: Goal Attainment Scaling, the Child Behavior Checklist, and Clinical Global Improvement Ratings conducted by the teachers, parents, and study psychiatrist. Moreover, parents determined how appropriate they believed the intervention was for their child's treatment by completing measures of treatment effectiveness and acceptability. Final outcome data was analyzed using visual analysis and by calculating effect sizes. Evidence for the effectiveness of the sertraline was demonstrated in that the parent GAS ratings were consistent for four of the five participants and changed with the onset of treatment in the hypothesized direction. However, there are some limitations to the Carlson and colleagues (1999) study. First, the onset of treatment effects, which theoretically take multiple weeks to develop, emerged more quickly than hypothesized. Therefore, the authors cautioned that the cause of the increase in speech in this study might have been related to behavioral disinhibition and not the intended mechanism of action of the medication. Second, since this study has been published, there has been much growth in the field of single-case design in regards to requirements for visual analysis and the number of available effect size measures that can be used to quantify outcomes.

Eke (2001) examined the use of sertraline at 50 to 100 mg/day paired with a behavioral consultation intervention for the treatment of selective mutism in four children with ages ranging from six to 10 using a two group multiple-baseline single-case design methodology with a double-blind placebo control medication components and visual analysis to examine the treatment outcomes. Dependent measures in the study included: ratings of Clinical Global Improvement provided by the teachers, parents, and study psychiatrist, the Child Behavior Checklist, Goal Attainment Ratings, and a standardized measure of side effects. Results

indicated the combined approach of the sertraline and psychosocial intervention was effective in reducing symptoms. However, the author noted several limitations to this study. One of these limitations is missing behavioral observations and reliability data due to difficulties in recruiting school personnel and project staff to complete observations. Moreover, this study also heavily relied on visual analysis. Unlike Carlson and colleagues (1999), this study did not calculate effect sizes for treatment outcomes.

Critical summary of sertraline studies. Both the Carlson and colleagues (1999) study and the Eke (2001) study provide initial evidence that sertraline may be beneficial for the treatment of selective mutism; however, because of the methodological limitations of these studies, more research is needed to draw stronger conclusions. Since these studies were published, improved guidelines for visual analysis and effect size calculations have been developed. The What Works Clearinghouse has accepted these guidelines as a means to identify evidence-based interventions (Kratochwill et al., 2013). Therefore, additional research with sertraline and other SSRIs in children with selective mutism is needed.

Paroxetine and fluvoxamine. In addition to fluoxetine and sertraline, two additional case studies have been published on the use of SSRIs to treat selective mutism. First, Lafferty and Constantino (1998) examined the use of fluvoxamine to treat a six-year-old female, who had been displaying symptoms for approximately a year and a half. The child was put on a dosage of fluvoxamine of 50 mg/day, which was increased to 100 mg/day after two weeks of no treatment response. According to the authors, two days after the dosage increase the child began to speak within the classroom and community settings, however, she continued to refrain from speaking when visiting the psychiatrist's office. A month later, the child began to display signs of behavioral disinhibition and was engaging in reckless behavior. This led to the tapering of the

medication. After the medication had been stopped, the child's reckless behavior ceased, and her mutism behaviors did not reoccur. Second, Lehman (2002) reported on the case of an eight-year-old female who had been diagnosed with selective mutism at age five. The child was prescribed paroxetine at five mg/day. After two to three weeks, the child was no longer displaying symptoms of selective mutism, and her parents reported a dramatic increase in social skills, school attendance, and socializing with friends.

Critical summary of fluvoxamine and paroxetine studies. The Lafferty and Constantino (1998) study and the Lehman (2002) study suggest that other SSRIs such as paroxetine and fluvoxamine may be beneficial for the treatment of selective mutism. However, much more methodologically rigorous research needs to be completed before conclusions can be drawn about either of these SSRIs. The findings in these case studies are consistent with the overall findings of other SSRI treatment quasi-experimental, single-case design, and case studies on the use of SSRIs to treat selective mutism.

Single-Case Research Design

Rationale for single-case design within selective mutism research. There are several unique characteristics to consider when examining psychopharmacological treatments for children with selective mutism, such as the rarity of the disorder and the need for frequent monitoring of improvements and potential side effects. Fortunately, single-case design methodologies have the capability to address these issues (see Table 4). The most salient of these characteristics is working with a small sample size due to the rarity of selective mutism. This reality makes it difficult to study treatments for selective mutism using randomized control trials, which are often considered the gold standard for the measurement of the efficacy of a treatment

and require a large number of participants (Kratochwill & Levin, 2010). Single-case designs address this issue by requiring fewer participants to draw reliable and valid conclusions.

Table 4

Rationale for Single-case Designs in Psychopharmacology Studies with Children Diagnosed with SM

Characteristics of SM Medication Studies	Attributes of Single-Case Design
Need for frequent monitoring of intervention effects and side effects	Requires repeated measurement
Rarity of Selective Mutism within the population	Requires a small number of participants
Lag of onset of treatment outcomes	Ability to analyze when changes in functioning occur
Need for standardized assessment with internal and external validity and quantitative analysis of outcomes	Randomization of start point, within and between subject comparisons, calculations of effect sizes, non-parametric statistical calculations
Need to determine if there is a socially valid change for the participants in the study	Allows researchers to examine clinical effectiveness and social validity of an intervention

Derived from APA (2000), Carlson and colleagues (2008), Gleason and colleagues (2007) Koehler and Levin (1998), and Riley-Tillman and Burns (2009).

Single-case designs are defined by Horner and colleagues (2005 p. 165) as "a rigorous, scientific methodology used to define basic principles of behavior and establish evidence-based practices." Single-case design studies are intended to accomplish the following three things. First, single-case designs identify if there is an "observable and important" change in a dependent variable. Second, single-case designs distinguish if the change caused in the dependent variable was a direct result of the application of an independent variable. Finally, single-case design methodologies are intended to determine if the change seen in the dependent variable is "generalizable across time, setting, and target" (Riley-Tillman & Burns, 2009 p. 9).

Single-case designs were created as a way to provide experimental control and internal validity with a small sample, similar to the control provided in randomized control-group experimental designs that consist of two randomized groups with one group receiving the independent variable and a control group not receiving the independent variable (Horner et al., 2005). In addition, single-case design methodology addresses some of the weaknesses associated with randomized control trials and traditional significance testing. For example, Carver (1993) believed that results from randomized control trials were frequently being reported as significant because they were statistically significant at a p value of less than .05. However, even though the results were statistically significant, when examined more closely, the intervention did not have a clinically important impact on the outcome variable for individual participants. Kazdin (1977) states that small changes in the outcome variable that are not seen as an acceptable level of change or a socially valid level of change by the individual or those around the individual do not attest to the effectiveness of an intervention. Therefore, behavior change must be observable and acceptable in order for an intervention to be determined effective.

Specific criteria for the evaluation of single-case design for school psychology interventions include: reliability of measures, multiple methods of assessment, multiple sources of data, validity of outcome measures, quality of the baseline data, educational and clinical significance, durability of the effects, identifiable intervention components, intervention implementation fidelity, replication, and the setting in which the intervention took place (Kratochwill & Stoiber, 2002). More recently, Kratochwill and colleagues (2010, p. 14) in conjunction with the *What Works Clearinghouse* specified the necessary components of single-case designs to "meet evidence standards" (See Table 5), including (a) a methodical

manipulation of the independent variable, (b) a minimum of three data points per series, (c) a minimum of three different phase repetitions for multiple baseline design studies, and (d) consistent assessment of the outcome variable across time.

Table 5

What Works Clearinghouse Requirements to Be Rated "Meets Evidence Standards" for SCD

#	Requirement
1.	The independent variable (i.e., the intervention) must be systematically manipulated, with the researcher determining when and how the independent variable conditions change.
2.	Each outcome variable must be measured systematically over time by more than one assessor, and the study needs to collect inter-assessor agreement in each phase and on at least twenty percent of the data points in each condition (e.g., baseline, intervention) and the inter-assessor agreement must meet minimal thresholds.
3.	The study must include at least three attempts to demonstrate an intervention effect at three different points in time or with three different phase repetitions.
4.	For a phase to qualify as an attempt to demonstrate an effect, the phase must have a minimum of three data points. To meet standards a multiple baseline design must have a minimum of six phases with at least 5 data points per phase.

Taken from Kratochwill and colleagues (2010 p. 14-16).

Multiple-baseline designs. Single-case designs have improved over time in order to more accurately measure outcome variables. These methodologies have historically used a repeated baseline A-B-A-B design, which is also known as a "reversal" design. In this design, "A" stands for the baseline phase, which is the phase in which the independent variable is not provided to the subject. Next, "B" stands for the intervention phase, where the independent variable (e.g., intervention) is implemented. In order to monitor the impact of the independent variable, change is measured between phase A and phase B. In addition, to ensure that the independent variable is the reason for the change observed between phase A and phase B, a return to baseline (i.e., A) and then another implementation of the intervention (i.e., B) is conducted (Baer, Wolf & Risley, 1968; Riley-Tillman & Burns, 2009). However, this design is

not well suited for psychopharmacology research for several reasons, including: a) the theoretical lag effect for some classes of psychotropic medications between the start of a treatment and the treatment effects (Stahl, 1998); b) the potential side effects caused by the abrupt removal of a medication (Haddad, 1998); and c) the potential for learned social behaviors to carry on past the removal of the medication (Riley-Tillman & Burns, 2009). In some psychopharmacological studies, a multiple-baseline design may be more appropriate. In this design, multiple subjects each receive the independent variable (B), but do so at different times throughout the experiment. For example, participant one may receive a baseline phase (A) for four weeks and then an intervention phase (B) for four weeks, while participant two receives a baseline phase (A) for six weeks and the intervention phase (B) for two weeks (Riley-Tillman & Burns, 2009). The goal of multiple baseline research is to determine if changes in the data coincide with changes in condition across participants when the independent variable is implemented regardless of when it is added (Hayes, 1981).

Concurrent versus nonconcurrent multiple baseline designs. There are two variations of the multiple-baseline design. Concurrent multiple-baseline designs include a staggered onset of the treatment across participants, but require the data for each participant to be collected at the same time. Concurrent data collection is argued to ward off threats to internal validity by controlling for temporal affects (Christ, 2007). However, a weakness of the concurrent multiple baseline design is it requires all participants to proceed through a study simultaneously.

Watson and Workman (1981) proposed the nonconcurrent baseline design, to address the difficulties that the concurrent baseline posed for researchers working in applied settings. The authors argued that it was not feasible for studies in applied settings to collect data on participants at the same time due to practical issues such as recruitment factors. This is a problem

for recruitment in selective mutism studies, as the rarity of the disorder prevents researchers from finding several participants who can start a treatment at an identical time.

In the nonconcurrent procedure, the baseline and intervention lengths are determined a priori. Through this a priori specification, researchers can have confidence that a treatment effect is occurring, as the probability improvement would begin at the start of each intervention phase across participants is very low. As participants become available, they are randomly assigned to one of the pre-specified baseline/treatment schedules. Here, random assignment insures participants do not get assigned to a baseline/treatment schedule based on any factor (i.e., time of enrollment in the study, age, severity of symptoms) other than chance. Overall, a priori determination of baseline and treatment lengths, repetitive assessments of outcome data, and the multiple replications of a potential treatment effect, provide substantial evidence that the nonconcurrent baseline design can be used to draw meaningful conclusions about a treatment approach (Christ, 2007). One weaknesses of this approach is that it does not allow baseline level of functioning to stabilize before beginning the treatment phase. In cases where a child shows high levels of variability in the baseline phase, the child's data may not be interpretable (Watson & Workman, 1981). This shortcoming is typically not a concern in selective mutism studies, where children have demonstrated a lack of speech for a significant amount of time, often several years.

There has been much debate in regards to the scientific merits of concurrent baseline designs in comparison to nonconcurrent baseline designs. Specifically, criticism has been raised regarding nonconcurrent multiple baseline designs that do not select the baseline and treatment lengths before the beginning of the study (Christ, 2007). However, Christ examined the qualities of nonconcurrent single-case designs in light of several possible threats to internal validity,

which include: a) history; b) maturation; c) testing; d) instrumentation; statistical regression; and, d) interactions. The author concluded that the Watson and Workman (1981) version of the nonconcurrent multiple baseline design addresses these concerns comparably to concurrent designs, except in the area of mortality (i.e., participant drop out/removal), as participants who fail to establish a steady baseline should be removed from the study. This poses a potential problem as these participants who have a varying baseline level may have certain characteristics that will not be accounted for in the final analysis.

Visual analysis of single-case design data. Visual analysis is the first step in identifying treatment effects, and is defined as the examination of graphed data between the baseline phase and the intervention phase (Kratochwill & Stoiber, 2002). For example, in a study examining selective mutism, data that demonstrates an effect for a treatment may display a consistent low level of speech behaviors in the baseline, and higher and increasing level of speech behaviors in the treatment phase. According to Kratochwill and colleagues (2010) visual analysis should include an examination of six variables. First, level, which refers to the frequency or intensity of a behavior, is considered. In the case of selective mutism studies, this would include the lack of speech when speech is expected. Second, the trend of the targeted behavior should be observed in the baseline consistently before a treatment phase should be initiated. This is to ensure that the behavior that is targeted is consistent, which allows more confidence that a change in the treatment phase is indeed the result of the treatment and not just a natural variation of that behavior. In single-case design studies examining selective mutism treatment, the establishment of trend during the baseline phase should not pose a challenge given these children have likely refrained from speaking in front of unfamiliar people for a substantial period of time. Third, the variability of the behavior in the baseline phase should be examined. If the behavior is

unpredictable and fluctuates greatly over time, it will be much more difficult to determine the effect of a treatment variable. Once these three variables are observed in the baseline phase, they should also be examined in the treatment phase to determine if there is a change in the level, trend, and variability in the treatment phase compared to the baseline phase. Depending on the hypothesis of a study, a change in level, trend, and/or variability can indicate a change that is attributed to the onset of the treatment variable. Fourth, the researcher should examine the immediacy of the effect of the treatment on the behavior of the participant. Fifth, researchers engaging in visual analysis of single-case design studies should determine how much the data from the baseline phase and the treatment phase overlaps in order to determine if a meaningful change has occurred from the baseline phase to the treatment phase. Finally, the researcher should take the data for each participant and combine it with the visual data from the rest of the participants to determine whether or not the data meets evidence standards (Kratochwill et al.). Interestingly, the very observable changes in the target behavior of speaking makes selective mutism an optimal condition to examine treatment effects under single-case design methods.

The What Works Clearinghouse (WWC) Standards proposed by Kratochwill and colleagues (2010) set several guidelines in identifying single-case design studies that display strong evidence. First, the study must demonstrate an effect across three different phases as determined by two WWC raters that are trained in single-case analysis. In addition to this, there must be no contradictory evidence when examining the following features of the data: a) level; b) trend; c) variability; d) immediacy of the effect; e) overlap of the data; f) an examination of the change from baseline to treatment phase; and g) anomalies in the data that occur within a phase (e.g., a sudden and dramatic increase in a behavior mid-phase with a known explanation). If there are three demonstrations of the effect, but one of the previous variables has been

identified as a potential problem in the data, the study will be determined to only have "moderate evidence." Likewise, if there are three participants who demonstrate the expected change, and one or more participants who do not demonstrate the expected change, the study will only have "moderate evidence."

Quantitative analysis of single-case design data. Several methods to quantify the impact of change in single-case design studies that go above and beyond visual analysis have been proposed. Best practice currently dictates these approaches only be utilized after determining an intervention has at least moderate evidence based upon visual analysis procedures (Kratochwill et al., 2010). Despite the option to quantitatively examine single-case design outcomes, there is much debate in the field regarding the most appropriate way to complete this task, and, to date, it appears no consensus has been reached (Kratochwill et al., 2013). However, strong arguments have been made for the use of single-case design randomization tests (Ferron & Levin, 2014) and measurement of intervention effect size (Kratochwill et al., 2013).

Randomization tests for the analysis of single-case design data. Randomization tests in single-case design research work similarly to randomization tests in group research. The goal is to determine if the probability a child displayed a better outcome during a certain period of time, such as during an active treatment, compared to a control period, such as during a placebo treatment, is greater than chance (Edgington, 1980). By calculating this statistic, one can determine if positive outcomes were likely due the active treatment (Ferron & Levin, 2014). Single- case design randomization tests were developed several decades ago (Edgington, 1980, Wampold & Furlong, 1981; Wampold & Worsham, 1986), and are capable of providing meaningful conclusions about treatment effectiveness.

The Wampold & Worsham (1986) technique appears to be the foundational randomization test for the quantitative analysis of multiple-baseline design data. A majority of the current tests appear to be variants on this procedure, tweaked to solve various types of research questions. The Wampold and Worsham test requires all treatment schedules stagger the onset of the treatment (e.g., active medication), allowing the researcher to better rule out for "history" effects. Next, a test statistic is calculated. If there are K subjects, then there are K! number of potential permutations (i.e., potential orders of intervention onset). Then, a randomization distribution is created by computing W for K! permutations. These permutations are rank ordered, and the significance of the findings is calculated by the following formula: P(Type I Error)= α =(number of Ws as large or larger than the obtained value) /k!. The test statistic can be compared to an alpha of .05.

As noted, variations on the Wampold & Worsham (1986) test appear throughout the literature. Marascuilo and Busk (1988) used a similar concept to Wampold and Worsham; however, instead of using fixed staggered start points, each participant's start point was randomly selected from all available time points in a particular treatment schedule to which the participant was randomly assigned. This increased the number of potential randomized start points, thus increasing the statistical power of the test. While there is a beneficial increase in statistical power, one drawback to this technique is individuals may not have enough of a baseline period to establish a consistent trend since any potential time point can be randomly selected as the intervention start-point. Additionally, participants may not receive an intervention until the last few available intervention start points. This approach is problematic for psychopharmacological research (e.g., SSRIs), as extended periods of time are often needed to show an effect. Koehler & Levin (1998) developed another variation of the Wampold and

Worsham approach. In this design, participants are first randomized to a treatment schedule. In each treatment schedule, the researcher designates a block of time points as potential start points. These potential start points are staggered for each participant so participants do not start the intervention at the same time. Next, a start point is randomly selected from a block of potential start points for each treatment schedule, thus improving the power of the statistical analysis. Again, while this increased power is desirable, it has drawbacks for research with psychopharmacological medications. Specifically, the issue of latency of effect negates the utility of this design for psychopharmacology research. Because each child may take a slightly different amount of time to respond to the medication, the Koehler and Levin approach could make an effective medication look ineffective, given the focus on individual time points. This design is most effective when there is an immediate expected outcome like when studying treatment response to psychostimulants (M. Koehler, personal communication, 2012).

Effect size calculations for single-case design data. As with group research, effect sizes can be used to quantify single-case design research after visual analysis indicates a treatment effect (Kratochwill et al., 2013). Some frequently utilized effect size approaches include the no assumptions effect size, percentage of non-overlapping data, percentage of all non-overlapping data, and R^2 (Riley-Tillman & Burns, 2009). However, all four of these methods have been criticized in the literature for weaknesses. Parker and colleagues (2011) developed the Tau-U effect size to address the problems with the previously mentioned effect sizes. The Tau-U was created through the combination of Kendall's rank correlation and the Mann-Whitney-U test. Tau-U improves on previous approaches by controlling phase A trend and combining nonoverlap between phases with trend from within the intervention phase. The Tau-U approach consists of multiple components. The first optional step is to create a time series data difference matrix of

pairwise data comparisons between all of the data points for a participant in a time forward direction, as a visual aid. Here, the left margin of the matrix contains the data series, while the top of the matrix contains the data series in reverse. In the matrix it is noted whether each comparison indicates an increase in score (+), a decrease in score (-) or a tie (T). The first objective consists of determining the improvement trend in Phase B by inputting the available data into a formula determined to establish the Kendal rank correlation (KRC) coefficient: "Percent of Non-Overlapping Data" = $(U_L - U_S) / (U_L + U_S) = S / \#Pairs = (\#pos - \#neg) / pairs =$ Tau. Second, the same formula can be used to determine the effect size and significance of improvement trend in Phase A. Third, overall improvement is calculated via the following formula by contrasting phase A against phase B, while including Phase B trend, and inputting the variables into the same formula: Tau=S/#pairs. Finally, overall improvement is calculated while controlling for Phase A improvement. To accomplish this calculation, the sign of Phase A trend is reversed followed by the recalculation of full trend. After the reversal of the sign, this procedure is completed via the following previously used formula: Tau=S/#pairs. Significance values, standard deviation, and z-scores for each task are obtained by inputting the previous information into a KRC model via a statistical program, such as SPSS.

Single-case design in selective mutism psychopharmacology studies. Although single-case design is a very suitable approach for psychopharmacology research with children who have selective mutism, only two studies have used single-case design methodology for this purpose. First, Carlson and colleagues (1999) used a non-concurrent multiple baseline single-case design to examine the impact that sertraline had in the treatment of selective mutism. The authors were able to identify change across phases with the addition of a medication treatment. This nuanced level of individual change would not have been detected with a randomized control

trial, as much more participants would be needed to run a t-test or ANOVA to examine the average change across participants of children who received sertraline and those that did not. Second, Eke (2001) used a two-group single-case design to examine a combined psychopharmacosocial treatment for children with selective mutism. In this study, the use of a single-case design allowed for an examination of behavioral and sertraline treatments for selective mutism. To complete this type of study with a randomized control approach, many participants would have been needed, which would be difficult to recruit given the rarity of selective mutism. Moreover, the use of a single-case design allowed for the examination of the social validity of the outcomes for each individual as opposed to a randomized control study, which would have averaged all of the participant's responses and then statistically compared the means across groups. The methods utilized in the current study are similar to those used by Carlson and colleagues (1999) examination of sertraline. However, the data analytic methods used in this project are more sophisticated given the use of visual analysis, the Wampold and Worsham (1986) randomization test, and the quantification of treatment effect using the newly developed Tau-U effect size (Parker et al., 2007).

Current Study

When psychosocial approaches fail to yield meaningful outcomes, a psychopharmacological approach may be appropriate to improve functionality and increase well-being (American Academy of Child and Adolescent Psychiatrists, 2009). Therefore, the identification of psychopharmacological interventions that can improve the quality of life of children affected with selective mutism children is necessary. Due to the current state of the literature, there is limited information available for practitioners and parents regarding the effectiveness of these treatments. This is troubling given that selective mutism has been linked to

difficulties with academics (Carbone et al., 2010) and later psychopathology (Steinhausen et al., 2006). Previous case studies (e.g., Bork & Snyder, 2013), a small open label study (Dummit et al., 19997), and a small-randomized control trial (Black & Uhde, 1994) suggest fluoxetine may be effective in the treatment of selective mutism with elevated social anxiety symptomology. The current study contributes to the greater understanding of the utility of fluoxetine for this indication through the use of a non-concurrent, multiple baseline, single-case design procedure, with a multi-gate data analytic approach including visual analysis (Kratochwill et al., 2010), the Wampold and Worsham (1986) randomization test, and the Tau-U effect size approach (Parker et al., 2011) for quantifying the impact of fluoxetine treatment in five children between the ages of 5 and 14. Side effects were documented, and the relationship between speaking behaviors and the possible development of behavioral disinhibition associated with the fluoxetine was examined to ensure that improvements were due to the hypothesized intended effect of the medication (i.e., social anxiety reduction). Treatment acceptability was examined in order to determine if this was perceived to be a reasonable intervention for families seeking treatment for their child's selective mutism.

Research questions and hypotheses.

Question 1: Will fluoxetine treatment lead to a significant reduction in social anxiety symptoms between the baseline/placebo phases and the treatment phase in five children diagnosed with selective mutism involving elevated levels of social anxiety symptoms?

According to the literature, selective mutism almost always occurs with high levels of social anxiety (APA, 2013; Black and Uhde, 1995; Dummit et al., 1997). Selective serotonin reuptake inhibitors are hypothesized to address the biological component of selective mutism disorder by increasing serotonin levels. Fluoxetine at 20 mg/day has demonstrated efficacy with

anxiety disorders in children and adolescents, and is approved by the FDA for obsessive-compulsive disorder in children (Birmaher et al., 2003; Eli Lilly and Company, 2009). Black & Uhde (1994) found that teachers rated children with comorbid social anxiety and selective mutism receiving fluoxetine 12 to 27 mg/day as significantly more improved compared to a placebo-control group on the Conner's Anxiety Factor, a standardized scale of generalized anxiety. In an open-label study, Dummit and colleagues (1996) found that there was a significant decrease in social anxiety symptoms on the Liebowitz Social Anxiety Scale and the Liebowitz Social Avoidance scale for children taking fluoxetine 20 to 60 mg/day. Finally, there have been several case studies conducted that have reported a reduction in anxiety in association with fluoxetine treatment for selective mutism (e.g., Boon, 1994; Harvey & Milne, 1998; Silveira et al., 2004; Wright, 1995). Therefore, it was hypothesized there would be a significant effect of the fluoxetine treatment on social anxiety symptoms. The primary outcome measure of social anxiety in this study was Direct Behavior Ratings (DBRs) of social engagement with unfamiliar adults completed by parents. Data on social anxiety symptoms were also collected using the following measures: 1) DBRs of social engagement completed by teachers or an additional parent if a teacher was unavailable (e.g., during summer break); 2) the MASC-2 Social Anxiety Scale (MASC-2: SAS) completed by parents; and 3) the Clinical Global Impression (CGI) improvement and severity rating scales, which were completed by teachers, parents, the study psychiatrist, or both parents if one of the previous raters was unavailable (e.g., teacher during summer break; see Table 6).

Table 6

Research Questions, Hypotheses, and Planned Assessment Procedures

Question	Hypotheses	Measures
Will fluoxetine treatment lead to a significant reduction in social anxiety symptoms?	Fluoxetine treatment will result in a significant decrease in symptoms of social anxiety.	*Primary* 1) Direct Behavior Ratings of Social Engagement with Unfamiliar Adults – Parent *Supplemental* 1) Multidimensional Anxiety Scale for Children (2nd Edition) – Social Anxiety Scale– Parent 2) Clinical Global Impression-Improvement Ratings (Global Shyness and Global Anxiety) - Parent, Teacher, Project Psychiatrist 3) Clinical Global Impression –Severity Ratings (Shyness Severity and Anxiety Severity) – Parent, Teacher, Project Psychiatrist 4) Direct Behavior Ratings of Social Enagagement - Teacher
Will fluoxetine treatment increase the frequency of spontaneous speech and responsive speech?	Fluoxetine treatment will lead to a significant increase in spontaneous speech and responsive speech.	*Primary* 1) Direct Behavior Ratings of Responsive and Spontaneous Speech with Unfamiliar Adults – Parent *Supplemental* 1) Selective Mutism Questionnaire – Parent 2) Direct Behavior Ratings - Teacher 3) Clinical Global Impression –Severity Ratings (Mutism Severity) – Parent, Teacher, Project Psychiatrist 4) Clinical Global Impression-Improvement Ratings (Global Mutism) - Parent, Teacher, Project Psychiatrist 5) Diagnostic Interview – Project Psychiatrist

Table 6 (cont'd)

What adverse side effects will children experience during fluoxetine treatment? Is there a positive risk to benefit profile?	Children will not experience any serious adverse events, but will experience mild adverse events. The benefits of the fluoxetine treatment will outweigh negative side effects.	*Primary* 1) Adapted Side Effect Form for Children and Adolescents (SEFCA) – Parent 2) Clinical Global Impression Ratings (Global Side Effect Severity) – Parent and Project Psychiatrist *Supplemental* 1) Medication Management Meetings- Project Psychiatrist
Does onset of active fluoxetine medication correspond with an increase in behavioral disinhibition?	The onset of active fluoxetine medication will not correspond with an onset of behavioral disinhibition.	1) Young Mania Rating Scale – Parent
Will parents find the use of fluoxetine for the treatment of selective mutism acceptable?	Parents will find the use of the fluoxetine treatment as acceptable for the treatment of selective mutism.	1) Treatment Evaluation Questionnaire, Acceptability Scale -Parent

Note: Adapted from Carlson and colleagues (1997) and Eke (2001)

Question 2: Will the fluoxetine treatment increase the frequency of spontaneous speech and responsive speech across the baseline/placebo phases and the treatment phase in five children diagnosed with selective mutism involving elevated levels of social anxiety symptoms?

According to the model of selective mutism proposed by Carlson and colleagues (2008), underlying biological aspects of anxiety may play a role in the reluctance to speak in children with selective mutism. By treating the anxiety, it can be expected that speaking behaviors will increase. Several case studies suggest fluoxetine may be effective in increasing the frequency of speech in children with selective mutism (e.g., Bork & Snyder, 2013; Silveira et al., 2004). Additionally, a small randomized control trial (Black & Uhde 1994) and an open label study (Dummit et al., 1997) found parents perceived improvement in speaking behaviors after treatment with fluoxetine at 12 to 60 mg/day. However, in these studies, ratings of speaking behavior were made infrequently, and raters were not asked to differentiate between spontaneous speech (e.g., initiating speech with others) and responsive speech (e.g., answering a question posed directly to the child). Delineating between spontaneous speech and responsive speech is essential, as some have argued that spontaneous speech is a better criteria to examine whether a child is engaging in speech for communication, which is the goal of treatment (Pionek Stone et al., 2002). Carlson and colleagues (1999) used sertraline, another SSRI, to treat selective mutism and found that there were increases in both spontaneous and responsive speech. Therefore, it was hypothesized that children would display a significant increase in all types of speech behaviors in the school and community setting. This study adds to the literature by requiring parents and teachers to provide Direct Behavior Ratings (Chafouleas, Riley-Tillman, & Christ, 2009) multiple times per week in the school and community settings. Direct Behavior Ratings completed by parents are the primary outcome variable; however, several other assessments will

be used to collect supplementary data on speaking behaviors, including: 1) the parent completed Selective Mutism Questionnaire (SMQ: Bergman et al., 2008); 2) CGI ratings provided by parents teachers, and the psychiatrist; and 3) a psychiatrist administered diagnostic interview for selective mutism (see Table 6).

Question 3: What adverse side effects, if any, will children experience during the fluoxetine treatment? Is there a positive risk to benefit profile for children taking fluoxetine for selective mutism?

SSRIs have a relatively low risk of moderate to severe adverse effects (Vaswani, Linda, & Ramesh, 2003). However, previous research indicates there are side effects associated with the use of SSRIs in children, including behavioral problems (i.e., behavioral disinhibition), somatic complaints (e.g., headache, upset stomach), and mood difficulties (e.g., increased anxiety). Safer (2011) argued that it is essential to examine the side effects associated with psychopharmacological agents in children as children may experience different side effects or more intense side effects than adults. Although the previous research on the use of fluoxetine for selective mutism provides evidence for the overall safety of this approach, it was hypothesized that children would experience mild to moderate adverse events such as upset stomach and a reduction in appetite at the onset of treatment. However, it was hypothesized that children would not experience any serious adverse events from the fluoxetine treatment. The frequent assessment of side effects in this study illuminates when and if side effects occured as well as when side effects dissipated during the course of treatment. It was hypothesized that if adverse effects were experienced the negative effects would not outweigh the benefits of the fluoxetine treatment such as improved anxiety ratings and an increase in speech production. In order to examine the adverse effects that were experienced by the children taking fluoxetine, a modified

version of the Side Effects Form for Children and Adolescents (SEFCA) that examines the most common side effects specific to the use of SSRIs with children was used. In addition, information provided to the psychiatrist regarding possible side effects during the bi-weekly medication management meeting was reported. Finally, the CGI-Global Side Effects Severity rating scale completed by parents on a weekly basis and the study psychiatrist on a bi-weekly basis was used (see Table 6).

Question 4: Does onset of active fluoxetine medication correspond with an increase in behavioral disinhibition?

Children treated with an SSRI may sometimes experience behavioral disinhibition (Walkup & Labellarte, 2001). When determining whether an SSRI has successfully treated selective mutism, it can be difficult to identify what behaviors can be attributed to the intended effects of the SSRI (e.g., anxiety reduction) and what behaviors can be attributed to the unintended effects of the SSRI (i.e., behavioral disinhibition), as the outcomes may appear similar (e.g., increased speech). Given this issue, Carlson and colleagues (2008) state that it is essential to examine the possibility that behavioral disinhibition may be occurring when examining the impact of SSRI treatment for selective mutism. Despite the possibility that behavioral disinhibition may arise as a result of the fluoxetine treatment, it was hypothesized that behavioral disinhibition would not occur after the onset of fluoxetine treatment. The literature indicates that the occurrence of behavioral disinhibition for children treated with SSRIs is rare. For example, Wilens and colleagues (2003) found that the development of behavioral disinhibition as a result of SSRI treatment was only noted in 6% of children who received treatment with an SSRI at a pediatric clinic. Additionally, in a review article of studies examining the use of SSRIs in children, Safer and Zito (2006) reported that only 10.7% of pre-

adolescent children and only 2.1% of adolescents in reviewed studies experienced this side effect. If behavioral disinhibition occurred, it was hypothesized it would not solely coincide with improvements in social engagement and speaking behaviors. Behavioral disinhibition was identified via the parent completed adapted version of the Parent-Young Mania Rating Scale (Appendix A; Gracious, Youngstrom, Findling, & Calabrese, 2002; see Table 6).

Question 5: Will parents find the use of fluoxetine for the treatment of selective mutism with elevated social anxiety symptoms acceptable?

Prescription rates of psychopharmacological agents for the treatment of internalizing disorders in children are on the rise (Debar et al., 2003). Therefore, understanding parent satisfaction of this intervention approach is essential. According to Kazdin (1977), an intervention is effective only if stakeholders can identify a socially valid level of change; therefore, a behavioral change needs to be both observable and acceptable. Carlson and colleagues (1999) and Eke (2001) examined the use of sertraline, another SSRI, for the treatment of selective mutism. Results from both studies indicated that parents found the intervention highly acceptable. Given these previous findings and the hypothesized improvements in social anxiety and speech in this study, it was hypothesized that parents would find fluoxetine as an acceptable approach for the treatment of selective mutism. Treatment acceptability was assessed by the Treatment Evaluation Questionnaire – Parent (TEQ-P; Kratochwill, Elliot, Loitz, Sladeczek, & Carlson, 2003; see Table 6).

CHAPTER 3

METHODS

Participants

Participants (N=6) were recruited by sending out letters via email and the postal service to mental health professionals (N= 874) within a 90-mile radius of East Lansing, Michigan (see Appendix B). Each letter contained an attached flyer for the mental health practitioner to provide to parents of children between the ages of five and 18 who appeared to meet the diagnostic criteria for the disorder (see Appendix C). First, the letter and attached flyer were sent to members of the Michigan Association of School Psychologists (MASP: N=130), National Association of School Psychologists (NASP: N=133), and American Psychological Association (APA: N= 201) in the specified radius. Second, local mental health practitioners in private, group, and community mental health practices (N= 410), including psychologists, psychiatrists, and social workers, in this radius were identified through an on-line search and sent the letter and attached flyer. Finally, principals at school districts within a 90-mile radius were also sent a letter (N= 2,129; see Appendix D). This mailing included the letter for mental health practitioners and the letter for parents. In the letter, principals were asked to pass the mental health practitioner letter and parent flyer to a mental health professional within their school. Twenty-one potential participants were identified via these methods. Of the 21, four children were not accepted into the study because they were previously or currently taking medication for selective mutism symptoms (n=2 fluoxetine; n=2 sertraline), four did not want to participate in the study because of travel, two could not participate because they were from out of state (Arizona and Colorado), two were averse to medication treatments and preferred a psychosocial approach, one spoke English as a second language, and two families did not respond to multiple attempts to schedule

a screening phone call. Of the six remaining eligible children, three became aware of the study via letters sent to school principals, while the remaining three were informed of the study through a psychologist in private practice who specializes in selective mutism treatment.

Five females and one male between the ages of 5 and 14 were enrolled after qualifying based on the inclusion and exclusion criteria (Appendix E; see Table 7). Despite meeting all screening requirements, ratings of social engagement and speaking behaviors indicated that one of the children, who was initially assigned to treatment schedule three, was consistently engaging in the desired behavior prior to the onset of the fluoxetine medication. A stable baseline trend indicating selective mutism symptomology could not be established for her across measures, necessitating her removal from the analysis of treatment outcomes per the guidelines provided by Watson and Workman (1981) and Christ (2007; see Figure 2). For the remainder of this paper, she will be identified as "Child R" for "child removed." This treatment schedule was re-opened and another participant was invited to participate in the study. The remaining five children who completed the screening process and qualified per the inclusion and exclusion criteria decided to participate and completed treatment (see Table 8). All five children began displaying symptoms at 4 or 5 years of age, and received some form of behavioral or cognitive behavioral therapy before enrolling in the study provided by private practitioners and school mental health professionals. All met the age-related duration criteria for prior psychosocial treatment (i.e., 10 weeks for children seven-years-old and older; 12 weeks for children six-years-old and younger). Previous practioners for all participants reported resistance to psychosocial treatment. Child Four continued to receive cognitive-behavioral therapy on a weekly basis throughout the study. Given he was not experiencing improvement with cognitive-behavioral therapy alone according to his therapist, he was allowed to enroll in the study while continuing to receive psychosocial

Table 7

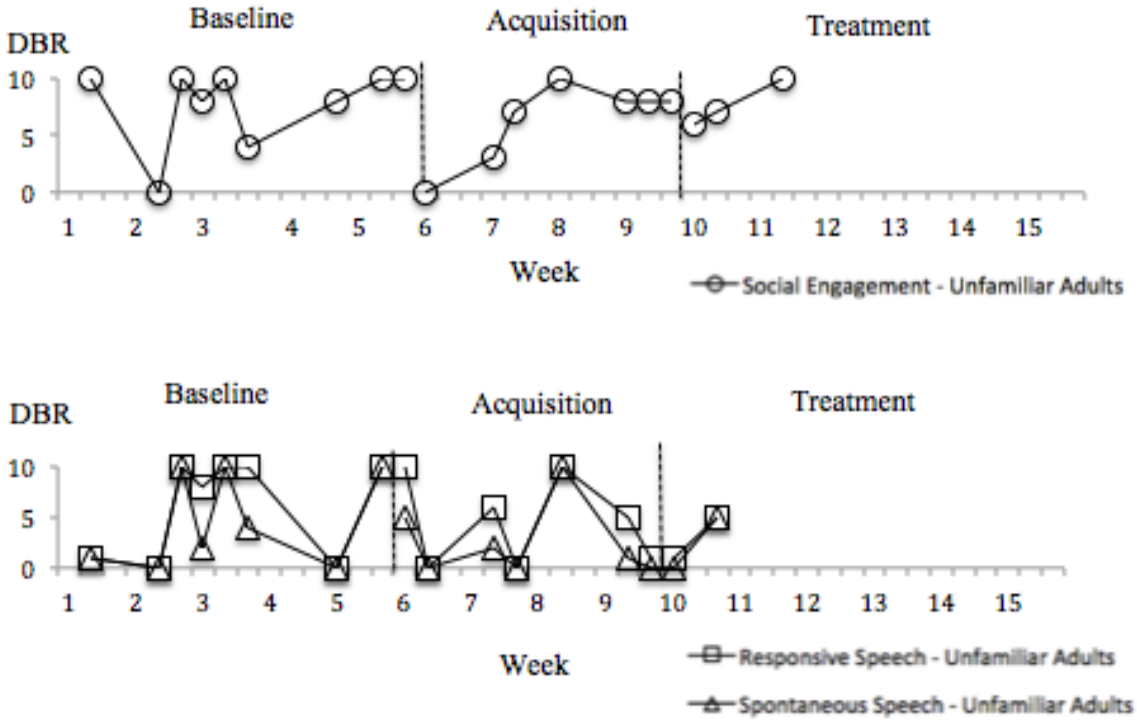
Demographic Characteristics and Baseline/Intervention Ratings for Six Participants

Child	Age/ Sex	Age of Onset	Relative w/ Anxiety	MASC-2: SAS Performance Fears - Screen	Previous Treatment	Concomitant Treatment
One	7/F	5	Sister – Undiagnosed Social Anxiety	T = 80**	Behavior Therapy; Social Skills	None
Two	5/F	4	Father – Undiagnosed Generalized Anxiety	T = 76**	Behavior Therapy	None
Three	7/F	5	Sister- Undiagnosed Social Anxiety	T = 76**	Behavior Therapy; Social Skills	None
Four	12/M	5	Father – Generalized Anxiety Disorder	T = 80	Cognitive-Behavioral Therapy	Cognitive-Behavioral Therapy
Five	14/F	5	Father – Generalized Anxiety Disorder	T = 83	Behavior Therapy	None
R*	10/F	4	Mother – Generalized Anxiety Disorder	T = 69	Behavior Therapy	None

*Participant removed from final analyses due to inconsistent baseline ratings across measures
**Based on 8-year-old normative sample.

Figure 2

Inconsistent Parent DBR Ratings of Social Engagement and Speaking Behaviors During Baseline for Participant Removed from Data Analysis by Week



Baseline = No Medication (Week One) and Placebo
Acquisition =Introductory Dose (10 mg/day, Two Weeks); Therapeutic Dose (20 mg/day; Two Weeks)
Treatment= Therapeutic Dose (20 mg/day)

Table 8

Pre-Treatment, During Treatment, and Post-Treatment Ratings by Treatment Schedule

	MASC-2			SMQ					
	Screen	Placebo – Mean (SD)	End of Treatment	Screen	Placebo – Mean (SD)	End of Treatment	Behavioral Disinhibition	End of Study SM Diagnosis	TEQ-P Rating
Child One	20	21.25 (0.5)	27	13	12 (0)	24	No	Yes	60
Child Two	25	25 (1.58)	26	5	8.8 (3.03)	11	Yes – Weeks 6, 7, and 10	Yes	56
Child Three	20	23.25 (2.85)	25	11	12 (0)	23	Yes – Weeks 13 and 14	Yes	60
Child Four	18	23 (0.63)	19	19	N/A*	N/A*	No	Yes	62
Child Five	27	26.27 (0.65)	26	17	10 (0)	N/A*	No	Yes	65

*School ratings not available for the SMQ due to summer vacation

treatment. All but one of the participants had never taken any kind of psychopharmacological medication prior to enrollment in the study. Child Four was previously treated under the care of his pediatrician with a low dose (10 mg/day) of fluoxetine for approximately four weeks over three years prior to enrolling in the research study. Given the medication treatment was discontinued quickly without the opportunity to have a lasting impact on functioning, this child was allowed to participate.

Measures

The dependent variables of this study were examined through the use of several measures completed once per school day (DBR-teacher), three times per week (DBR-Parent), twice per week (i.e., Clinical Global Impression Ratings – Parents/Teachers, MASC-2: SAS, SMQ, P-YMRS), bi-weekly throughout the project (Clinical Global Impression Ratings – Study Psychiatrist, SEFCA), and at the end of treatment (DSM-IV-TR Diagnostic Interview for Selective Mutism; Treatment Evaluation Questionnaire-Parent; See Table 9). See Appendix F for a correlation matrix of all parent-completed measures of anxiety and mutism symptoms. In addition, other forms were on hand to collect supplemental information regarding treatment integrity as well as examine the perceptions of parents and participants if a child was withdrawn in the middle of the study or when a participant completes the study. These forms included the medication compliance form (See Appendix G), which was completed everyday by the parent, the early withdrawal form (see Appendix H), which did not need to be used as no children withdrew from the study early, and the End of Study Form (see Appendix I), which was completed at the end of the study. The measures used to identify the utility of fluoxetine for the treatment of selective mutism with elevated social anxiety symptoms are discussed below.

Table 9

Assessments Planned for Each Phase

Phase	Assessment Plan
Screening	1) Phone Interview - Project Coordinator 2) Diagnostic Interview – Project Coordinator and Project Psychiatrist 3) Medical/Psychosocial History Form - Parent 4) Multidimensional Anxiety Scale for Children (2nd Edition) – Social Anxiety Scale - Parent 5) Parent-Young Mania Rating Scale – Parent 6) Physical Exam – Project Psychiatrist
Baseline/ Treatment	1) Direct Behavior Rating – Parent (3x per week) 2) Parent-Young Mania Rating Scale – Parent (2x per week) 3) Adapted Side Effect Form for Children and Adolescents – Psychiatrist (bi-weekly) 4) Medication Compliance Form – Parent (daily) 5) Multidimensional Anxiety Scale for Children (2nd Edition) – Social Anxiety Scale – Parent (2x per week) 6) Selective Mutism Questionnaire – Parent (2x per week) 7) Direct Behavior Rating – Teachers (5x per week; once per school day) 8) Clinical Global Impression Ratings – Parent/Teacher (2x per week) 9) Clinical Global Impression Ratings - Project Psychiatrist (bi-weekly)
End of Treatment	1) Treatment Evaluation Questionnaire – Parent 2) Diagnostic Interview – Project Psychiatrist 3) End of Study Form – Parent

Note: Adapted from Carlson and colleagues (1997) and Eke (2001).

Social anxiety.

Direct behavior rating (DBR): Social engagement. Direct Behavior Rating (DBR; Chafouleas, Riley-Tillman, & Christ, 2009; Appendix J) is an assessment technique that can be completed by observers, such as teachers, parents, and school psychologists. The procedure requires observers (e.g., teachers, parents) to provide a rating of an operationally defined behavior (e.g., social interaction) on a scale (e.g., 1 to 10; Never to Always; 0% to 100%), during a pre-specified period of time (e.g. hour, day, class period). DBRs are designed to supplement or be an alternative to systematic direct observations (SDO), which often require extensive

resources to complete over multiple periods of time (Chafouleas et al.). DBRs are a less resource intensive solution when SDOs cannot be completed, as SDOs and DBRs have been shown to be significantly correlated ($r \geq .81$, $p < .01$), with regression analysis revealing DBR ratings accounted for 76% of the variance of SDO ratings (Riley-Tillman, Chafouleas, Sassu, Chanese & Glazer, 2008). Research has demonstrated that DBRs have the capacity to accurately quantify target behaviors. In a study examining the concurrent validity between the Social Skills Rating System (SSRS) and DBRs in identifying problem behaviors of kindergarten students, the authors found significant correlations ranging from 0.28 to 0.88, with most correlations significant at the $p < .01$ level (Chafouleas, Kilgus, & Hernandez, 2009).

Repeated SDOs in the school and community context were not feasible due to several barriers. For example, training parents to document social engagement and speaking behaviors in the community using a SDO method would be challenging and possibly inaccurate given their inexperience with this complex assessment procedure. Further, funding and distance prevented study personnel from conducting SDOs at schools multiple times per week for each child. The alternative to have teachers videotape classroom activities was considered but deemed impractical within this dissertation study. Parents completed two ratings on a ten-point scale three times per week ranging from zero (Never) to 10 (Always) to address social anxiety (e.g., "When appropriate, my child appeared comfortably and socially engaged with other unfamiliar adults"), with one rating focusing on social engagement with unfamiliar adults and the other addressing social engagement with friends. Parents were instructed not to base the ratings targeting social engagement on speaking behaviors, as the purpose of these items were to determine frequency and ease of engagement not frequency of speech. Children in this study were consistently socially engaged with their friends during the baseline phase, which makes

sense given the familiarity participants had with these children. Therefore, parent ratings of social engagement with unfamiliar adults were the primary outcome measure for social anxiety symptomology. Teachers also completed supplementary DBR ratings of social engagement on a daily basis using the same 10-point scale and similar questions tailored for the classroom (e.g., "When appropriate, the student was comfortably and socially engaged with the classroom teacher"). Given DBRs are designed to track behaviors in individual children, no standardized scoring system has been developed. In this study, higher ratings indicate a higher rate of social engagement.

Multidimensional anxiety scale for children – 2nd edition (MASC-2) – Social anxiety scale (SAS). The Multidimensional Anxiety Scale for Children, 2nd Edition: Social Anxiety Scale (MASC-2: SAS; March, 2013; Appendix K) is a nine-item parent-report measure used to assess social anxiety symptoms in children between the ages of eight and 19. Given the lack of norm-referenced assessments for social anxiety designed for children younger than eight years of age, the MASC-2 was used as a supplementary measure of social anxiety for all children in this study given it's face validity. The MASC-2: SAS has excellent test-retest reliability (r=. 90, $p < .001$), and significantly correlates with the Conner's Comprehensive Behavior Rating Scales – Parent (CBRS-P; r= .55, $p < .01$). Parents completed the MASC-2: SAS twice per week, and provided ratings of "never," "rarely," "sometimes," or "often," for statements such as "my child worries about other people laughing at him/her" and "my child has trouble asking other children to play with him/her." The MASC-2: SAS raw scores can be converted into T-scores for comparison to same-aged peers. When T-scores were required (i.e., inclusion criteria) for children younger than eight, eight-year-old norms were used as an approximation of the severity of symptomology. In

this study, raw scores will be used to track progress over time, with higher scores indicating higher levels of social anxiety symptomology.

Clinical global impressions (CGI): Anxiety/Shyness. An adapted Clinical Global Impressions scale (CGI; National Institute of Mental Health, 1985; See Appendix L), which was used by Carlson and colleagues (1999) to examine the effectiveness of sertraline with children diagnosed with selective mutism, was used as a supplementary measure to examine the impact of fluoxetine on anxiety and shyness symptoms. Ratings were provided by parents and teachers twice per week and by the study psychiatrist bi-weekly. Research has demonstrated that the CGI has adequate reliability and validity. For example, in an adapted version of the CGI to examine the symptoms of social anxiety disorder, correlations between the CGI and the Social Interactions Anxiety Scale were all significant at the .01 level, with correlations ranging from .44 to .74 (Zaider, Heimberg, Fresco, Schneir, & Liebowitz, 2003). In this study, parents provided shyness and anxiety severity ratings on five-point Likert scales from one (absent) to five (severe), across the home, school, and community settings, while teachers provided the same ratings only for the classroom setting. The study psychiatrist also completed anxiety and shyness severity ratings based on parent report and observations during medication management meetings. Parents and psychiatrists provided global change ratings for the constructs of anxiety and shyness by using seven-point Likert scales, which ranged from one (much improved) to seven (much worse). Teachers completed five-point likert-scales on global shyness and anxiety change that ranged from one (much improved) to five (much worse). Given CGIs are global ratings of improvement and severity, there is no standardized way of scoring CGIs aside from the ratings themselves. Higher ratings across severity and improvement scales indicate worse symptomology.

Frequency of speech.

Direct behavior rating (DBR): Speech. The same DBR technique (Chafouleas et al., 2009; Appendix J) used to identify levels of social engagement was also used to evaluate speaking behaviors. Parents provided ratings for spontaneous and responsive speech with unfamiliar adults and friends three times per week (i.e., "When appropriate, my child spontaneously spoke to unfamiliar adults") on a scale of zero (never) to 10 (always) during situations where speaking behaviors would be expected. Given participants spoke freely with friends on a regular basis at the beginning of the study, parent ratings of responsive and spontaneous speech with unfamiliar adults were used as the primary outcome measure. For children who received treatment during the school year, teachers provided supplementary ratings of responsive and spontaneous speaking behaviors in the classroom on a daily basis (i.e., "When appropriate, the student spontaneously spoke to the teacher") on the same scale (i.e., zero to 10).

Selective mutism questionnaire (SMQ). The Selective Mutism Questionnaire (SMQ; Bergman et al., 2008; See Appendix M) is a 17-item parent-report assessment used to determine the degree of mutism symptoms a child is experiencing, and was completed by the parent twice per week as a supplementary measure of speaking behaviors. Research has demonstrated that the selective mutism questionnaire has adequate reliability and validity. Bergman and colleagues found that internal consistency ratings for the SMQ were excellent and ranged from .88 on the Home/Family scale to .97 on the School scale, with an overall internal consistency coefficient of .97. In addition, Bergman and colleagues found that the SMQ was sensitive enough to capture the impact of treatment. Moreover, Letamendi and colleagues (2008) found that the SMQ correlated with the Anxiety Disorders Interview Schedule for Children for DSM-IV parent Version (ADIS/CP) with a correlation coefficient of 0.48 suggesting that the measure has

adequate convergent validity. Parents provide ratings of each speaking behavior in each setting as occurring never (0), seldom (1), frequently (2), or often (3). For example, one statement is "My child speaks to most teachers or staff at school" (Bergman et al., 2008 p. 458). Lower scores on the School, Home, and Community and Total scales indicate more significant symptomology, with average scores for children with selective mutism on the Total scale ranging from 13.18 for three to five year olds to 15.73 for nine to eleven year olds.

Clinical global impressions (CGI): Mutism. The same adapted CGI technique (National Institute of Mental Health, 1985; see Appendix L) used to gather information on shyness and anxiety symptoms was used to collect supplementary information on mutism symptomology at home, in the community, at the clinic, at school, and overall. Ratings were provided by parents and teachers twice per week and the study psychiatrist bi-weekly. Parents and the study psychiatrist provided selective mutism severity ratings on a scale of one (absent) to five (severe), while providing global mutism change ratings on a scale of one (much improved) to seven (much worse). For children who received treatment during the school year, teachers also provided mutism severity ratings on a scale of one (absent) to five (severe) and global change ratings of mutism behaviors on a scale of one (much improved) to five (much worse).

Adverse events.

Clinical global impressions (CGI): Side effects. Parents, two times per week, and clinicians, bi-weekly, provided side effect severity ratings using the same CGI (see Appendix L) approach discussed for social anxiety and mutism behaviors in order to examine the perceived risk to benefit profile of fluoxetine for each of the participants. Ratings ranged from one ("Positive changes greatly outweigh negative changes. Medication effects are overall extremely

positive.") to six ("Negative changes significantly outweigh positive changes. Medication effects are overall extremely negative").

Side effects form for children and adolescents (SEFCA). A 12-item adapted version of the Side Effects Form for Children and Adolescents (SEFCA; Klein, Abikoff, & Barkley, 1994; See Appendix N) was used to examine the side effects participants experienced while taking fluoxetine and was administered bi-weekly by the study psychiatrist. This original SEFCA consists of 54-items that inquire about the frequency and severity of side effects of several different classes of psychopharmacological medications. If an item is endorsed, the administrator of the rating scale has the parent rate the severity from one to three, with one being defined as mild and three being defined as severe. Side effects examined on the SEFCA include the broad categories of cardiovascular, gastrointestinal, central nervous system, ocular, mouth and nose, genito-urinary, dermatology, and musculo-skeletal side effects. The measure does not have psychometric properties. However, it has been used frequently in published studies examining psychotropic medication use in children (e.g., Birmaher et al., 2003). Scoring is completed on an item level basis, allowing for the identification of types and severity of side effects each child experienced. In order to reduce the data collection burden on parents, an adapted version of the SEFCA that only includes adverse events associated with SSRIs that occur in 5% or more of children and adolescents (Wilens et al., 2003), such as drowsiness, difficulty falling asleep, and irritability, was used. In addition, an item capturing behavioral disinhibition was also included as this kind of adverse event is important to note as a possible confounding variable (Carlson et al., 2008).

Behavioral disinhibition.

Parent version of the young mania rating scale (P-YMRS). In addition to the item on the adapted SEFCA completed by the study psychiatrist, parent ratings on the P-YMRS were also examined to identify the potential occurrence of behavioral disinhibition. Gracious and colleagues (2002) developed the Parent Version of the Young Mania Rating Scale (P-YMRS; Appendix A) as an adaptation of the Young Mania Rating Scale (Young et al., 1978). The P-YMRS, which was completed twice per week by parents, consists of 11 multiple-choice questions and was designed to examine manic symptoms in children ages five to 17. For example, the P-YMRS asks, " Is your child's mood higher (better) than usual?" with the following response options "no," "mildly or possibly increased," "definite elevation-more optimistic", "self-confident; cheerful, appropriate to their conversation," "elevated but inappropriate to content; joking, mildly silly," and "Euphoric; inappropriate laughter, singing/making noises; very silly." Gracious and colleagues (2002) found that the P-YMRS has an internal consistency of .75, and has adequate discriminative ability when identifying children who have bipolar disorder compared to other diagnoses such as depression. Scores on the P-YMRS range from 0 to 60, with higher scores indicating greater psychopathology and a score of 21 or higher indicating a likely episode of mania (Gracious et al.). Since the purpose of the P-YMRS in this study was to identify possible behavioral disinhibition associated with the onset of fluoxetine treatment, this measure was not scored conventionally. Instead, responses that may indicate the onset of manic symptom have been determined, a priori, and highlighted in yellow in Appendix O. Three items have been removed for this study, as they have been deemed inappropriate for the age group. First, an item about appearance was determined to be inappropriate due to the young age of some of the children. Second, an item regarding insight

into manic symptoms was removed, as these children are not expected to have manic symptoms at the beginning of the study. Finally, an item about sexual interest was removed due to the anticipated age of the majority of participants.

Treatment acceptability.

Treatment evaluation questionnaire - acceptability scale (TEQ-P). The acceptability scale on the Treatment Evaluation Questionnaire, parent version (TEQ-P; Kratochwill et al., 2003; See Appendix P) was used to examine treatment acceptability as rated by the parents of the participating children at the end of the study. The TEQ-P was developed from the Treatment Evaluation Inventory (TEI; Kazdin, 1980), which was developed by conducting a factor analysis on data gathered piloting the measure with college students rating the appropriateness of various treatment options for externalizing behaviors. Kazdin (1980) found that the TEI was able to delineate between treatments that individuals considered acceptable and not acceptable. The TEQ-P consists of 21 statements that parents are asked to rate on a six point Likert scale. However, only the 11 questions associated with the acceptability scale were provided to parents, as these are the items most closely aligned to the research questions in this study. Each statement is rated on a Likert scale with a rating of one being "strongly disagree" and a rating of six being "strongly agreed." Examples of questions on the modified TEQ-P acceptability scale included: "This was an acceptable intervention for the child's problem behavior" and "I would suggest the use of this intervention to other parents." Possible scores on the acceptability scale range from 11 to 66. A score of 55 or higher has historically been used to indicate high treatment acceptability (Kratochwill et al., 2003). Carlson and colleagues (1999) and Eke (2001) used the TEQ-P to examine the acceptability and effectiveness of SSRI treatments for children with selective mutism. Carlson and colleagues (1999) and Eke (2001) found high treatment acceptability in

studies examining the use of sertraline, with average scores of 58.6 and 56.8, respectively. Therefore, using this measure to examine treatment acceptability created continuity with previous studies that have examined parental treatment acceptance for children with selective mutism who are being treated with a psychopharmacological approach.

Medication compliance measure. Parents reported medication compliance on a form requiring them to document the time they provided the medication each day (e.g., Monday at 8:00AM; see Appendix G). This allowed for the examination of missed doses, and provided insight into treatment acceptability, as higher rates of compliance indicated parents were successful at meeting the requirements of the treatment procedure. This data was compiled in the form of the percentage children were provided their medication within 6 hours of the recommended time. In addition, this information was helpful to examine in conjunction the timing of the onset of treatment effects. For example, if a child missed a significant amount of doses, the treatment outcomes may have become difficult to interpret without compliance data. There is no reliability and validity data available on this measure, as it was designed specifically for this study.

End of study form. The End of Study Form (Carlson, 1999; Appendix I) inquired about follow up care and parent perceptions of the positive and negative aspects of participation. This brief interview provides additional information on treatment satisfaction, while also ensuring children received appropriate follow up care. No reliability or validity data exists for this interview.

Procedures

The Michigan State University – Institutional Review Board (MSU-IRB) approved the procedures used in this study. Of note, the MSU-IRB required a number of conditions be met

before granting approval. First, children could be no younger than five years of age. At the start of the study, the lower age limit was seven-years-old, which was decreased to five after selective mutism experts wrote letters to the IRB describing the common practice of prescribing SSRIs to young children with selective mutism and the need for systematic data collection on this approach. Second, for children younger than seven, the project psychiatrist was required to write a treatment summary following every medication management meeting. These treatment summaries along with the most recent participant data forms were provided to a safety committee, which was composed of a pediatrician and a child and adolescent psychiatrist who were not affiliated with the project in any other way. The two members of the safety committee individually reviewed the information after each medication management meeting, and approved all of the medication decisions made by the psychiatrist. Finally, the IRB stipulated a maximum dose of 20 mg/day. In addition to these requirements, all project personnel completed the IRB training regarding responsible practices in research.

Project personnel.

Project coordinator. The project coordinator was a Michigan State University graduate student in school psychology who is completing this project in partial fulfillment of the requirements to obtain a Doctorate of Philosophy in School Psychology. The project coordinator was responsible for the following: (a) organizing and completing participant recruitment and screening efforts; (b) contacting schools, parents, and mental health professionals; (c) explaining the treatment procedure to parents and teachers; (d) training the project assistants, psychiatrists, teachers, and parents; (e) organizing the responsibilities of the project assistants; (g) meeting with families before their medication management meetings (h) obtaining consent and assent; (i)

distribution and collection of data from parents, teachers, and project psychiatrists; (j) visual analysis of graphs; and k) organizing and compiling the data.

Project assistants. The project assistants were four Michigan State University graduate students who completed the requirements to receive a Masters of Arts degree in school psychology. The primary responsibility of the project assistants was visual analysis of graphs. The project coordinator also delegated some of his responsibilities to project assistants in the scenario of scheduling conflicts or other events that prohibited him from carrying out his duties. These responsibilities included: a) meeting with families before their medication management meetings; b) distribution and collection of data from parents, teachers, and project psychiatrists; and c) organizing and inputting data obtained from the various outcome measures. The project assistants were reimbursed for hours spent working on the project (i.e., $10 per hour).

Study psychiatrist. The study psychiatrist was a resident at the Michigan State University Psychiatry clinic, working under the supervision of a board certified child and adolescent psychiatrist. The study psychiatrist was responsible for the following: (a) confirming a diagnosis of selective mutism; (b) a physical evaluation; (c) prescription of fluoxetine and dosage decisions; (d) biweekly medication management meetings; (e) monitoring of adverse treatment effects; and (d) administering assessments (e.g., CGI; SEFCA). The study psychiatrist received incentives for collaboration in this project including authorship on any publications that arise from this study as well as $250 for books for a professional library.

Training.

Study psychiatrist. The project coordinator met with the study psychiatrist prior to the study to discuss the protocol in detail. During this time, the scope and goals of the study, the multiple baseline design procedure, the responsibilities of the psychiatrist, the Clinical Global

Improvement rating system, the SEFCA, and the goals of the bi-weekly medication management meeting were discussed.

Project assistants. The project coordinator met with the project assistants prior to their participation in the project. The following topics were discussed: (a) the responsibilities of the project assistant, (b) meetings with participants, and (c) visual analysis of single-case design data. Project assistants received additional training on visual analysis of data. They were asked to read the Kratochwill and colleagues (2010) guidelines for the analysis of single-case design data. Next, there was an additional meeting to ensure an accurate understanding of visual analysis principles. During this meeting, the following variables were discussed: a) level; b) trend; c) within phase variability; d) proportion of overlap; e) comparison of baseline and intervention phase data; e) immediacy of effect; and f) anomalies in the data. Project assistants were each asked to code simulated data for 10 participants. The project coordinator reviewed the ratings and discussed discrepancies between ratings provided by the project coordinator and the project assistants. Project assistants were given more data to code until a minimum of .90 reliability was achieved.

Teachers. Teachers were required to meet with the project coordinator in person or by phone to receive training on DBRs that included the following components based on research conducted by Chafouleas, Kilgus, Riley-Tillman, Jaffery, & Harrison (2012): a) modeling of the rating procedure on pre-recorded video tapes displaying children engaging in simulated selective mutism behaviors; b) practice and feedback rating six 1-minute videotaped recordings; c) frame-of reference training (e.g., viewing a performance and discussing the important aspect of a performance); and d) a discussion of common rater errors (e.g., halo effect, central tendency). Teachers were provided with a $50 Target gift card for school supplies for their time.

Parents. Parents also met with the project coordinator during their first meeting to the MSU psychiatry clinic to review the assessment measures. During this time, parents received the same training on DBR ratings as teachers. Additionally, they were instructed on the completion of all of the other required forms. In order to compensate parents for their data collection efforts, medication management appointments at the MSU psychiatry clinic and the fluoxetine medication was provided without charge. Additionally, parents were reimbursed for mileage accrued while driving to the clinic, with those driving less than or equal to 25 miles receiving $100, those traveling 26 to 50 miles receiving $150, and those driving 50 miles or more receiving $270.

Study Phases

Project overview. Participants were required to attend medication management meetings at the MSU psychiatry clinic to meet with the project coordinator/assistants and psychiatry resident at the beginning of weeks 1, 2, 4, 6, 8, 10, 12, 14, and after week 15. During these meetings, the project coordinator/assistant collected parent completed measures (e.g., SMQ, P-YMRS, CGI, CPRS-R, DBR) from the previous two weeks and provided families with measures for the following two weeks. Starting at the second meeting with the psychiatrist, families were provided with containers of medication for the two-week period before the next medication management meeting. Alternatively, at times, the medication bottles were mailed to families directly from the pharmacy. The containers were marked with the week parents were to give children the elixir from that container, and parents were provided with a medication schedule. The fluoxetine and placebo were indistinguishable elixirs, made by BioMed Pharmacy in Lansing, Michigan.

Inclusion and exclusion criteria. Several rule out criteria were implemented (see Appendix E) to ensure symptoms were solely the result of selective mutism, and, secondly, to align with the ethical requirements of conducting a risk-benefit analysis when using psychopharmacological medications with children. First, according to the differential diagnosis criteria in the DSM-5 (APA, 2013), children were not diagnosed with a speech condition, mental retardation, a pervasive developmental disorder or schizophrenia, and spoke English as a first language. Since fluoxetine is hypothesized to address a biological component in selective mutism symptomology (see Carlson et al., 2008; Nutt et al., 1998), only children who had an immediate family member (i.e., biological mother, father, and siblings) diagnosed with an anxiety disorder or an immediate family member who displayed symptoms of an anxiety disorder were included. Only children who failed to respond to at least 10 weeks of an evidence-based psychosocial treatment for selective mutism according to their practitioners were included to ensure psychosocial approaches were attempted first. Ten weeks is the typical amount of time that children can receive psychological services through managed care insurance programs. For children younger than seven, 12 weeks of failed psychosocial treatment were required to meet the guidelines provided by Gleason and colleagues (2007) for the use of psychopharmacological medications in young children. In order to control external validity and to prevent possible complications associated with multiple psychopharmacological medications, children taking any psychopharmacological medication were excluded. Moreover, in order to ensure child safety and promote an adequate risk benefit profile for each child, children who had a negative experience with a psychopharmacological drug were not included in this study. Children with a medical illness that could become worse during psychopharmacological treatment as determined by the project psychiatrist were not considered. Finally, children had to demonstrate significant social

anxiety symptoms as indicated by a T-score greater than 65 (moderately atypical) on the MASC-2: SAS/Performance Fear scale. T-Scores are only provided for children eight-years and older on the MASC-2. Therefore, participants younger than eight-years-old were evaluated based on the T-scores for eight-year old children, given there are no normed assessments for young children that reliably and validly assess social anxiety symptoms.

Screening. The flyer parents received from the mental health practitioners instructed parents to call the project coordinator. During that phone call, the project coordinator conducted a diagnostic interview to determine if the child met DSM-5 criteria. Parents were asked if anyone in the immediate family displayed symptoms of anxiety. Finally, the project coordinator requested contact information for teachers. If criteria were met, parents were mailed the screening packet. The packet included: a) the consent form (Appendix Q); b) the MSU psychiatry clinic medical/psychosocial history form (Appendix R); c) the MASC-2: SAS; d) the P-YMRS; and c) the Release of Confidential Information form (Appendix S; see Table 9). This information was returned to Michigan State University using a pre-paid envelope. To ensure children received the required psychosocial treatment, a form detailing treatments and interventions was sent to previous mental health care providers (see Appendix T). Parents signed a release of confidential information form (See Appendix S) to allow the project coordinator to collect this information. If children met inclusion criteria, they were invited to the MSU Psychiatry clinic. During this meeting, the project psychiatrist: a) confirmed the diagnosis of selective mutism; b) clarified outstanding questions regarding medical and treatment history; and c) conducted a physical exam to ensure the child did not have any medical problems that may be exacerbated by fluoxetine (Appendix U; see Table 9).

Consent and assent procedures. Parents were provided with a consent form that discussed the purpose and scope of the study, possible risks and benefits, costs of participation, and alternative treatment options (see Appendix Q). Informed assent from the children was also obtained. In adherence with the MSU IRB guidelines, participants under 13-years of age were required to sign an assent document. Participants who were 13 years and older signed the consent form to signify their assent to the project (see Appendix Q). Since some of this study overlapped with the summer break, only three teachers participated in data collection. Teachers were required to consent to participation, as they were frequently asked to complete ratings of the student's behavior (see Appendix Q).

Baseline. Previous studies show children with selective mutism demonstrate very little response to placebo (Carlson, 1999; Eke, 2001). Despite this finding, it is possible that a placebo response may occur. To account for this possibility, a one-week no-medication component was included in the baseline. This allowed for visual inspection of a possible placebo response after the introduction of the placebo. Therefore, children did not receive any elixir during their first week in the study. Families were provided with rating scales for the week and returned to the clinic the following week. At the beginning of week two, children were provided with the placebo treatment. The placebo was administered for four to six weeks based on the randomized treatment schedule (see Table 10). The no-medication component and the placebo component were grouped together in the overall baseline phase, which was compared to the outcomes of the treatment phase. The first child (i.e., Child R) to enroll in this study demonstrated consistent engagement in the desired outcome behaviors prior to the onset of fluoxetine across the domains of social engagement, responsive speech, and spontaneous speech. Therefore, she was removed

from the final analyses per the guidelines of Watson and Workman (1981) and Christ (2007). Visual inspection indicated there were placebo responses for the remaining five children, but these occurrences quickly returned to the established trend for each child. Child Four and Child Five experienced a brief improvement in social engagement during the placebo phase; however, both of these responses returned to normal within one week. Therefore, these children were included in the analyses for social engagement. Occurrences of responsive speech were evident during the placebo phase for Children One, Two, and Five. Again, these behaviors quickly returned to baseline. Child Four displayed responsive speech during both the no medication phase and the placebo phase; however, the speaking behavior did not establish a consistent trend of response as it frequently returned to low levels. Therefore, this child as well as Children One, Two, and Five were included in the analyses for responsive speech. Finally, none of the children consistently spoke spontaneously with unfamiliar adults prior to the onset of the fluoxetine medication. However, Child Two and Child Five had brief responses during the placebo phase, which quickly returned to the original trend. Therefore, these children were included in the analyses for spontaneous speech.

During the baseline phase, several data collection procedures occurred. One parent for each participant completed the medication compliance measure daily, the DBR ratings three times per week and, the CGI scales, the MASC-2: SAS, the SMQ, and the P-YMRS twice per week. Available teachers (n=4) provided DBR ratings five times per week (i.e., once per school day) and CGI ratings twice per week. For children whose teacher could not provide ratings, a second parent completed CGI ratings twice per week and DBRs three times per week. Finally, the study psychiatrist completed CGI ratings and adapted-SEFCA at bi-weekly medication management meetings.

Table 10

Randomized Multiple Baseline Design Baseline and Treatment Schedule

Child/Week	*1**	*2**	*3*	*4**	*5*	*6**	*7*	*8**	*9*	*10**	*11*	*12**	*13*	*14**	*15*
Child One	A	B	B	C	C	D	D	D	D	D	D	D	D	D	D
Child Two	A	B	B	B	C	C	D	D	D	D	D	D	D	D	D
Child Three	A	B	B	B	B	C	C	D	D	D	D	D	D	D	D
Child Four	A	B	B	B	B	B	C	C	D	D	D	D	D	D	D
Child Five	A	B	B	B	B	B	B	C	C	D	D	D	D	D	D

*Meetings with psychiatrists occur at the beginning of these weeks (Participants meet with psychiatrists after week 15 for debriefing)

A= No Medication
B= Placebo
C= Fluoxetine - Introductory Dose
D= Fluoxetine -Therapeutic Dose

Treatment. The treatment phase encompassed the treatment with active medication. Children were randomly assigned to a schedule. The onset of the active medication varied in accordance with the multiple-baseline design (see Table 10). The same assessment schedule used during the baseline phase was implemented during the treatment phase (see Table 9).

The pharmacological treatment consisted of two doses of fluoxetine: (a) an introductory dose and (b) a therapeutic dose. The elixirs were identical in flavor, color, consistency, and quantity (i.e., ml) to the placebo elixir, and were obtained from BioMed Pharmacy in Lansing, Michigan. A child and adolescent psychiatry resident, under the supervision of a board certified child and adolescent psychiatrist, at the Michigan State University Psychiatry Clinic treated all of the participants. Since each child is unique, varying doses are often required (American Academy of Child and Adolescent Psychiatry, 2009). While the psychiatry resident decided medication doses, the Michigan State University - Investigational Review Board (MSU-IRB)

required a dose range be specified apriori to ensure optimum patient safety. Through consultation with experts in the psychiatry department, the MSU IRB approved a dose range of 2.5 mg/day to 20 mg/day. Based on his expertise, the study psychiatrist prescribed 10 mg/day as the introductory dose and 20 mg/day as the therapeutic dose for all participants. The initial dose (10 mg/day) was provided for two weeks, starting when children began the treatment phase of their randomized condition. After two weeks on the introductory dose, the psychiatrist increased to a therapeutic dose (20 mg/day) for all children.

During week 10 of the study, the psychiatrist and the project coordinator/assistant began to discuss end of treatment options with the families. Parents were encouraged to identify a provider that was able to continue treatment at the end of the study. To assist in this search, families were informed about various options for continued treatment, and provided with phone numbers to experienced practitioners.

End of treatment phase. Several data collection tasks were completed during the end of treatment phase (see Table 9). This phase began for each participant at the last medication management meeting, after week 15 of treatment and after the regular data collection tasks were completed for the bi-weekly medication management meeting. During this meeting, the TEQ-P and the End of Study form were completed.

Experimental Design

A randomized non-concurrent multiple baseline single-case design was used to answer the research questions. This study was single blind, as the prescribing psychiatrist was aware of the treatment schedule and prescribed the medication. This specification was necessary, as the psychiatrist determined the dose of fluoxetine for each child based on unique individual characteristics. Five treatment schedules were determined apriori, and varied based on when

children received the placebo or fluoxetine treatment. The five participants were randomly assigned to one of these treatment schedules once enrolled in the study (see Table 10). While the first child to enroll in this study (i.e., Child R) was assigned to treatment schedule three at the start of the study, the family did not return the rating forms for the last several weeks of the study despite multiple attempts to collect them. Therefore, when a parent of a set of twins with selective mutism symptoms became interested after four participants had already been recruited, this treatment schedule was re-opened for random assignment (i.e., Child Three). It was intended that both children who received this treatment schedule be included in the data analysis. However, Child R did not establish consistent baseline trends and already was engaging in the desired behaviors at a frequent rate. Therefore, she was subsequently removed from the analyses per the guidelines of Watson and Workman (1981) and Christ (2007).

Data Analysis

Multi-gate analysis. In order to determine if fluoxetine was effective for the treatment of social anxiety and speaking behaviors, a multi-gate analysis approach consisting of the Kratochwill and colleagues (2010) visual analysis procedure, the Wampold and Worsham (1986) randomization test, and the Tau-U effect size was used to analyze parent DBRs of social engagement and speaking behaviors with unfamiliar adults. Of note, selective serotonin reuptake inhibitors have a delayed effect on behavioral outcomes; however, research suggests 90% of individuals experience positive changes in symptomology within the first two weeks of treatment (Mitchell, 2006). Therefore, an acquisition period of two weeks of the therapeutic dose of medication was factored into the analysis, meaning data collected during the introductory dose and first two weeks of the therapeutic dose of fluoxetine treatment were not included in visual or statistical analysis.

The analysis procedure included three gates. If one step did not indicate significant results, the remainder of the procedure was discontinued. First, two project assistants using the Kratochwill and colleagues (2010) guidelines for visual analysis reviewed each graph to determine if there was an improvement in symptomology using the Visual Analysis Decision Tree (see Appendix V). If raters disagreed regarding a response to treatment for a child on an outcome measure (i.e., social engagement), the project coordinator made the final decision. Inter-rater reliability between the project assistants was calculated using Cohen's Kappa and indicated moderate agreement ($\kappa = 0.53$, $p = .04$). Ultimately, the project coordinator had to make the final decision for three cases (i.e., social engagement: n=1; responsive speech: n = 2). If there was evidence of at least a moderate effect based on the Kratochwill and colleagues guidelines (i.e., three replications with one or more incident of contradicting evidence), significance was assessed at the $p \leq .05$ level using the Wampold and Worsham (1986) randomization test. The Wampold and Worsham technique requires that there be no missing data at time points when children switch from the baseline to treatment phase. However, raters failed to complete some scheduled assessments. For example, on Direct Behavior Ratings of social engagement and speaking behaviors, which were the primary outcome measures, completion rates varied. Adherence for DBR ratings ranged from 62% to 98% for primary raters (i.e., mothers). Overall, completion rates for DBRs completed by the primary raters across the baseline phase (i.e., 93%) and treatment phase (i.e., 94%) were consistent. See Table 11 for a summary of completion rates by measure and rater. To account for missing data at critical time points during the Wampold and Worsham (1986) analysis, the conservative approach of averaging the previous and following

Table 11

Percent Completion Rate of Data Forms per Observer.

	Baseline	Treatment	DBR	MASC-2	SEFCA	P-YMRS	SMQ	CGI	TIF
Child One									
Mom	98%	99%	98%	97%		100%	100%	100%	100%
Teacher	28%	39%	45%					35%	
Psychiatrist	66%	50%			56%			56%	
Child Two									
Mom	94%	96%	98%	93%		100%	97%	97%	100%
Teacher	39%	71%	59%					63%	
Psychiatrist	66%	83%			78%			78%	
Child Three									
Mom	100%	97%	96%	97%		100%	100%	100%	100%
Teacher	43%	57%	53%					37%	
Psychiatrist	66%	50%			56%			56%	
Child Four									
Mom	74%	89%	62%	93%		90%	93%	93%	100%
Dad	67%	92%	73%					90%	
Psychiatrist	100%	100%			100%			100%	
Child Five									
Mom	99%	89%	91%	97%		97%	100%	97%	100%
Dad	6%	16%	20%					27%	
Psychiatrist	100%	100%			100%			100%	

data points of the missing data point was employed. Data points only needed to be estimated for parent DBRs of responsive speech with unfamiliar adults (n = 4). If the randomization test indicated significant results, the Tau-U effect size measure was calculated to quantify the impact of treatment, with a large effect (i.e., Tau-U $\geq$ 0.50) considered as evidence for improvement.

Question one. The multi-gate analysis procedure was used to determine if changes occurred across the baseline and intervention phases on parent completed DBRs of social engagement with unfamiliar adults. An examination of the standard deviation across parent ratings during the baseline phase demonstrated minimal variability (SD =1.72), indicating the parent ratings of social engagement were a reliable measure of social anxiety. In addition to the multi-gate procedure, the means of several supplementary assessments (i.e., DBRs, CGI, MASC-2: SAS) completed by parents, teachers, and/or the psychiatrist were calculated to gain additional insight into the effect of fluoxetine on social anxiety symptoms in children diagnosed with selective mutism (see Table 12).

Question two. In order to determine if fluoxetine treatment increased speaking behaviors, the multi-gate analysis procedure was used to identify changes in parent DBRs of responsive and spontaneous speech with unfamiliar adults. An examination of the standard deviation for DBRs across participants during the baseline phase for responsive speech (SD = 1.72) and spontaneous speech (SD = .66) indicated these ratings were reliable. To provide additional information of the impact of fluoxetine on speaking behaviors, means of supplementary assessments (i.e., DBRs, SMQ, CGI, Diagnostic Interview) completed by parents, teachers, and/or the psychiatrist were calculated (see Table 13 and 14).

Question three. In order to examine adverse events, a descriptive analysis of parental reports on the adapted SEFCA was conducted. This analysis focused on the types (e.g., nausea,

irritability, behavioral disinhibition) and intensity of side effects reported. Next, descriptive statistics regarding CGI Severity of Side Effect ratings provided throughout the study by the parents and study psychiatrists were examined. In addition, a mean parent rating and a mean psychiatrist rating were calculated. For the purposes of calculating the mean outcome, a rating of "0 - no positive or negative changes" will be entered into the equation as a "4 – positive and negative changes are approximately equal" instead of a "0" as listed on the Clinical Global Side Effect Scale to prevent skewing the ratio in a positive direction if no changes were noted. A mean rating of 3 (i.e., "Positive changes outweigh negative changes. Medication effects are overall somewhat positive"), was used to determine a positive risk to benefit profile.

Question four. In order to ensure that possible improvements in selective mutism symptoms were not the result of behavioral disinhibition, which is a common side effect of SSRI treatment in children, responses on the P-YMRS were analyzed individually. Item responses that reflect the possible development of behavioral disinhibition have been highlighted in Appendix O. Positive reports of behavioral disinhibition were examined to determine if they occured primarily when a child is showing improvement in social anxiety, responsive speech, or spontaneous speech.

Question five. In order to assess parental acceptability of the fluoxetine treatment, parent answers on the Treatment Evaluation Questionnaire were examined. Previous research has determined a score of 55 on this scale to be interpreted as high acceptability (Kratochwill et al., 2003). Therefore, parent scores of 55 or higher were used as the criterion to determine if parents found the fluoxetine treatment acceptable for the child with selective mutism. Additionally, descriptive statistics of medication compliance were calculated to determine the feasibility of the intervention for families.

Table 12

Means of Social Anxiety Symptom on Outcome Measures Across Baseline and Treatment Phases

Measure	Possible Ratings	Baseline (SD, Range)	Intervention (SD; Range)
DBR	0 (Never) – 10 (All of the Time)		
Mother (Adults)		1.13 (1.72, 0-10)	2.96 (2.84, 0-9)
Mother (Friends)		5.7 (3.8, 0-10)	5.7 (3.02, 1-10)
Teacher (Teacher)		4.04 (3.46, 1-9)	8.01 (5-9)
Teacher (Students)		5.77 (2.34, 3-9)	8.42 (6-10)
MASC-2: SAS	0 (Absent) – 27 (Severe)	23.82 (2.31, 21-27)	23.95 (2.76, 19-27)
CGI – Anxiety Severity	1 (Absent) – 5 (Severe)		
Mother (Home)		1.71 (1.01, 1-2)	1.38 (.46, 1-2)
Mother (Community)		3.92 (1.07, 3-5)	2.46 (.85, 2-4)
Teacher		3.92 (.35, 3-4)	2.28 (.44, 2-3)
Psychiatrist		4 (0, 4)	3.72 (.97, 3-4)
CGI – Shyness Severity	1 (Absent) – 5 (Severe)		
Mother (Home)		1.06 (.28, 1-2)	1 (0, 1)
Mother (Community)		4.12 (.40, 4-5)	3.2 (.89, 3-5)
Teacher		3.92 (.35, 3-4)	2.68 (.44, 2-3)
Psychiatrist		4.3 (.26, 4-5)	3.73 (.97, 3-4)
CGI – Anxiety Change			
Mother	1 (Much Improved) – 7 (Much Worse)	3.88 (.31, 3-4)	2.49 (.83, 1-4)
Teacher	1 (Much Improved) – 5 (Much Worse)	2.58 (.53, 2-3)	1.58 (.50, 1-2)
Psychiatrist	1 (Much Improved) – 7 (Much Worse)	4 (0, 4)	2.83(.74, 2-4)
CGI – Shyness Change			
Mother	1 (Much Improved) – 7 (Much Worse)	3.88 (.31; 3-4)	2.73 (.69, 2-4)
Teacher	1 (Much Improved) – 5 (Much Worse)	2.58 (.53, 2-3)	1.5 (.51, 1-2)
Psychiatrist	1 (Much Improved) – 7 (Much Worse)	4 (0, 4)	3.33 (.53, 3-4)

Note: Adapted from Carlson (1997)

Table 13

Direct Behavior Ratings – Mean Speaking Behaviors Across Baseline and Treatment Phases

Condition	Baseline (SD; Range)	Intervention (SD; Range)
Responsive Speech - Friends/Students		
Mother (Primary)	5.58 (3.83, 0-10)	7.18 (2.97, 1-10)
Teacher	4.15 (3.78, 0-9)	6.63 (3.26, 0-9)
Spontaneous Speech - Friends/Students		
Mother (Primary)	5.06 (4.02, 0-10)	6.22 (3.2, 0-10)
Teacher	2.11 (1.74, 0-6)	5.05 (2.9, 0-10)
Responsive Speech – Unfamiliar Adults/Teacher		
Mother (Primary)	0.71 (1.72, 0-10)	2.61 (2.75, 0-10)
Teacher	3.15 (4.09, 0-9)	5.19 (3.02, 0-9)
Spontaneous Speech – Unfamiliar Adults/Teacher		
Mother (Primary)	0.08 (.66, 0-5)	0.81 (1.59, 0-8)
Teacher	0.96 (1.15, 0-3)	3.58 (3.27, 0-9)

Table 14

Means of Supplementary Selective Mutism Outcome Measures Across Baseline and Treatment Phases

Measure	Possible Ratings	Baseline (SD; Range)	Intervention (SD; Range)
SMQ			
Home/Family	0 (Severe) – 16 (Absent)	9.81 (2.49, 4-12)	12.07 (1.81, 7-14)
Social Situations	0 (Severe) – 14 (Absent)	0.82 (1.03, 0-3)	1.59 (1.27, 0-8)
Interference/Distress	0 (Extreme Interference) – 18 (No Interference)	2.29 (2.19, 0-5)	4.36 (3.9, 0-11)
CGI - SM Severity	1 (Absent) – 5 (Severe)		
Mother		4.52 (.49, 4-5)	3.76 (.88, 2-5)
Teacher		4.5 (.71, 4-5)	2.8 (.65, 2-4)
Psychiatrist			
School		4.35 (.49, 4-5)	3.85 (.32, 3-4)
Home		1.4 (.42, 1-4)	1.6 (.67, 1-3)
Clinic		4.5 (.51, 4-5)	4 (0, 4)
Peers		4 (0, 4)	3.83 (.42, 3-4)
Overall		4 (0, 4)	3.8 (.32, 3-4)
CGI – SM Change			
Mother	1 (Much Improved) – 7 (Much Worse)	3.89 (.37, 3-4)	2.75 (1.06, 1-4)
Teacher	1 (Much Improved) – 5 (Much Worse)	2.83 (.42, 2-3)	1.83 (.31, 1-2)
Psychiatrist	1 (Much Improved) – 7 (Much Worse)		
School		4 (0, 4)	3.2 (.71, 2-4)
Home		3.9 (.29, 3-4)	3 (1.05, 1-4)
Clinic		4 (0, 4)	3. 4 (1.07, 1-4)
Overall		4 (0, 4)	3.56 (.53, 3-4)

Note: Adapted from Carlson (1997).

CHAPTER 4

RESULTS

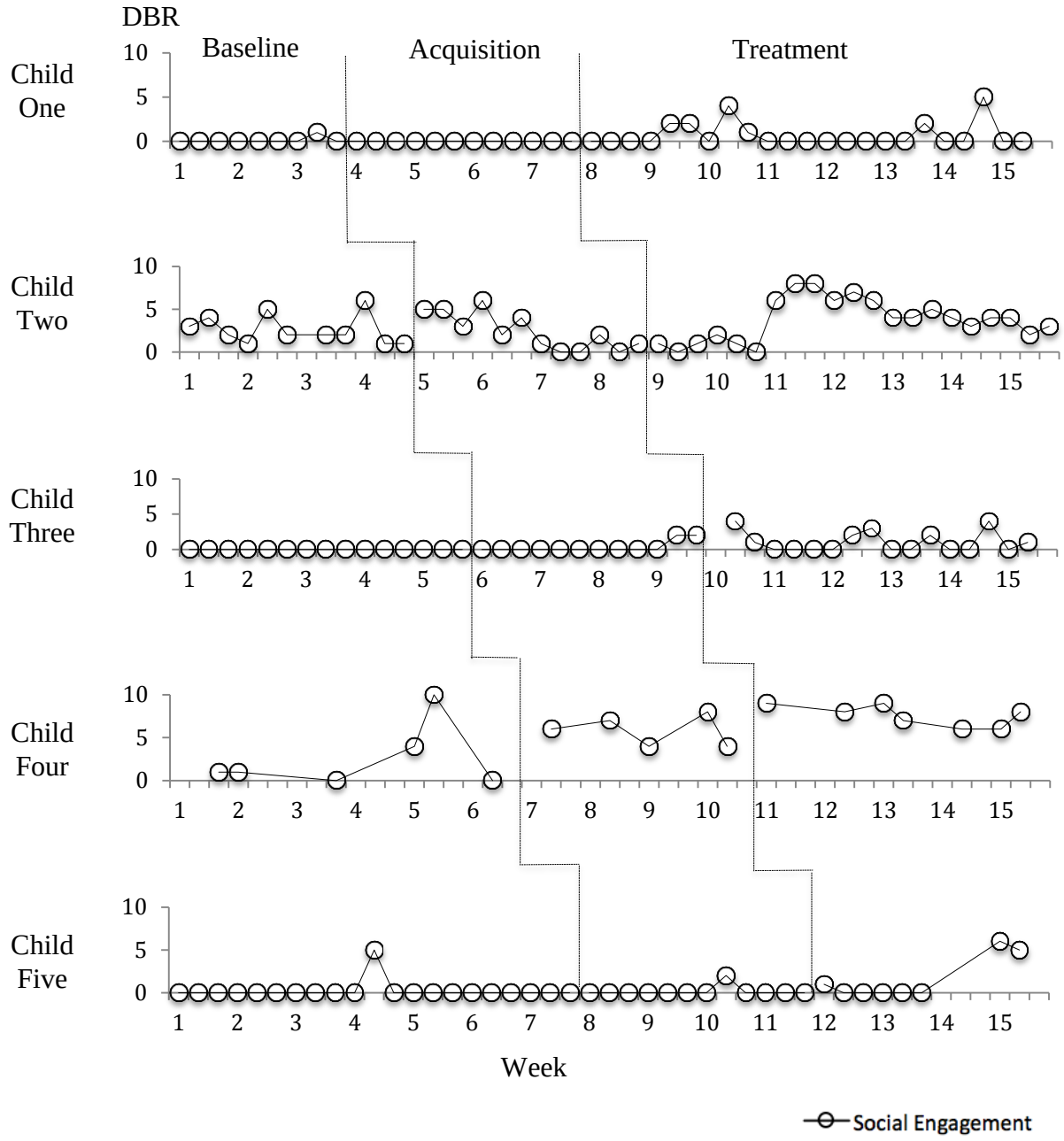
Question One

Will fluoxetine treatment lead to a significant reduction in social anxiety symptoms between the baseline/placebo phases and the treatment phase in five children diagnosed with selective mutism involving elevated levels of social anxiety symptoms?

As a group, fluoxetine did not lead to a significant reduction in social anxiety symptoms for the five children in this study. Visual analysis of parent DBR ratings of comfortable social engagement with unfamiliar adults indicated there were changes in level, trend, variability, overlap, immediacy of effect and consistency after the onset of fluoxetine treatment for only one of the five participants (i.e., Child Three; see Figure 3). Raters indicated the remaining four participants did not show improvement because of contradictory evidence in the domains of slope (i.e., Child One, Child Two, Child Four), mean (Child Five), and immediacy of effect (Child One). Although children were rated as not improving via visual analysis, the Wampold and Worsham (1986) randomization test was still performed due to the less than optimal reliability between the raters performing visual analysis. The randomization test confirmed there was no improvement in social engagement with unfamiliar adults across participants after the onset of the fluoxetine treatment (p=.38). Supplementary ratings on the MASC-2 indicated similar results, with baseline (M= 23.82, SD=2.31) and treatment (M=23.95, SD=2.76) means across participants remaining stable. Overall psychiatrist ratings of improvement indicate similar findings with a mean rating of 4 (SD=0) during the baseline phase and 3.73 (SD=.97) during the intervention phase on the CGI – Anxiety Severity scale. For an overview of DBR ratings and supplementary measures provided by parents, teachers, and the psychiatrist, see Table 12.

Figure 3

Parent DBR - Social Engagement with Unfamiliar Adults by Week



Baseline = No Medication (Week One) and Placebo
Acquisition =Introductory Dose (10 mg/day, Two Weeks); Therapeutic Dose (20 mg/day; Two Weeks)
Treatment= Therapeutic Dose (20 mg/day)

Note: Baseline/Intervention administered non-concurrently across participants.

Question Two

Will the fluoxetine treatment increase the frequency of spontaneous speech and responsive speech across the baseline/placebo phases and the treatment phase in five children diagnosed with selective mutism involving elevated levels of social anxiety symptoms?

Fluoxetine treatment resulted in a significant improvement in responsive speaking behaviors; however, the effect of the treatment was not as large as hypothesized. Visual analysis revealed three of the participants experienced improvements in responsive speech consistent with the onset of fluoxetine in level, trend, variability, overlap, immediacy of effect and consistency (see Figure 4). Two of the children were deemed non-responders because of a lack of immediacy of effect (i.e., Child One) and no change in mean (i.e., Child Five). Given three replications of the treatment effect were identified, there is moderate visual evidence for improvement as a group. The Wampold and Worsham (1986) randomization technique indicated the improvement in responsive speech was significant ($p=.03$). However, calculation of the Tau-U effect size indicated only a moderate improvement (Tau-U = .44; $p <.001$), with a value below the apriori value (i.e., Tau-U=.50) set to identify a substantial improvement.

Fluoxetine treatment did not lead to a significant improvement in spontaneous speaking behaviors. Visual analysis of parent DBR ratings of spontaneous speech with unfamiliar adults indicated changes in level, trend, variability, immediacy of effect, overlap and consistency after the onset of fluoxetine treatment for only two participants (Child Three and Child Four; see Figure 4), indicating there were not enough replications to identify a treatment effect. Three of the children were determined to be non-responders because raters perceived unexpected outcomes in slope (i.e., Child One, Child Two), mean (i.e., Child Five), and immediacy of effect (i.e., Child One, Child Two, Child Five) from the baseline to treatment phases. Although there

was not enough evidence to indicate a treatment effect using the guidelines provided by Kratochwill and colleagues (2010), the Wampold and Worsham (1986) test was used to identify the possibility of a significant change in spontaneous speaking behaviors due to the less than optimal reliability between visual analysis raters. The randomization test confirmed that there was not a significant change in spontaneous speaking behaviors for all five children across the baseline and treatment phases (p=.10).

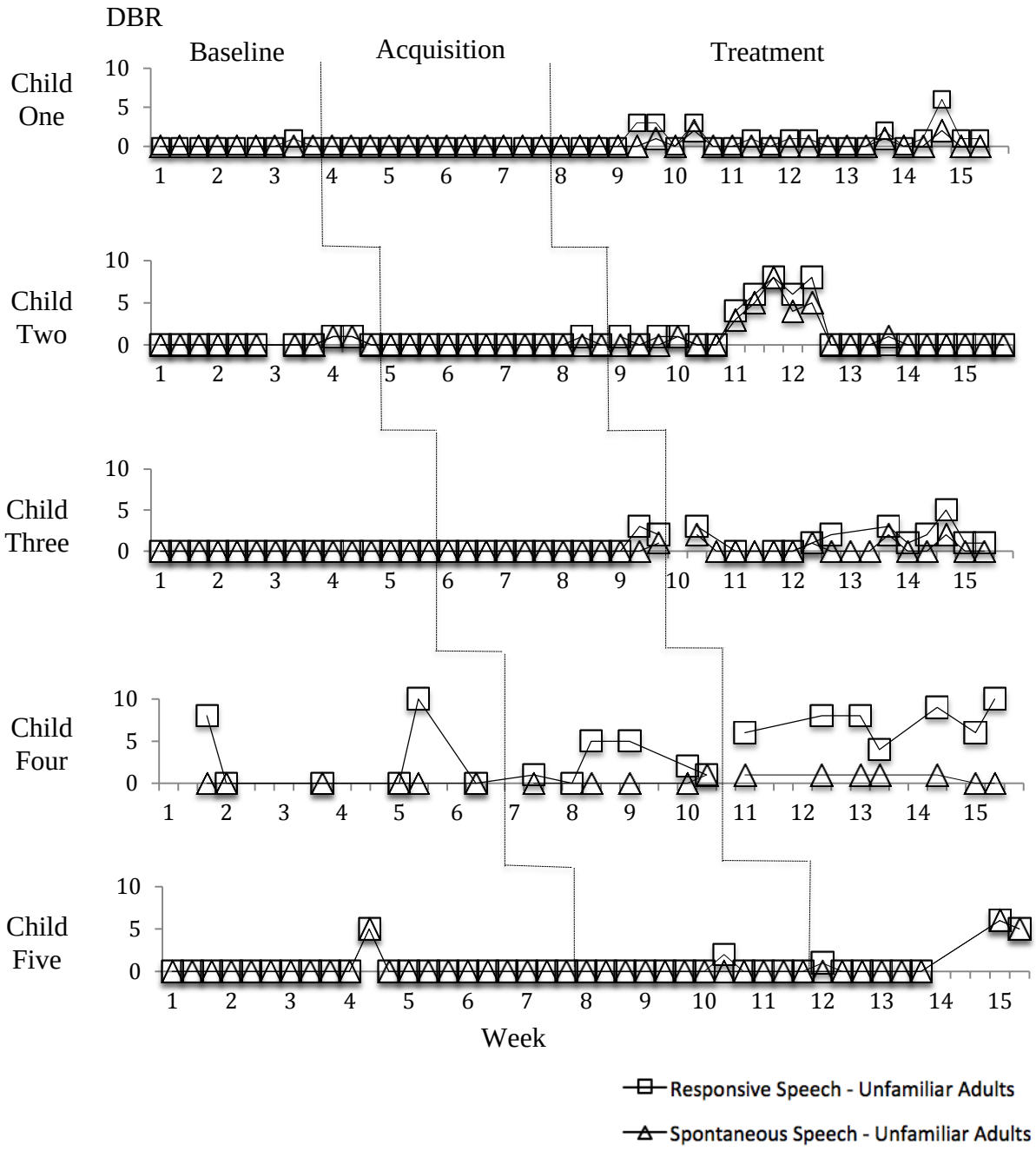
Despite improvements in responsive speech, all children continued to meet DSM-5 criteria for selective mutism at the end of the study. While there was no significant improvement in spontaneous speaking behaviors, supplementary ratings indicated improvements in unspecified (i.e., not responsive or spontaneous) speaking behaviors from the placebo phase to the treatment phase. On the SMQ parents perceived an overall improvements from baseline to treatment phase for speaking behaviors at home with family (Baseline: M=9.81, SD=2.49; Treatment: M=12.07, SD=1.81) and in social situations (Baseline: M=0.82, SD=1.03; Treatment: M=1.59, SD=1.27). The study psychiatrist saw a similar improvement in overall mutism symptoms as rated on the CGI-Mutism when comparing baseline ratings (M=4, SD=0) to intervention ratings (M=3.56, SD=.53). For an overview of scores on Direct Behavior Ratings as well as additional supplementary ratings for speaking behaviors provided by teachers, parents, and the child psychiatrist, see Tables 13 and 14.

Question Three

What adverse side effects, if any, will children experience during the fluoxetine treatment? Is there a positive risk to benefit profile for children taking fluoxetine for selective mutism?

Figure 4

Parent DBR – Spontaneous and Responsive Speech with Unfamiliar Adults by Week



Baseline = No Medication (Week One) and Placebo
Acquisition =Introductory Dose (10 mg/day, Two Weeks); Therapeutic Dose (20 mg/day; Two Weeks)
Treatment= Therapeutic Dose (20 mg/day)

Note: Baseline/Intervention administered non-concurrently across participants.

According to the psychiatrist completed SEFCA, none of the participants experienced adverse events during the fluoxetine treatment. As a group, parents perceived more positive than negative changes during the fluoxetine phase (M=2.12, SD=.83). Further, the study psychiatrist also perceived a positive benefit to risk ratio (M$= 2.43, SD = 1.09$; see Table 15).

Table 15

CGI – Means of Global Side Effect Ratings

	Baseline (SD; Range)	Intervention (SD; Range)
Child One		
Mother	4 (0, 4)	2.13 (.81, 1-3)
Psychiatrist	4 (0, 4)	1 (0, 1)
Child Two		
Mother	2.5 (1.6,1-4)	1.38 (.50, 1-2)
Psychiatrist	4 (0, 4)	2.5 (.71, 2-3)
Child Three		
Mother	4 (0,4)	2 (.85, 1-3)
Psychiatrist	4 (0, 4)	2 (0, 2)
Child Four		
Mother	3.9 (.33, 3-4)	1.6 (.73, 1-3)
Psychiatrist	3.75 (3-4)	2.67 (.58, 2-3)
Child Five		
Mother	4 (0, 4)	3.5 (.53, 3-4)
Psychiatrist	4 (0, 4)	4(0, 4)

Question Four

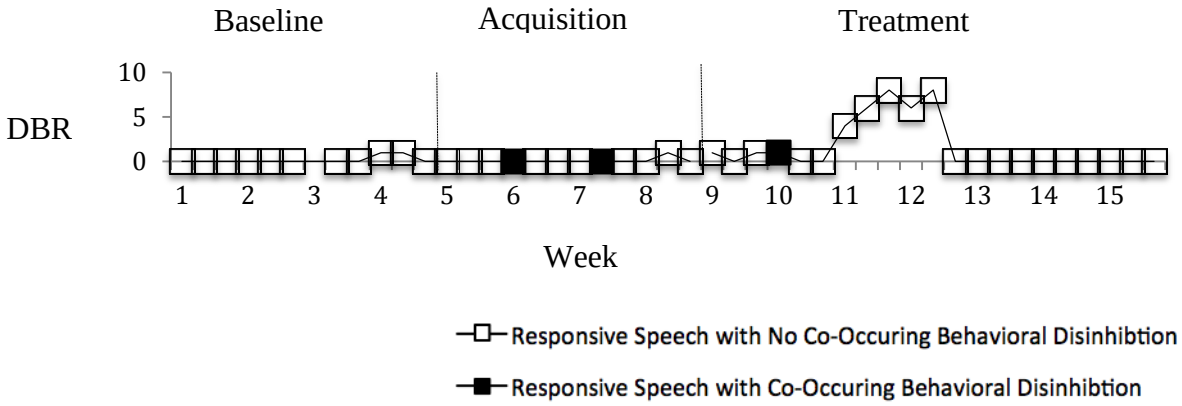
Does onset of active fluoxetine medication correspond with an increase in behavioral disinhibition?

The onset of active fluoxetine medication did correspond with incidents of behavioral disinhibition for two participants as rated by parents on the P-YMRS (Child Two and Child Three). These two children were also noted to have improved in at least one domain of selective mutism symptomology. Despite this finding, visual inspection indicated improvements in

selective mutism symptomology did not solely correspond to the onset of behavioral disinhibition (see Figures 5 and 6).

Figure 5

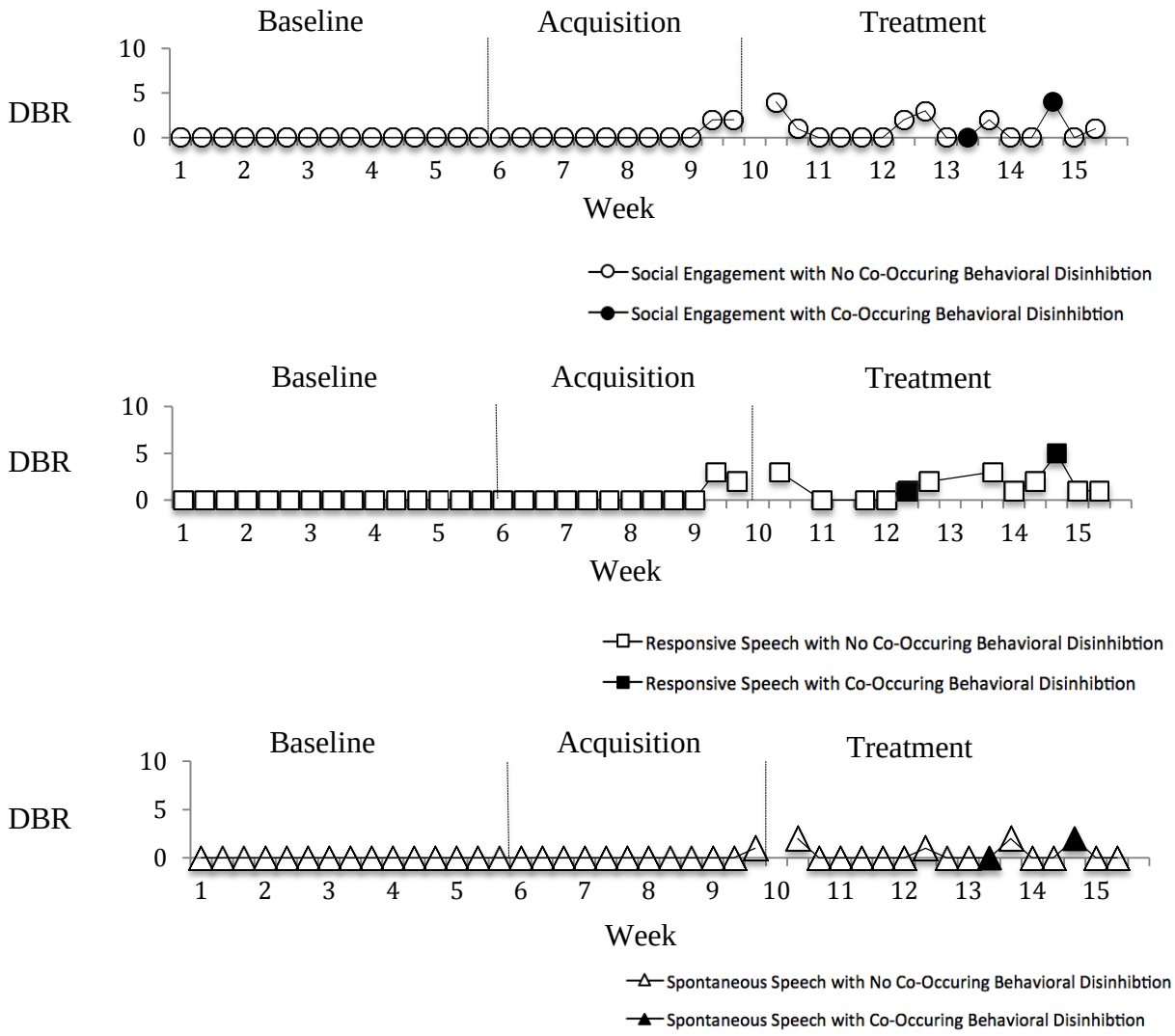
Child Two: Parent DBR Rating of Responsive Speech with Unfamiliar Adults and Onset of Behavioral Disinhibition



Baseline = No Medication (Week One) and Placebo
Acquisition =Introductory Dose (10 mg/day, Two Weeks); Therapeutic Dose (20 mg/day; Two Weeks)
Treatment= Therapeutic Dose (20 mg/day)

Figure 6

Child Three: Parent DBR Ratings of Social Engagement, Responsive Speech, and Spontaneous Speech with Unfamiliar Adults and Onset of Behavioral Disinhibition



Baseline = No Medication (Week One) and Placebo
Acquisition =Introductory Dose (10 mg/day, Two Weeks); Therapeutic Dose (20 mg/day; Two Weeks)
Treatment= Therapeutic Dose (20 mg/day)

Question Five

Will parents find the use of fluoxetine for the treatment of selective mutism and social anxiety symptoms acceptable?

Parents found the use of fluoxetine for the treatment of selective mutism and social anxiety symptoms highly acceptable. A score of 55 or higher on the TEQ-P indicates an intervention is highly acceptable (Kratochwill et al., 2003), with the average across raters in this study being 60.6. Four of five parents indicated they "strongly agreed" fluoxetine was an acceptable intervention for the problem behavior, with the parent of Child Four indicating she "agreed" with this statement. All parents "agreed" fluoxetine was effective at addressing the problem behavior. Finally, four of five parents "strongly agreed" fluoxetine did not lead to negative side effects, with the parent of Child Two indicating she "agreed" with this statement. See Table 16 for all ratings across parents.

Parent reported medication compliance data was collected for each child via a daily parent-completed form indicating the time the medication was provided. The study psychiatrist instructed parents to either give the medication in the morning (n=3) or in the evening (n=2) based on each child's individual needs. Parents were considered compliant with the treatment each day if they provided the medication within six hours of the instructed time. Parents provided the medication 82% to 100% of the time during the baseline phase. The parents of Child Two who indicated 82% compliance noted they had forgotten to give the medicine some days. They were encouraged to be consistent with providing the medication, and were informed that SSRIs work over an extended period of time, which requires doses to be provided consistently. During the treatment phase, parents were compliant 98% to 100% of the time (see Table 17).

Table 16

Answers on the TEQ-P Across Participants

Question/Participant	Child One	Child Two	Child Three	Child Four	Child Five	Average
1. This was an acceptable intervention for my child's problem behavior.	6	6	6	5	6	5.80
2. Most parents would find this intervention appropriate for behavior problems in addition to the one described.	6	5	6	5	6	5.60
3. This intervention was effective in changing the problem behavior.	5	5	5	5	5	5
4. I would suggest the use of this intervention to other parents.	6	5	6	6	6	5.80
5. My child's behavior problem was severe enough to warrant use of this intervention.	6	5	6	6	6	5.80
6. Most parents would find this intervention suitable for the behavior problem described.	5	5	5	6	6	5.4
7. The intervention did not result in negative side effects for my child.	6	5	6	6	6	5.80
8. The intervention would be appropriate for a variety of children.	5	5	5	5	6	5.20
9. The intervention was a fair way to handle my child's problem behavior.	5	5	5	6	6	5.4
10. I liked the procedures used in this intervention.	5	5	5	6	6	5.4
11. The intervention was a good way to handle my child's behavior problem.	5	5	5	6	6	5.4
Sum of Ratings	60	56	60	62	65	60.6

Adapted from Carlson (1997) & Eke (2001)

Ratings: 1 (strongly disagree) to 6 (strongly agree); Sum of 55 or higher considered acceptable intervention

Table 17

Medication Compliance Rates per Phase

	Baseline	Fluoxetine
Child One	95 %	99%
Child Two	82%	100%
Child Three	100%	100%
Child Four	94%	100%
Child Five	100%	98%

Individual Improvements

While improvements were only identified as a group in the domain of responsive speech, parents found the intervention highly acceptable. Given the lack of expected results in the other domains, it was deemed important to examine individual improvements in order to account for the high level of acceptability. All children were noted as improving in at least one area. For example, Child One was rated as improving in the domain of responsive speech; however, she was not considered a "responder" due to a lack of immediacy of effect. Visual analysis revealed that Child Two was a responder in the domain of responsive speech. Visual analysis and the Tau-U effect size measure revealed that Child Three was a responder in the domains of social engagement (Tau-U= .44, p=.04) and responsive speech (Tau-U=.75, p=.001), and visual analysis alone indicated Child Three was a responder in the domain of spontaneous speech. Child Four was deemed a responder via visual analysis and the Tau-U effect size in the domains of responsive speech (Tau-U=.99, p=.001) and spontaneous speech (Tau-U=.71, p=.03). Finally, although Child Five was not rated as improving via visual analysis, her mother did report "minimal improvement" on CGI-Shyness and Anxiety ratings at the end of the study. In addition to these indicators of change for individual children, parents and teachers provided feedback and comments on forms and during medication management meetings indicating progress after the onset of fluoxetine treatment (see Table 18).

Table 18

Parent and Teacher Reports of Progress after the Onset of Fluoxetine Treatment

	Sample of Positive Reports
Child One	"Child is much less anxious" "Talked well with a partner" "Increased gesturing in the classroom"
Child Two	"Child ran to the door when the doorbell rang to see who it was instead of running to her room" "Child is more socially involved with her extended family members" "Extended family member heard child speak for the first time" "Child is much less anxious. It's like night and day"
Child Three	"Child is less anxious" "Raising hand (in class) a lot more!" "Overall, I feel Child has made wonderful progress"
Child Four	"Child is much less anxious" "Child is much less nervous to go to school" "Child more easily provides one word answers" "Child no longer experiences stomachaches before school"
Child Five	"Child is less anxious than before the study" "Child is socializing more at school"

CHAPTER 5

DISCUSSION

The findings and implications of this multiple-baseline single-case design study are summarized below and discussed in the context of previous research. The results of this study shed light on the effectiveness of fluoxetine for the treatment of selective mutism in children and adolescents. While generalizability is limited, the outcomes can significantly inform future research and may provide some insight for practicing mental health clinicians. There are many questions regarding psychopharmacological treatments for children with selective mutism that are unanswered. The findings from this study are small steps towards answering these questions by demonstrating how some symptomology changes occurred or did not occur in correspondence with the active medication treatment.

Fluoxetine Treatment for Associated Social Anxiety

Visual analysis revealed there was not an improvement in social anxiety with unfamiliar adults across the baseline and fluoxetine phases. Given findings from previous research, it was surprising there were not significant improvements in social anxiety symptomology. Previous research has documented positive improvements in social anxiety symptoms in children with and without selective mutism in response to treatment with fluoxetine and other SSRIs. However, in these studies, there were also children who did not benefit from treatment. For example, in an open label study with 21 children, Dummit and colleagues (1997) found that 76% of children with selective mutism experienced a reduction in social anxiety symptoms when treated with fluoxetine. In a study examining the use of fluoxetine for anxiety disorders non-specific to selective mutism, Birmaher and colleagues (2003) found that 61% of children improved while

taking fluoxetine, which was statistically significant when compared to the response of a placebo group.

It is possible that children in this study may have needed higher doses to obtain a more optimal response. In children with obsessive-compulsive disorder, the FDA has approved doses up to 60 mg/day (Eli Lilly and Company, 2011). In the Dummit and colleagues study (1997) doses as high as 60 mg/day were prescribed to some participants with selective mutism, with higher doses prescribed to older children. Potentially, the dose of fluoxetine used in this study may have been too conservative for each participant to achieve a substantial gain in social anxiety symptomology. Additionally, all children in this study were resistant to psychosocial treatments according to their pracitioners and have exhibited symptoms of social anxiety for a long period of time. Children with severe selective mutism symptomology that has persisted for years may need a more aggressive psychopharmacological approach. While not fully examined in the anxiety literature for children, there are examples of those with severe depression symptoms needing higher doses of SSRIs (Montgomery, Rasmussen, Lyby, Conner, & Tanghosj, 1992).

Contradictive to the findings in this study, previous SSRI studies conducted with children with selective mutism and elevated social anxiety symptoms and those with social anxiety disorder alone have noted improvements for children on measures of social anxiety. However, in these studies children received treatment for longer periods of time. In this study, children received a therapeutic dose of the medication for six to ten weeks. In prior fluoxetine studies using a double-blind design to examine the effectiveness of fluoxetine on social anxiety symptoms, children received treatment for 12 weeks (Birmaher et al., 2003; Black & Uhde, 1994). However, prior research suggests that some responses to SSRIs should be seen by at least

4 to 6 weeks (Garfield et al., 2004), with some studies suggesting that 90% of individuals given an SSRI show a response within two weeks (Mitchell, 2006). Given the children in this study have been experiencing social anxiety symptomology for many years, more time may have been needed to identify more substantial improvements in functioning. Timing of the onset of fluoxetine treatment based on the severity of symptomology has not been studied in children with any anxiety diagnosis. However, research suggests that regardless of the severity of symptoms, 75% of adults treated for depression with fluoxetine exhibited a response by four weeks of treatment (Nierenberg et al., 2000). Children in this study were taking fluoxetine for four weeks, including the introductory and therapeutic dose phases, suggesting that a response would have been expected at this point. More research into the onset of fluoxetine treatment effects on social anxiety symptoms for children with selective mutism is imperative to help practitioners judge if fluoxetine should be used to treat selective mutism and how long children should be provided with the medication before changing the intervention approach.

Fluoxetine Treatment for Speaking Behaviors

Selective mutism is currently listed as an anxiety disorder in the recently published DSM-5 (APA, 2013). Previous research has demonstrated that selective mutism almost always occurs comorbidly with symptoms of social anxiety (Black & Uhde, 1994; Dummit et al., 1997). Furthermore, in an examination of comorbid psychopathology experienced by children with selective mutism, social anxiety was the only abnormal characteristic consistent within the sample (Black & Uhde, 1992). The joint biopsychosocial framework of social anxiety and selective mutism put forth by Carlson and colleagues (2008) theorized that that the etiological underpinnings of social anxiety and selective mutism include both biological (e.g., autonomic symptoms) and psychosocial factors (i.e., social skills; see Figure 1). Therefore, in this study, an

intervention targeting the hypothesized underlying biological cause of social anxiety (i.e., serotonin system) was introduced to lower social anxiety symptoms. It was hypothesized that speaking behaviors would increase in conjunction with a decrease in social anxiety. Since non-significant outcomes were noted for social anxiety symptoms, improvements in speaking behaviors were not expected. However, results indicated that fluoxetine led to a significant improvement in responsive speech.

Previous research has also identified improvements in speaking behaviors with fluoxetine treatment; however, these studies possessed weaknesses. In an open label study that did not include a control group, Dummit and colleagues (1997) found that 76% of their sample (n = 21) exhibited an increase in speech production after treatment with fluoxetine, as indicated by CGI ratings. Black and Uhde (1994) conducted a small-randomized control trial with six children receiving active fluoxetine medication and nine children receiving placebo. Analogous to the findings of Dummit and colleagues (1997), Black and Uhde (1994) found parents of children who received fluoxetine rated mutism behaviors as improved on the CGI; however, results were limited due to the small sample size for the data analysis procedure. In addition to these two studies, a handful of case studies have also noted increased speech in children treated with fluoxetine (Boon, 1994; Guna-Dumestrica & Pelletier, 1996; Harvey & Milne, 1998; Rupp, 1999; Silveira et al., 2004; Wright, 1995). The current study contributes additional evidence to the phenomenon of fluoxetine increasing speaking behaviors, and adds to these previous findings, as the type of speech (i.e., responsive), and with whom the speech was occurring was specified (i.e., unfamiliar adults).

The finding that responsive speaking behaviors improved without changes in social anxiety symptomology highlights a potentially complicated relationship between social anxiety

and selective mutism. Two schools of thought regarding this relationship are predominant in the literature. First, Black and Uhde (1995) suggested that selective mutism might be an extreme form of social anxiety, noting that the anxiety is so severe in these children that it prevents a child from speaking during a social situation. In contrast, children only experiencing social anxiety disorder have anxiety in social situations, but not enough to prevent speech. Second, Mannasis and colleagues (2003) postulated that selective mutism is similar to social anxiety disorder, but unique etiological factors (e.g., speech problems, social skills) have resulted in the refusal of speech as a way to cope with the anxiety. This theory is supported by their research indicating similar levels of social phobia in children diagnosed with social anxiety disorder and children diagnosed with selective mutism. A recent review completed by Muris and Ollendick (2015) highlighted the lack of longitudinal research investigating the etiological origins of selective mutism. The authors noted that it is important that selective mutism be classified as an anxiety disorder given the consistent findings that these children experience heightened levels of anxiety, but stressed the lack of understanding of the relationship between social anxiety and selective mutism. One possibility is that selective mutism is a specific phobia of expressive speech in certain situations and with unfamiliar people (Omdal & Galloway, 2008). Therefore, children with selective mutism are not afraid of being around or engaging non-verbally with others, but are afraid of speaking or being required to speak in these social interactions. Here, an improvement in speaking might be observed if an SSRI treatment were to lower anxiety associated with expressive speech.

Delineating between responsive and spontaneous speech is essential in selective mutism treatment studies. Spontaneous speech has been deemed a better indicator of progress, as it is considered speech that is intended to communicate (Pionek Stone et al., 2002). Conceptually,

the notion children may first begin engaging in responsive speech after the onset of treatment before engaging in spontaneous speech makes sense. For example, effective behavioral treatment for selective mutism focuses on systematic desensitization of anxiety provoking speaking situations (Pionek Stone et al., 2008), where less anxiety provoking behaviors are engaged in first followed by more difficult behaviors. Here, it is possible that the fluoxetine treatment impacted anxiety surrounding speaking behaviors just enough to allow children to provide a brief response, but did not lower the anxiety enough for children to engage in conversation using spontaneous speech. Given the relatively low dose of medication and shortened treatment time compared to previous studies (i.e., Black & Uhde, 1994; Dummit et al., 1997) it is possible that children may have displayed spontaneous speaking behaviors if they received a higher dose of the medication or were treated for a longer period of time. Second, it is possible that the fluoxetine treatment was impacting the serotonin system in another unknown way other than reducing anxiety symptomology. Given that serotonin receptors are widespread throughout the brain (Stahl, 1998), it may be difficult to untangle the unintended ways fluoxetine may be impacting speaking behaviors. Future research should continue to explore this issue.

Behavioral Disinhibition and Other Adverse Events

Previous studies have noted rapid improvements in speaking behaviors for children with selective mutism after the onset of treatment with an SSRI. To explain this phenemenon, researchers have suggested that the unintended side effect of behavioral disinhibition may be playing a role in the improvement of speech instead of the intended anxiety reduction mechanism (i.e., Carlson, 1999). Carlson and colleagues (2008) noted that researchers should examine the potential that behaviors associated with behavioral disinhibition are mimicking an improvement in symptomology of selective mutism symptoms. For example, children who are experiencing

behavioral disinhibition may take more risks, such as yelling out in class or interrupting the games of other children. To the untrained eye, these behaviors may look like a reduction in social anxiety, while they are a display of increased inappropriate risk taking behaviors. It was hypothesized that children in this study would not experience behavioral disinhibition, as it is a relatively rare side effect of treatment with selective serotonin reuptake inhibitors (Wilens et al., 2003). However, one child who experienced improvement in responsive speech and one child who was rated as improving in social engagement, responsive speech, and spontaneous speech experienced symptoms indicative of behavioral disinhibition for brief periods of time. Although the occurrences of behavioral disinhibition in the current study were brief, they were interestingly timed right before a rapid improvement in in responsive speech for one child. Additionally, they occurred during the highest positive ratings in social engagement, responsive speech, and spontaneous speech for the other child. There was not enough evidence in this study to indicate that behavioral disinhibition was the cause of improvements in individual children; however, future studies should continue to examine the potential relationship between behavioral disinhibition and improvements in the frequency of speech in children with selective mutism.

Aside from the behavioral disinhibition experienced by two participants, parents of children in this study reported no adverse events during treatment with the active medication. This lends evidence to the notion that fluoxetine is a safe treatment for selective mutism, especially at the doses (i.e., 10 mg/day and 20 mg/day) utilized in this study. Overall, this finding is consistent with previous research examining the use of fluoxetine for selective mutism and other internalizing disorders. For example, Black and Uhde (1994) examined the use of fluoxetine for the treatment of selective mutism in children between the ages of six and 11, finding no statistical difference in adverse events between the placebo group and the treatment

group. In a study examining fluoxetine for internalizing disorders at a dosage of 20 mg/day, Birmaher and colleagues (2003) found a higher prevalence of adverse events, with approximately half of the seven to 17 year old children treated with fluoxetine experiencing gastrointestinal side effects. This was a statistically significant difference from the placebo group. The difference between the low frequency of side effects in this study with a similar dose of medication in the Birmaher and colleagues study may be due to the small sample size in this project. Given all of the side effect data collected in previous clinical trials indicating a small but reliable level of side effects with fluoxetine (FDA, 2011), it is likely there would have been a greater percentage of mild side effects with a larger pool of participants.

Interestingly, Dummit and colleagues (1997) provided evidence indicating fluoxetine is a safe and effective treatment for selective mutism; however, participants in their study experienced more side effects than participants in this project with 19% of children experiencing behavioral disinhibition and another 10% experiencing other side effects such as headaches, insomnia, and or jitteriness. One possible reason for the higher rates of adverse events in the Dummit and colleagues study may be the use of higher doses of fluoxetine (e.g., up to 60 mg/day). However, it should be noted Dummit and colleagues found more robust results with these higher doses. This highlights the delicate balance between finding a dose that is effective for a child with selective mutism while also finding a dose that does not lead to unpleasant side effects (American Academy of Child and Adolescent Psychiatrists, 2009). It also calls into question the possibility that these children were improving based upon symptoms of behavioral disinhibition, instead of the intended anxiety reducing effect of the medication. Overall, parents and the study psychiatrist reported that there were more positive gains than negative side effects on the CGI – Global Side Effect Scale. Therefore, in this study, the risk was low while the

benefit was perceived to be high given parent acceptability ratings; however, it is possible that children may have experienced a more substantial improvement in symptomology from higher doses. Future research should continue to look at the optimal doses for children with selective mutism and the kinds of side effects that are associated with those doses.

Medication Compliance

Medication compliance was high for this study, with compliance equal to or higher than medication compliance reported in previous research studies in child and adolescent psychopharmacology (Hack & Chow, 2001). According to Hack and Chow (2001), psychotropic medication compliance in children and adolescents can be encouraged by several practical methods including: a) establishing a treatment alliance with the family/child; b) providing education on the rationale for the use of the medication; c) minimizing the frequency of providing a dose (e.g., one time per day); d) ensuring the timing and simplicity of the dosing regimen is acceptable to the family; e) ensuring the medication is palatable to the child; and f) minimizing cost. This study utilized all of these methods as a strong rapport was built with families via the project coordinator/assistants and the treating psychiatrist during the screening phase and weekly medication management meetings. Additionally, parents and families were informed about the hypothesized mechanism of action of fluoxetine in the treatment of selective mutism. The fluoxetine only needed to be administered once daily, and was provided to the family in pre-measured weekly bottles. Most children found the mint flavoring of the medication acceptable; however, one did not. This child was provided with suggestions (e.g., take with a spoonful of peanut butter immediately after) to help improve palatability. Additionally, the treatment was provided free of charge to families, further eliminating barriers to compliance.

Other factors promoting treatment feasibility in this study included frequent monitoring of medication compliance at bi-weekly medication management meetings and the desperation of parents to find a treatment that works. Parents were required to bring in forms indicating the time the provided the medication each day. Making parents document the time they provided the medication, and providing performance feedback to parents on a regular basis likely boosted treatment compliance (Hagermoser Sanetti & Kratochwill, 2008). All of the children in this project had failed a previous course of psychosocial treatment. Given selective mutism is a debilitating disorder that affects several areas of a child's life (Bergman et al., 2002; Carbone et al., 2010; Steinhausen & Juzzi, 1996), parents appeared more than willing to comply with treatment recommendations.

Treatment Acceptability

All children experienced some positive changes in symptomology albeit these changes varied across participants. Given each family experienced failed treatments in the past, it makes sense that all parents rated the intervention as highly acceptable. While consistent improvement across all five cases was not as robust as hoped for, all parents reported the requirements of the intervention were highly acceptable. They further reported they believed this intervention was highly acceptable for other children and families. Overall acceptability ratings were higher than previous studies examining the use of sertraline (i.e., Carlson et al., 1999; Eke, 2001) for the treatment of selective mutism symptoms. In this study, parents provided an overall acceptability rating of 60.6, while parents in the Carlson and colleagues (1999) provided an average rating of 58.6 and parents in the Eke (2001) study reporting an average rating of 56.8. This high acceptability rating may be useful for practitioners to share with families of children diagnosed with selective mutism who may benefit from treatment with fluoxetine. Overall, this study

suggests fluoxetine treatment for selective mutism with co-occurring social anxiety symptoms was an acceptable treatment approach according to participants' parents.

Implications for Research

Selective mutism is a severely debilitating disorder with social and academic implications (Bergman et al., 2002). Future research needs to continue to search for effective treatments in order to improve the quality of life for these children, and subsequently improve long-term outcomes. First, research should continue to focus on the relationship between social anxiety and speaking behaviors in children with selective mutism. As noted by Muris and Ollendick (2015), much of the research examining the relationship between social anxiety and selective mutism is cross sectional leaving questions about the relationship between social anxiety and selective mutism unanswered. One possible explanation is that selective mutism is better described as a specific phobia of expressive speech (Omdal & Galloway, 2008). Given the lack of data regarding this relationship as well as the findings from this study that indicate there was an improvement in speaking behaviors without an overall improvement in social anxiety symptoms, more research is needed. Second, more single case design studies need to be conducted to examine the individual changes children experience in response to fluoxetine treatment for selective mutism symptoms. Single case designs have the capability to determine if an intervention effect is observable and important, and can determine if the change in behavior was due to the implementation of an independent variable. Kazdin (1977) stated that the impact of an intervention needs to be both observable and acceptable in order for an intervention to be determined effective. In this study, every child showed improvement in at least one domain, and every parent rated the intervention as highly acceptable. Future single case design studies may better illuminate treatment outcomes by recruiting children who are similar in their current

functioning (i.e., engaging in social interactions but not speaking) and demographic characteristics (e.g., age, gender, socio-economic status), and identifying the effect fluoxetine has across these similar participants. Third, future research needs to focus on the types of speech (i.e., responsive, spontaneous) children engage in during SSRI treatment. This study only noted improvements in responsive speech, which is not considered conversational speech. Finally, future research should focus on the combination of psychopharmacology and behavior therapy to determine how psychosocial treatments can augment psychopharmacological treatments for selective mutism.

Limitations

This study used a single blind, placebo-controlled, non-concurrent multiple baseline design to examine the impact of fluoxetine treatment on symptoms of social anxiety and selective mutism. Parents were required to rate the child's symptoms across several domains. This methodology has several benefits in regards to providing internal and external validity within the study; however, the sole reliance on pre-specified parent observations and ratings for the primary outcome measures across all children is a limitation of this study. Future studies should work to identify an evaluation approach that specifically targets the individual symptom profiles of each of the participants.

To be included in this study, children needed to be resistant to psychosocial treatment according to their prior practitioner for at least 10 to 12 weeks depending on age. Relying on practitioner reports of resistance to psychosocial treatment was a limitation of this study. Data regarding intervention integrity was not provided to the study coordinator or the study psychiatrist. Consequently, it is possible that the interventions provided by these practitioners were not completed with fidelity making it seem like children were non-responders. Future

research on psychopharmacological interventions with children with selective mutism should strive to ensure that children are truly treatment resistant by monitoring the integrity of an evidence-based manualized treatment approach for selective mutism.

The reliance on DBRs as a primary outcome measure is a limitation of this study. Research has demonstrated that DBRs can perform adequately in comparison to SDOs, which are considered the gold standard in observations of problem behaviors. For instance, research has demonstrated that SDOs and DBRs of the same observation periods are highly correlated, and DBRs account for 75% of the variance of SDOs (Riley-Tillman et al., 2008). Despite this, DBR is a relatively new observation approach and more research needs to be conducted regarding their sensitivity to changes in behavior due to treatment. The sole reliance on parents to complete DBRs for the primary outcome variables of social anxiety, responsive speech, and spontaneous speech was also a limitation of this study. Parents are not trained mental health practitioners and, therefore, may not have always reliably reported the observed data. Analyzing teacher data in the same manner as parent data would have added more information regarding selective mutism symptoms across contexts; however, some teachers were not available due to the time of year of the intervention (i.e., summer vacation), thus rendering the sample size too small for any kind of statistical analysis. Systemic direct observations (SDOs) completed by an observer trained in mental health and assessment are the gold standard in documenting treatment outcomes. Despite receiving training in DBRs, it is possible that parents committed observation errors (e.g., observer drift, observer bias) given the lack of mental health and assessment training. While the reliance on parent-completed ratings is a limitation, Chafouleas and colleagues (2012) reported improvements in accuracy on DBRs completed by non-mental-health practitioners after training was implemented. The training parents received in the current study was modeled after the

Chafouleas and colleagues approach. Future studies should strive to involve SDOs conducted by trained mental health practitioners.

The removal of Child R from this study is a limitation and is one of the weaknesses of a non-concurrent multiple-baseline design, as additional time cannot be provided to wait for ratings to stabilize (Christ, 2007; Watson & Workman, 1981). The consistent engagement in the target behaviors according to parent report was unexpected, given the intensive screening process. Although it was not ideal to have to remove this child from the analysis, there were no specific variables that were apparent to the researchers that make this child significantly different from the remainder of the sample.

The use of a single blind and the constraints of the dosing schedule were also limitations. In order for the psychiatrist to be able to adjust doses as necessary in the best interest of the child, a double-blind procedure was not feasible. Although this is the case, there were multiple pieces of data collected from multiple stakeholders. The data from the psychiatrist was viewed in lieu of the data collected from parents and teachers who were not aware of the treatment schedule. The constraints of the dosing schedule (i.e., two weeks of an introductory dose followed by the therapeutic dose) left little flexibility for the study psychiatrist to increase doses to an optimal level. Future single-case design studies examining SSRI treatment for selective mutism may benefit from having an introductory dose, a first therapeutic dose, and then a second therapeutic dose if there is still potential for improvement.

A reason for the lack of a more robust response in social anxiety symptoms may be that more time was need for the fluoxetine treatment to be effective. While some studies report tangible improvements can be obtained within the first week of treatment (Mitchell, 2006), it may take six weeks or longer for some individuals to begin to show an improvement (Garfield et

al., 2004). In a larger scale study of childhood anxiety disorders, approximately two thirds of children responded to 20 mg/day of fluoxetine after four to six weeks of treatment (Birmaher et al, 2003). It is possible that children in this study may have exhibited a more robust response given more time on the therapeutic dose of the medication. Future studies should extend the treatment phase to allow a demonstration of a treatment effect after six to eight weeks of the therapeutic dose.

APPENDICES

Appendix A

Young Mania Rating Scale – Parent Version (Adapted)

Directions: Please read each question below and circle the answer number that best describes your child.

1. **Mood –** ***Is your child's mood higher (better) than usual?***

    A. No
    B. Mildly or possibly increased
    C. Definite elevation – more optimistic, self-confident, cheerful, appropriate to their conversation.
    D. Elevated but inappropriate to content; joking, mildly silly
    E. Euphoric, inappropriate laughter; singing/making noises, very silly

2. **Motor Activity/Energy –** ***Does your child's energy level or motor activity appear to be greater than usual?***

    A. No
    B. Mildly or possibly increased
    C. More animated; increased gesturing
    D. Energy is excessive; hyperactive at times; restless but can be calmed
    E. Very excited; continuous hyperactivity; cannot be calmed

3. **Sleep –** ***Has your child's sleep decreased lately?***

    A. No
    B. Sleeping less than normal amount by up to one hour
    C. Sleeping less than normal amount by more than one hour
    D. Need for sleep appears decreased; less than four hours
    E. Denies need for sleep; has stayed up one night or more

4. **Irritability –** ***Has your child appeared irritable?***

    A. No more than usual
    B. More grouchy or crabby
    C. Irritable openly several times throughout the day; recent episodes of anger with family, at school, or with friends
    D. Frequently irritable to point of being rude or withdrawn
    E. Hostile and uncooperative about all the time

5. **Speech (rate and amount) –** ***Is your child talking more quickly or more than usual?***

    A. No Change
    B. Seems more talkative
    C. Talking faster or more to say at times
    D. Talking more or faster to point he/she is difficult to interrupt
    E. Continuous speech; unable to interrupt

6. **Thoughts –** ***Has your child shown changes in his/her thought patterns?***

    A. No
    B. Thinking faster; some decrease in concentration; talking "around the issue"
    C. Distractible; loses track of the point; changes topics frequently; thoughts racing
    D. Difficult to follow; goes from one idea to the next; topics do not relate; makes rhymes or repeats words
    E. Not understandable; he/she doesn't seem to make any sense

7. **Content –** ***Is your child talking about different things than usual?***

    A. No
    B. He/she has new interests and is making more plans
    C. Making special projects; more religious or interested in God
    D. Thinks more of him/herself; believes he/she has special powers; believes he/she is receiving special messages
    E. Is hearing unreal noises/voices; detects odors no one else smells; feels unusual sensations; has unreal beliefs

8. **Disruptive-Aggressive Behavior –** ***Has your child been more disruptive or aggressive?***

    A. No; he/she is cooperative
    B. Sarcastic; loud; defensive
    C. More demanding; making threats
    D. Has threatened a family member or teacher; shouting; knocking over possessions/furniture or hitting a wall
    E. Has attacked a family member, teacher, or peer; destroyed property; cannot be spoken to without violence

Appendix B
Letter to School Psychologists, Private Practitioners, and Early Childhood Mental Health Workers

Figure 7

Letter to Professionals

Selective Mutism Research Study

Dear Professional,

We are writing to inform you about a research study we will be conducting at Michigan State University on the treatment of selective mutism* in children and adolescents (ages seven to eighteen). You may have an opportunity to have contact with a child or adolescent who has been diagnosed with or has symptoms of selective mutism. As part of a dissertation project at Michigan State University, coordinated efforts have been undertaken by members of the School Psychology Program at Michigan State University and the Department of Psychiatry at Michigan State University to provide a comprehensive medication treatment investigation for the childhood disorder, Selective Mutism, free of charge to participants. We encourage you to pass along the attached flyer to parents of those children, ages seven to eighteen, who may be diagnosed with Selective Mutism. If you have any questions about this project please contact the study coordinator **Justin Barterian, MA** at **586-899-3715.** Thank you for your help in our attempts to better understand this rare and complex childhood condition.

Sincerely,

Justin A. Barterian, MA
Graduate Student
School Psychology

John S. Carlson, PhD
Professor and Psychologist
School Psychology

Jed Magen, DO
Professor and Psychiatrist
Department of Psychiatry

Justin Barterian, M.A.
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586-899-3715
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MICHIGAN STATE UNIVERSITY

Appendix C
Recruitment Flyer

Figure 8

Recruitment Flyer

Does Your Child Have Trouble Speaking in Social Situations?

Selective Mutism Research Study

The Department of Counseling, Educational Psychology, and Special Education and the Department of Psychiatry at Michigan State University have coordinated efforts to provide a diagnostic evaluation and treatment investigation for children, ages seven to eighteen, with **Selective Mutism*.** Those individuals meeting study criteria will be invited to participate in a research study investigating a medication treatment for selective mutism.

The research study will occur in two phases. In the first phase, parents of children with symptoms of selective mutism will be sent and asked to complete a series of questionnaires about their child's behavior. These questionnaires will then be sent back to the study coordinator who will examine and score the information to determine eligibility for participation. In phase two, the study coordinator will contact parents of children who appear to meet study criteria. Parents and their children will then be invited to the Michigan State University Psychiatry Clinic to undergo a thorough medical assessment by a psychiatrist. Information will be collected during this visit to verify study eligibility and an overview of the treatment program will be presented. The research project will last approximately 15 weeks, with visits to the clinic occurring approximately once every two weeks. A total of 8 visits will be made to the clinic to complete all aspects of this research study.

For information about this study, please contact the study coordinator:

Justin A. Barterian, MA at 586-899-3715

You may also contact one of the other principal investigators, Dr. John Carlson at 517-432-4856 or Dr. Jed Magen at 517-353-4363.

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MICHIGAN STATE UNIVERSITY

* **Selective Mutism** is a childhood disorder characterized by persistent failure to speak in specific social situation in which there is an expectation for speech (e.g., in the school) despite speaking in other situations (e.g., in the home). These children typically comprehend and have knowledge of the spoken language and interact normally at home. This disorder was formerly known as elective mutism.

Appendix D
Letter to Principals

Figure 9

Letter to Principals

Selective Mutism Study
Michigan State University

Dear Principal,

We are writing to inform you about a study we will be conducting at Michigan State University on the treatment of selective mutism* in children and adolescents (ages seven to eighteen). The mental health professionals (e.g., school psychologists, social workers, and school counselors) in your school may have an opportunity to have contact with a child or adolescent who has been diagnosed with or has symptoms of selective mutism. As part of a dissertation project at Michigan State University, coordinated efforts have been undertaken by members of the School Psychology Program at Michigan State University and the Department of Psychiatry at Michigan State University to provide a comprehensive medication treatment investigation for the childhood disorder, Selective Mutism, free of charge to participants. If possible, it would be of great help if you could pass along the attached documents to mental health professionals in your school in order to recruit participants for this study. If you have any questions about this project please contact the study coordinator **Justin Barterian, MA** at **586-899-3715.** Thank you for your help in our attempts to better understand this rare and complex childhood condition.

Sincerely,

Justin A. Barterian, MA
Graduate Student
School Psychology

John S. Carlson, PhD
Professor and Psychologist
School Psychology

Jed Magen, DO
Professor and Psychiatrist
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Appendix E
Inclusion and Exclusion Criteria

To be completed by the study psychiatrist on the participant's first clinic visit.

A. Inclusions:
Please check all those that apply. If all criteria are not met then child is not eligible for participation in this research project.

_____ Male or female from five to 17 years of age at their last birthday
_____ Met DSM-5 criteria for Selective Mutism
_____ No history of medication treatment for Selective Mutism
_____ Child has an immediate biological family member who is diagnosed with an anxiety disorder or has experienced symptoms of an anxiety disorder at some point in time
_____ Child has received 10 weeks of an evidence-based psychosocial treatment if seven years or older; Child has received 12 weeks of an evidence based psychosocial treatment if six years or younger
_____ Child has never had a negative reaction to a psychopharmacological medication
_____ T-Scores of 65 or higher on MASC-2:SAS scale

B. Exclusions:
Please write "NO" in the blank provided for all criteria that do not apply. If any of the criteria are not negated, the child is not eligible for participation in this research project.

_____ Diagnosed with a speech condition, mental retardation, pervasive developmental disorder, or has a diagnosis of schizophrenia
_____ Child is an English language learner or from a different culture than the culture predominately represented within his or her school
_____ Child is taking or has taken any kind of a psychopharmacological medication (e.g., SSRI, MAO-I, stimulant, etc.)
_____ Child has a medical illness that may be complicated through the use of a psychopharmacological treatment as determined by the project psychiatrist

Adapted from Carlson (1997).

Appendix F
Correlation Matrix

Table 19

Correlation Matrix

Correlations Across Parent Completed Measures of Anxiety and Mutism Symptoms

		DBR - Engagement (Adults)	DBR - Engagement (Friends)	MASC-2	CGI - Anxiety Severity (Home)	CGI - Anxiety Severity (School)	CGI - Anxiety Severity (Community)	CGI - Shyness Severity (Home)	CGI - Shyness Severity (School)	CGI - Shyness Severity (Community)	CGI - Shyness Change	CGI - Anxiety Change	DBR - Responsive (Adults)	DBR - Responsive (Friends)	DBR - Spontaneous (Adults)	DBR - Spontaneous (Friends)	SMQ	CGI - SM Severity	CGI - SM Change
DBR - Engagement (Adults)	Pearson Correlation	1	.382**	-.475**	-.058	.133	.057	-.031	.274*	-.063	-.171	-.405**	.694**	.268**	.487**	.218**	-.227*	.110	-.004
	Sig. (2-tailed)		.000	.000	.531	.208	.553	.738	.013	.511	.062	.000	.000	.000	.000	.004	.032	.232	.963
	N	190	165	117	119	91	111	119	82	112	119	119	185	168	189	173	90	120	119
DBR - Engagement (Friends)	Pearson Correlation	.382**	1	-.401**	.303**	.382**	.257**	.169	.484**	.182	-.087	-.072	.314**	.813**	.284**	.816**	-.266*	.296**	.088
	Sig. (2-tailed)	.000		.000	.001	.000	.009	.076	.000	.065	.366	.454	.000	.000	.000	.000	.014	.002	.358
	N	165	176	109	111	84	103	111	79	104	111	111	163	171	166	176	85	112	111
MASC-2	Pearson Correlation	-.475**	-.401**	1	-.401**	-.287**	-.222*	.065	-.490**	-.149	.027	.142	-.301**	-.146	-.194*	-.125	.326**	-.349**	-.202*
	Sig. (2-tailed)	.000	.000		.000	.005	.013	.469	.000	.096	.761	.115	.001	.126	.037	.185	.002	.000	.024
	N	117	109	141	126	94	125	126	86	125	125	125	115	112	116	115	90	127	125
CGI - Anxiety Severity (Home)	Pearson Correlation	-.058	.303**	-.401**	1	.484**	.323**	.329**	.592**	.383**	.547**	.343**	-.042	.379**	-.127	.425**	-.453**	.466**	.509**
	Sig. (2-tailed)	.531	.001	.000		.000	.000	.000	.000	.000	.000	.000	.652	.000	.169	.000	.000	.000	.000
	N	119	111	126	144	107	136	144	98	137	142	142	117	114	118	117	82	144	142
CGI - Anxiety Severity (School)	Pearson Correlation	.133	.382**	-.287**	.484**	1	.742**	.188	.828**	.677**	.510**	.488**	-.213*	.387**	-.214*	.391**	-.745**	.587**	.617**
	Sig. (2-tailed)	.208	.000	.005	.000		.000	.053	.000	.000	.000	.000	.043	.000	.043	.000	.000	.000	.000
	N	91	84	94	107	107	99	107	98	100	106	106	90	88	90	90	71	107	106
CGI - Anxiety Severity (Community)	Pearson Correlation	.057	.257**	-.222*	.323**	.742**	1	.161	.598**	.823**	.548**	.584**	-.232*	.274**	-.146	.320**	-.759**	.531**	.649**
	Sig. (2-tailed)	.553	.009	.013	.000	.000		.061	.000	.000	.000	.000	.015	.004	.127	.001	.000	.000	.000
	N	111	103	125	136	99	136	136	91	135	134	134	109	106	110	109	81	136	134
CGI - Shyness Severity (Home)	Pearson Correlation	-.031	.169	.065	.329**	.188	.161	1	.291**	.356**	.150	.136	-.106	.140	-.078	.140	-.392**	.171*	.094
	Sig. (2-tailed)	.738	.076	.469	.000	.053	.061		.004	.000	.075	.106	.255	.138	.399	.132	.000	.040	.264
	N	119	111	126	144	107	136	144	98	137	142	142	117	114	118	117	82	144	142
CGI - Shyness Severity (School)	Pearson Correlation	.274*	.484**	-.490**	.592**	.828**	.598**	.291**	1	.677**	.469**	.268**	-.080	.462**	-.125	.491**	-.784**	.746**	.621**
	Sig. (2-tailed)	.013	.000	.000	.000	.000	.000	.004		.000	.000	.008	.476	.000	.265	.000	.000	.000	.000
	N	82	79	86	98	98	91	98	98	92	97	97	81	79	81	81	70	98	97
CGI - Shyness Severity (Community)	Pearson Correlation	-.063	.182	-.149	.383**	.677**	.823**	.356**	.677**	1	.529**	.566**	-.286**	.260**	-.182	.322**	-.821**	.515**	.659**
	Sig. (2-tailed)	.511	.065	.096	.000	.000	.000	.000	.000		.000	.000	.002	.007	.056	.001	.000	.000	.000
	N	112	104	125	137	100	135	137	92	137	135	135	110	107	111	110	81	137	135
CGI - Shyness Change	Pearson Correlation	-.171	-.087	.027	.547**	.510**	.548**	.150	.469**	.529**	1	.733**	-.197*	.081	-.176	.187*	-.574**	.453**	.824**
	Sig. (2-tailed)	.062	.366	.761	.000	.000	.000	.075	.000	.000		.000	.033	.393	.057	.043	.000	.000	.000
	N	119	111	125	142	106	134	142	97	135	143	143	117	114	118	117	81	143	143
CGI - Anxiety Change	Pearson Correlation	-.405**	-.072	.142	.343**	.488**	.584**	.136	.268**	.566**	.733**	1	-.399**	.055	-.179	.157	-.575**	.195*	.616**
	Sig. (2-tailed)	.000	.454	.115	.000	.000	.000	.106	.008	.000	.000		.000	.560	.052	.090	.000	.020	.000
	N	119	111	125	142	106	134	142	97	135	143	143	117	114	118	117	81	143	143
DBR - Responsive (Adults)	Pearson Correlation	.694**	.314**	-.301**	-.042	-.213*	-.232*	-.106	-.080	-.286**	-.197*	-.399**	1	.298**	.607**	.273**	.283**	-.177	-.164
	Sig. (2-tailed)	.000	.000	.001	.652	.043	.015	.255	.476	.002	.033	.000		.000	.000	.000	.008	.056	.078
	N	185	163	115	117	90	109	117	81	110	117	117	187	170	186	171	87	118	117
DBR - Responsive (Friends)	Pearson Correlation	.268**	.813**	-.146	.379**	.387**	.274**	.140	.462**	.260**	.081	.055	.298**	1	.263**	.943**	-.096	.349**	.196*
	Sig. (2-tailed)	.000	.000	.126	.000	.000	.004	.138	.000	.007	.393	.560	.000		.001	.000	.383	.000	.036
	N	168	171	112	114	88	106	114	79	107	114	114	170	179	169	179	84	115	114
DBR - Spontaneous (Adults)	Pearson Correlation	.487**	.284**	-.194*	-.127	-.214*	-.146	-.078	-.125	-.182	-.176	-.179	.607**	.263**	1	.267**	.107	-.306**	-.167
	Sig. (2-tailed)	.000	.000	.037	.169	.043	.127	.399	.265	.056	.057	.052	.000	.001		.000	.320	.001	.071
	N	189	166	116	118	90	110	118	81	111	118	118	186	169	190	174	89	119	118
DBR - Spontaneous (Friends)	Pearson Correlation	.218**	.816**	-.125	.425**	.391**	.320**	.140	.491**	.322**	.187*	.157	.273**	.943**	.267**	1	-.198	.375**	.270**
	Sig. (2-tailed)	.004	.000	.185	.000	.000	.001	.132	.000	.001	.043	.090	.000	.000	.000		.066	.000	.003
	N	173	176	115	117	90	109	117	81	110	117	117	171	179	174	184	87	118	117
SMQ	Pearson Correlation	-.227*	-.266*	.326**	-.453**	-.745**	-.759**	-.392**	-.784**	-.821**	-.574**	-.575**	.283**	-.096	.107	-.198	1	-.682**	-.706**
	Sig. (2-tailed)	.032	.014	.002	.000	.000	.000	.000	.000	.000	.000	.000	.008	.383	.320	.066		.000	.000
	N	90	85	90	82	71	81	82	70	81	81	81	87	84	89	87	94	82	81
CGI - SM Severity	Pearson Correlation	.110	.296**	-.349**	.466**	.587**	.531**	.171*	.746**	.515**	.453**	.195*	-.177	.349**	-.306**	.375**	-.682**	1	.582**
	Sig. (2-tailed)	.232	.002	.000	.000	.000	.000	.040	.000	.000	.000	.020	.056	.000	.001	.000	.000		.000
	N	120	112	127	144	107	136	144	98	137	143	143	118	115	119	118	82	145	143
CGI - SM Change	Pearson Correlation	-.004	.088	-.202*	.509**	.617**	.649**	.094	.621**	.659**	.824**	.616**	-.164	.196*	-.167	.270**	-.706**	.582**	1
	Sig. (2-tailed)	.963	.358	.024	.000	.000	.000	.264	.000	.000	.000	.000	.078	.036	.071	.003	.000	.000	
	N	119	111	125	142	106	134	142	97	135	143	143	117	114	118	117	81	143	143

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Appendix G
Medication Log

Please fill out this form for the following week: _____

Please write the time when you provided your child with the medication for each day of the week.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Time							

Appendix H
Early Exit Form

Figure 10

Early Exit Form

EARLY EXIT FORM

CHILD:
AGE:
DESIGN #:

REASON FOR DISCONTINUATION:

SIDE EFFECTS ENCOUNTERED

ADDITIONAL COMMENTS, PLEASE:

PLEASE COMPLETE END OF STUDY FORM:

APPENDIX I
End of Study Form

Figure 11

End of Study Form

END of STUDY FORM

CHILD:
AGE:
DESIGN #:

Follow-up Care Information

WHERE:

WITH WHO:

WHAT TREATMENT:

Please solicit the participants thoughts regarding this research study:

Positive:

Negative:

Changes:

Would they have participated after knowing what was to be involved?

Appendix J
Direct Behavior Rating Forms – Teacher and Parent

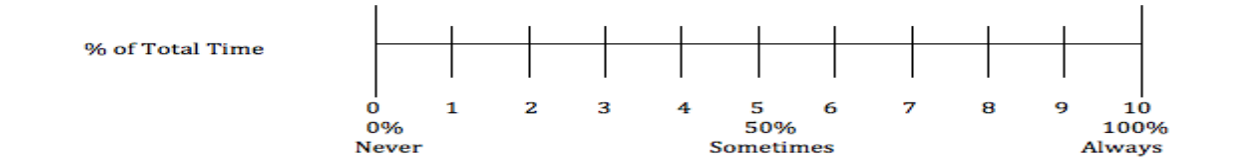
Teacher - Daily Behavior Rating Form

Date:_____ Day (Please Circle) : M T W TH F

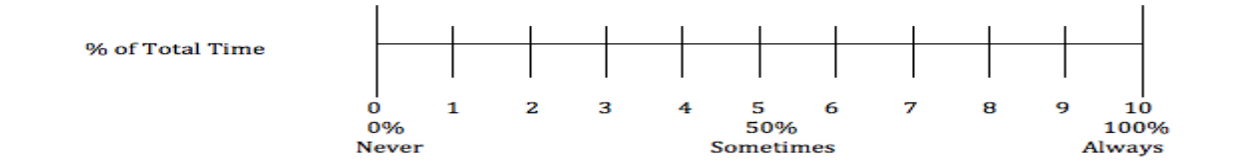
Directions: Place a mark along the line that best reflects the percentage of total time the student exhibited each target behavior each day he/she is at school. Note that the percentages do not need to total 100% across behaviors because some behaviors may co-vary.

1. Behavior: When appropriate, the student appeared comfortably and socially engaged with other students (e.g., completing group work, playing). *Note: This rating does not include whether the child spoke to other students.

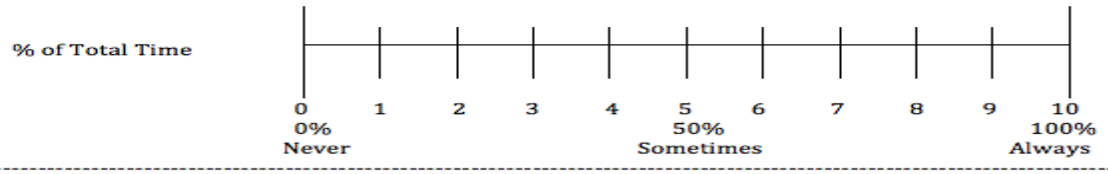
2. Behavior: When appropriate, the student was comfortably and socially engaged with the classroom teacher. *Note: This rating does not include whether the child spoke to the teacher.



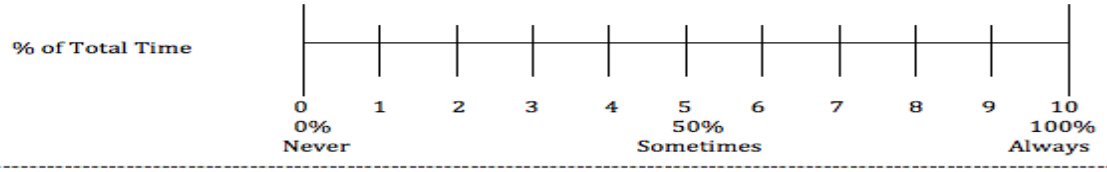
3. Behavior: When appropriate, the student spontaneously spoke to other students.



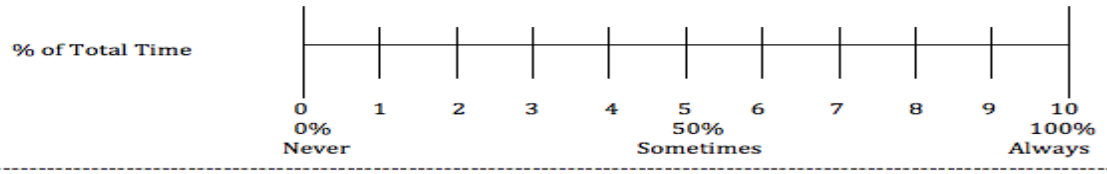
4. Behavior: When appropriate, the student spontaneously spoke to the teacher.



5. Behavior: When appropriate, the student responded (e.g., saying yes or no) when spoken to by other students.



6. Behavior: When appropriate, the student responded (for example, saying yes or no) when spoken to by the teacher.

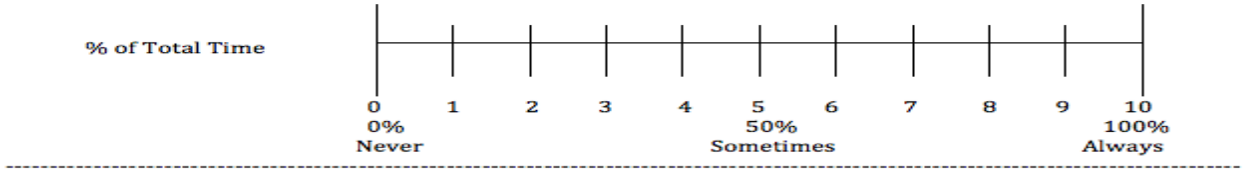


Parent - Daily Behavior Rating Form

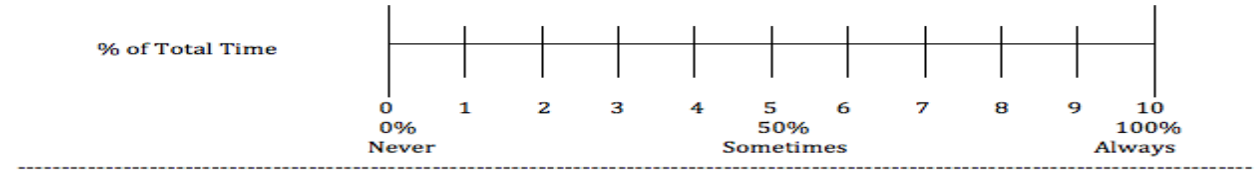
Date:_____ Day (Please Circle) : M T W TH F

Directions: Place a mark along the line that best reflects the percentage of total time the student exhibited each target behavior. Note that the percentages do not need to total 100% across behaviors. Please cross out behaviors you did not get a chance to observe during a day. It is important that you attempt to rate each behavior (1-4) at least 3 times per week.

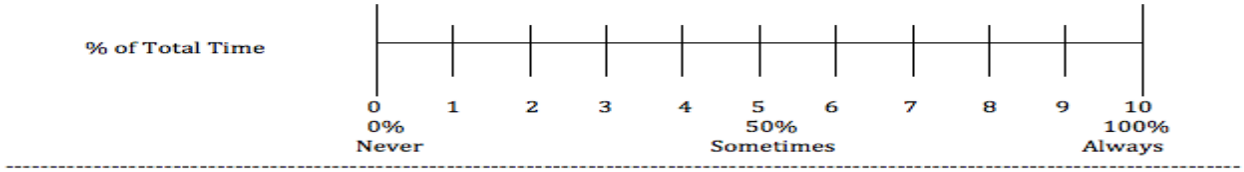
1. Behavior: My child appeared comfortably and socially engaged with friends (e.g., playing with a neighborhood friend). *Note: This rating does not include whether the child spoke to the children.



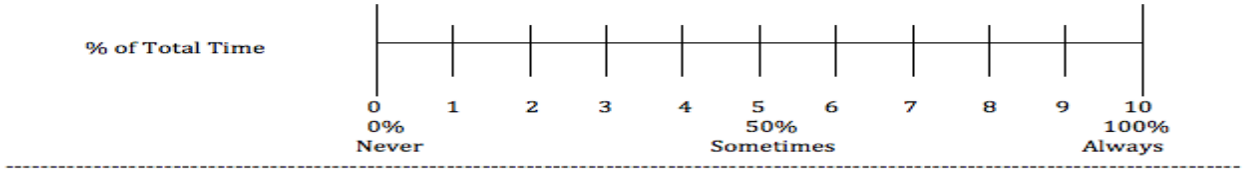
2. Behavior: My child appeared comfortably and socially engaged with the unfamiliar adults. *Note: This rating does not include whether the child spoke to the unfamiliar adult.



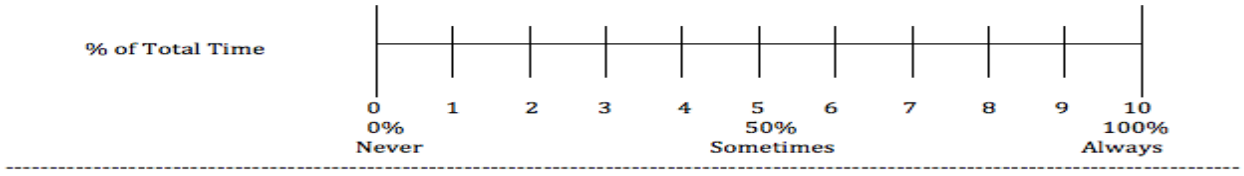
3. Behavior: When appropriate, my child spontaneously spoke to friends.



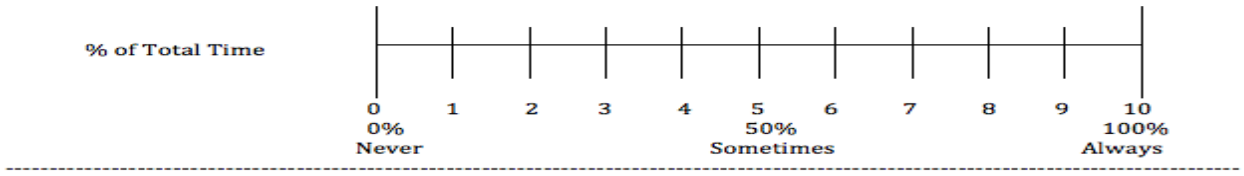
4. Behavior: When appropriate, my child spontaneously spoke to unfamiliar adults.



5. Behavior: When appropriate, my child responded (for example, saying yes or no) when spoken to by friends.



6. Behavior: When appropriate, my child responded (for example, saying yes or no) when spoken to by unfamiliar adults.



Appendix K

Multidimensional Anxiety Scale for Children – 2nd Edition: Social Anxiety Scale

Instructions: These sentences ask you how your child might have been thinking, feeling, or acting recently. For each item, please circle the number that describes **how often the statement is true about your child.**

Circle 0 if a sentence is Never true about your child.
Circle 1 if a sentence is Rarely true about your child.
Circle 2 if a sentence is Sometimes true about your child.
Circle 3 if a sentence is Often true about your child.

Remember, there are no right or wrong answers, just answer how your child has been feeling since the last time you completed this form.

Here is an example to show you how to complete the questionnaire. In the example, if your child is hardly ever scared of dogs you would circle the 1 meaning that the sentence is "rarely" true about your child.

		Never	Rarely	Sometimes	Often
Example	My child is scared of dogs.	0	(1)	2	3

		Never	Rarely	Sometimes	Often
1.	My child worries about other people laughing at him/her..……	0	1	2	3
2.	My child is afraid that other kids will make fun of him/her……	0	1	2	3
3.	My child worries about getting called on in class……	0	1	2	3
4.	My child is afraid other people will think he/she is stupid…….....	0	1	2	3
5.	My child worries about what other people think of him/her……...	0	1	2	3
6.	My child worries about doing something stupid or embarrassing…	0	1	2	3
7.	My child gets nervous if he/she has to perform in public……	0	1	2	3
8.	My child has trouble asking other kids to play with him/her……	0	1	2	3
9.	My child feels shy……	0	1	2	3

Appendix L
Clinical Global Impressions (Severity and Change)–Clinician, Parent, Teacher

Severity of Behavior Form – Clinician

Participant _____ Date_____
Clinician Name _____
Phase of study: _____

I. Selective Mutism Severity
Provide a rating for each of the following settings:
A. School _____ B. Home _____ C. Clinic_____ D. Peers _____ E. Overall_____

1.	Absent	No apparent difficulty or reluctance to speak or communicate in any situation.
2.	Minimal	Some reluctance to speak or communicate in one or more situations, in excess of normal, but not significantly impairing the child's ability to speak or communicate in any situation. For example, child speaks up or raises his or her hand to speak less often than most children, may be slow to respond when spoken to or may speak softly. Does not appear particularly distressed when expected to speak.
3.	Moderate	Modest reluctance or unwillingness to speak or communicate in one or more situations. The reluctance or unwillingness to speak or communicate is significant enough that there is some interference with the child's ability to speak or communicate in one or more situations. For example, the child rarely speaks spontaneously to teacher, and is moderately reluctant to respond even when spoken to, responding slowly or very quietly. May appear somewhat distressed when expected to speak.
4.	Marked	Reluctance or unwillingness to speak or communicate in one or more situations is markedly abnormal, and is significant enough that there is marked interference with the child's ability to speak or communicate in one or more situations. For example, the child never speaks spontaneously to teacher, and is notably reluctant to respond even when spoken to, responding very slowly, or in a mere whisper, and sometimes not at all. May appear quite distressed when expected to speak.
5.	Severe	Child is completely unwilling or unable to speak or communicate in one or more situations, and that is significant enough that there is severe interference with the child's ability to speak or communicate in one or more situations. For example, the child does not speak at all to the teacher even in a whisper and even in response to direct questions. May appear extremely distressed when expected to speak, for example, by crying.
X	Unable to assess.	

II. Shyness Severity
(Circle one of the items below)

1	Absent	No problem, comfortable, conversant.
2	Minimal	Somewhat shy, some avoidance of eye contact, delayed verbal responses to questions, short answers.
3	Moderate	Moderately shy, very brief responses (yes or no)
4	Marked	Very shy, no verbal responses, but nodded or provided written responses, some eye contact
5	Severe	Virtually no interaction with examiner, no responses at all to any questions, virtually no eye contact.

X Unable to assess.

III. Anxiety Severity

1	Absent	No anxiety, fear, or nervousness, and normal school, family, and social activities.
2	Minimal	Some anxiety, fear, or nervousness some days; but they are not interfering with normal school, family, and social activities.
3	Moderate	Anxiety, fear, or nervousness most days, interfering with normal school, family, and social activities in minor ways.
4	Marked	Considerable anxiety, fear, or nervousness most days or everyday; interfering with normal school, family, or social activities.
5	Severe	Severe anxiety, fear or nervousness every day or nearly every day; normal school, family, and social activities are very disrupted.

X Unable to assess.

Severity of Behavior Form-Teacher

Participant_____ Date_____
Teacher_____

I. Selective Mutism Severity: Please rate the overall severity of the child's reluctance, unwillingness, or inability to speak since the last rating. Circle one number.

1	Absent	No apparent difficulty or reluctance to speak or communicate in any situation.
2.	Minimal	Some reluctance to speak or communicate in one or more situations, in excess of normal, but not significantly impairing the child's ability to speak or communicate in any situation. For example, child speaks up or raises his or her hand to speak less often than most children, may be slow to respond when spoken to or may speak softly. Does not appear particularly distressed when expected to speak.
3.	Moderate	Modest reluctance or unwillingness to speak or communicate in one or more situations. The reluctance or unwillingness to speak or communicate is significant enough that there is some interference with the child' ability to speak or communicate in one or more situations. For example, the child rarely speaks spontaneously to teacher, and is moderately reluctant to respond even when spoken to, responding slowly or very quietly. May appear somewhat distressed when expected to speak.
4.	Marked	Reluctance or unwillingness to speak or communicate in one or more situations in markedly abnormal, and is significant enough that there is marked interference with the child's ability to speak or communicate in one or more situations. For example, the child never speaks spontaneously to teacher, and is notably reluctant to respond even when spoken to, responding very slowly, or in a mere whisper, and sometimes not at all. May appear quite distressed when expected to speak.
5.	Severe	Child is completely unwilling or unable to speak or communicate in one or more situations, and that is significant enough that there is severe interference with the child's ability to speak or communicate in one or more situations. For example, the child does not speak at all to the teacher even in a whisper and even in response to direct questions. May appear extremely distressed when expected to speak, for example, by crying.
X	Unable to assess.	

I. SELECTIVE MUTISM SEVERITY (contd.)

To your knowledge, in which of the following situations has the child been reluctant, unwilling, or unable to speak since the last rating? Please use the following ratings:

0=no difficulty in speaking
1=somewhat difficulty in speaking
2=very reluctant to speak
3=never speaks in this situation
X=don't know or unsure

Situations:

In the classroom, to other children? _____
In the classroom, to teacher? _____
In the classroom, to other adults? _____
In other situations (e.g., in hallways, on playground, in gym), to other children? _____
In other school situations, to teacher? _____
In other school situations, to other adults? _____

II. SHYNESS SEVERITY

(Circle one of the items below):

1	Absent	No problem, comfortable, conversant
2	Minimal	Somewhat shy, some avoidance of eye contact, delayed verbal responses to questions, short answers
3	Moderate	Moderately shy, very brief responses (yes or no).
4	Marked	Very shy, no verbal responses, but nodded or provided written response, some eye contact.
5	Severe	Virtually no interaction with examiner, no response at all to any questions, virtually no eye contact

X Unable to assess.

III. Anxiety Severity

(Circle one of the items below):

1	Absent	No anxiety, fear, or nervousness, and normal school, family, and social activities.
2	Minimal	Some anxiety, fear, or nervousness some days; but they are not interfering with normal school, family, and social activities.
3	Moderate	Anxiety, fear, or nervousness most days, interfering with normal school, family, and social activities in minor ways.
4	Marked	Considerable anxiety, fear, or nervousness most days or everyday; interfering with normal school, family, or social activities.
5	Severe	Severe anxiety, fear or nervousness every day or nearly every day; normal school, family, and social activities are very disrupted.

X Unable to assess

Severity of Behavior Form – Parent

Participant _____ Parent_____ Date:

I. Selective Mutism Severity: Please rate the overall severity of the child's reluctance, unwillingness, or inability to speak since the last rating. Circle one number

1	Absent	No apparent difficulty or reluctance to speak or communicate in any situation.
2.	Minimal	Some reluctance to speak or communicate in one or more situations, in excess of normal, but not significantly impairing the child's ability to speak or communicate in any situation. For example, child speaks up or raises his or her hand to speak less often than most children, may be slow to respond when spoken to or may speak softly. Does not appear particularly distressed when expected to speak.
3.	Moderate	Modest reluctance or unwillingness to speak or communicate in one or more situations. The reluctance or unwillingness to speak or communicate is significant enough that there is some interference with the child's ability to speak or communicate in one or more situations. For example, the child rarely speaks spontaneously to teacher, and is moderately reluctant to respond even when spoken to, responding slowly or very quietly. May appear somewhat distressed when expected to speak.
4.	Marked	Reluctance or unwillingness to speak or communicate in one or more situations in markedly abnormal, and is significant enough that there is marked interference with the child's ability to speak or communicate in one or more situations. For example, the child never speaks spontaneously to teacher, and is notably reluctant to respond even when spoken to, responding very slowly, or in a mere whisper, and sometimes not at all. May appear quite distressed when expected to speak.
5.	Severe	Child is completely unwilling or unable to speak or communicate in one or more situations, and that is significant enough that there is severe interference with the child's ability to speak or communicate in one or more situations. For example, the child does not speak at all to the teacher even in a whisper and even in response to direct questions. May appear extremely distressed when expected to speak, for example, by crying.
X	Unable to assess.	

To your knowledge, in which of the following situations has your child been reluctant, unwilling, or unable to speak since the last rating? Please use the following ratings:

0=no difficulty in speaking
1= somewhat difficulty in speaking
2=very reluctant to speak
3= never speaks in this situation
X=don't know or unsure

Situations

with mother in your home? _____
with mother away from home? _____
with father in your home? _____
with father away from home? _____
with siblings in your home? _____
with siblings away from home? _____
with extended family in your home? _____
with extended family away from home? _____
with familiar adults in your home? _____
with familiar adults away from home? _____
with unfamiliar adults in your home? _____
with unfamiliar adults away from home? _____
with familiar children in your home? _____
with familiar children away from home? _____
with unfamiliar children in your home? _____
with unfamiliar children away from home? _____
other _____?

II. Shyness Severity

Please provide a rating for each of the following settings.

Home_____ School_____ Community_____

1	Absent	No problem, comfortable, conversant
2	Minimal	Somewhat shy, some avoidance of eye contact, delayed verbal responses to questions, short answers.
3	Moderate	Moderately shy, very brief responses (yes or no).
4	Marked	Very shy, no verbal responses, but nodded or provided written responses, some eye contact.
5	Severe	Virtually no interaction with examiner, no responses at all to any questions, virtually no eye contact.

X Unable to assess.

III. Anxiety Severity
Please proved a rating for each of the following settings:

Home_____ School_____ Community_____

1	Absent	No anxiety, fear, or nervousness, and normal school, family, and social activities
2	Minimal	Some anxiety, fear, or nervousness some days; but they are not interfering with normal school, family, and social activities.
3	Moderate	Anxiety, fear, or nervousness most days; interfering with normal school, family, and social activities in minor ways.
4	Marked	Considerable anxiety, fear, or nervousness most days or everyday; interfering with normal school, family, and social activities.
5	Severe	Severe anxiety, fear or nervousness every day or nearly every day; normal school, family, and social activities are very disrupted.

X Unable to assess.

Global Change Form – Clinician

Participant _____ Date_____

Clinician Name_____

I. GLOBAL MUTISM CHANGE

A. School _____ B. Home_____ C. Clinic_____ D. Overall_____

1. Markedly improved
2. Moderately improved
3. Minimally improved
4. No change
5. Minimally worse
6. Moderately worse
7. Markedly worse

II. GLOBAL SHYNESS CHANGE

A. Clinic setting _____

1. Markedly improved
2. Moderately improved
3. Minimally improved
4. No change
5. Minimally worse
6. Moderately worse
7. Markedly worse

III. GLOBAL ANXIETY CHANGE

A. Generalized Anxiety_____ B. Social Anxiety_____

1. Markedly improved
2. Moderately improved
3. Minimally improved
4. No change
5. Minimally worse
6. Moderately worse
7. Markedly worse

IV. GLOBAL SIDE EFFECT SEVERITY RATING SCALE

How do medication side effects compare with beneficial medication effects?

0 Not applicable (there have been no positive changes or negative changes)

1 Positive changes greatly outweigh negative changes.
Medication effects are overall extremely positive.

2 Positive changes significantly outweigh negative changes.
Medication effects are overall somewhat positive.

3 Positive changes outweigh negative changes.
Medication effects are overall somewhat positive.

4 Positive and negative changes are approximately equal.

5 Negative changes outweigh positive changes.
Medication effects are overall somewhat negative

6 Negative changes significantly outweigh positive changes.
Medication effects are overall very negative

7 Negative changes greatly outweigh positive changes
Medication effects are overall extremely negative

Global Change Form – Teacher
Participant _____ Date_____
Teacher_____

I. SELECTIVE MUTISM CHANGE: Do you think it has become any easier for the child to talk in school (or in other situations or places where it has been hard for him or her to talk) than it was before he or she began participating in this treatment study, or is it getting more difficult, or has there not been any change? Circle one number.

1 Much easier
2 A little easier
3 No change
4 A little more difficult
5 Much more difficult

II. SHYNESS CHANGE: Do you think the child has been any less shy recently compared to before he or she began participating in this treatment study, or has he or she been more shy, or has there not been any change? Circle one number.

1 Much less shy
2 A little less shy
3 No change
4 A little more shy
5 Much more shy

III. ANXIETY OR NERVOUSNESS CHANGE: Do you think the child has been any less anxious or nervous recently compared to before he or she began participating in this treatment study, or has he or she been more anxious or nervous, or has there not been any change? Circle one number.

1 Much less nervous
2 A little less nervous
3 No change
4 A little more nervous
5 Much more nervous

IV. COMMENTS: Have you noticed any changes in the child's behavior other than those mentioned above?

Global Change Form- Parent

Participant_____ Date_____
Parent_____
Person completing this form: Mother_____ Father_____ Both parents_____

I. SELECTIVE MUTISM CHANGE: Do you think it has become any easier for your child to talk in school (or in other situations or places where it has been hard for him or her to talk) than it was before he or she began participating in this treatment study, or is it getting more difficult, or has there not been any change? Circle one number.

1	Much easier	5	A little more difficult
2	Somewhat easier	6	Somewhat more difficult
3	A little easier	7	Much more difficult
4	No change		

II. SHYNESS CHANGE: Do you think your child has been any less shy recently compared to before he or she began participating in this treatment study, or has he or she been more shy, or has there not been any change? Circle one number.

1	Much less shy	5	A little more shy
2	Somewhat less shy	6	Somewhat more shy
3	A little less shy	7	Much more shy
4	No change		

III. ANXIETY OR NERVOUSNESS CHANGE: Do you think your child has been any less anxious or nervous recently compared to before he or she began participating in this treatment study, or has he or she been more anxious or nervous, or has there not been any change? Circle one number.

1	Much less nervous	5	A little more nervous
2	Somewhat less nervous	6	Somewhat more nervous
3	A little less nervous	7	Much more nervous
4	No change		

IV. GLOBAL SIDE EFFECT SCALE

How do medication side effects compare with beneficial mediation effects?

0 Not applicable (there have been no positive changes or negative changes)

1 Positive changes greatly outweigh negative changes
Medication effects are overall extremely positive.

2 Positive changes significantly outweigh negative changes.
Medication effects are overall very positive.

3 Positive changes outweigh negative changes
Medication effects are overall somewhat positive.

4 Positive and negative changes are approximately equal.

5 Negative changes outweigh positive changes.
Medication effects are overall somewhat negative.

6 Negative changes significantly outweigh positive changes.
Medication effects are overall extremely negative.

V. COMMENTS: Have you noticed any changes in your child's behavior other than those mentioned above?

Appendix M
Selective Mutism Questionnaire

Selective Mutism Questionnaire (SMQ) ©

Please consider your child's behavior in the last two weeks and rate how frequently each statement is true for your child.

AT SCHOOL

1. When appropriate, my child talks to most peers at school.

Always Often Seldom Never

2. When appropriate, my child talks to selected peers (his/her friends) at school.

Always Often Seldom Never

3. When my child is asked a question by his/her teacher, s/he answers.

Always Often Seldom Never

4. When appropriate, my child asks his or her teacher questions.

Always Often Seldom Never

5. When appropriate, my child speaks to most teachers or staff at school.

Always Often Seldom Never

6. When appropriate, my child speaks in groups or in front of the class.

Always Often Seldom Never

HOME/ FAMILY

7. When appropriate, my child talks to family members living at home when other people are present.

Always Often Seldom Never

8. When appropriate, my child talks to family members while in unfamiliar places.

Always Often Seldom Never

9. When appropriate, my child talks to family members that don't live with him/her (e.g. grandparent, cousin).

Always Often Seldom Never

10. When appropriate, my child talks on the phone to his/her parents and siblings.

Always Often Seldom Never

11. When appropriate, my child speaks with family friends who are well-known to him/her.

Always Often Seldom Never

12. My child speaks to at least one babysitter.

Always Often Seldom Never N/A

IN SOCIAL SITUATIONS (OUTSIDE OF SCHOOL)

13. When appropriate, my child speaks with other children who s/he doesn't know.

Always Often Seldom Never

14. When appropriate, my child speaks with family friends who s/he doesn't know.

Always Often Seldom Never

15. When appropriate, my child speaks with his or her doctor and/or dentist.

Always Often Seldom Never

16. When appropriate, my child speaks to store clerks and/or waiters.

Always Often Seldom Never

17. When appropriate, my child talks when in clubs, teams or organized activities outside of school.

Always Often Seldom Never

Interference/Distress*

18. How much does not talking interfere with school for your child?

Not at all Slightly Moderately Extremely

19. How much does not talking interfere with family relationships?

Not at all Slightly Moderately Extremely

20. How much does not talking interfere in social situations for your child?

Not at all Slightly Moderately Extremely

21. Overall, how much does not talking interfere with life for your child?

Not at all Slightly Moderately Extremely

22. Overall, how much does not talking bother your child?

Not at all Slightly Moderately Extremely

23. Overall, how much does your child's not talking bother you?

Not at all Slightly Moderately Extremely

Scoring: Always = 3; Often = 2; Seldom = 1; Never = 0
*These items are not included in total score and are for clinical purposes only.

Appendix N
Adapted Side Effects for Children and Adolescents (SEFCA)

To be obtained from patient and caretaker:

Are complaints or signs present? 1= No _____
2 = Yes

If YES, complete appropriate items below rating frequency and severity as follows:

Frequency (days per week)

1= 1-2 days
2= 3-4 days
3= 5-7 days

Severity:

1 = mild, does not interfere with functioning
2= moderate, some interference with functioning
3= severe, functioning is significantly impaired because of side effects

	Frequency	Severity
1. Drowsiness……..	_____	_____
2. Difficulty falling asleep….	_____	_____
3. Irritability ……...	_____	_____
4. Anxiety ……...	_____	_____
5. Excitement ……..……...	_____	_____
6. Depression (reduction of ability to enjoy self or anticipate pleasure)……..	_____	_____
7. Appetite Decrease …...……...	_____	_____
8. Nausea …….……...	_____	_____
9. Appetite Increase ……...	_____	_____
10. Headache ……...……...	_____	_____
11. Verbal/Motor Tics ……...	_____	_____
12. Behavioral Activation/Manic Behaviors/ Impulsivity…….……	_____	_____

Appendix O

Answers on the Parent-Mania Rating Scale that May Indicate Behavioral Disinhibition as a Result of Fluoxetine Treatment

1. **Mood –** ***Is your child's mood higher (better) than usual?***

   A. No
   B. Mildly or possibly increased
   C. Definite elevation – more optimistic, self-confident, cheerful, appropriate to their conversation.
   D. Elevated but inappropriate to content; joking, mildly silly
   E. Euphoric, inappropriate laughter; singing/making noises, very silly

2. **Motor Activity/Energy –** ***Does your child's energy level or motor activity appear to be greater than usual?***

   A. No
   B. Mildly or possibly increased
   C. More animated; increased gesturing
   D. Energy is excessive; hyperactive at times; restless but can be calmed
   E. Very excited; continuous hyperactivity; cannot be calmed

3. **Sleep –** ***Has your child's sleep decreased lately?***

   A. No
   B. Sleeping less than normal amount by up to one hour
   C. Sleeping less than normal amount by more than one hour
   D. Need for sleep appears decreased; less than four hours
   E. Denies need for sleep; has stayed up one night or more

4. **Irritability –** ***Has your child appeared irritable?***

   A. No more than usual
   B. More grouchy or crabby
   C. Irritable openly several times throughout the day; recent episodes of anger with family, at school, or with friends
   D. Frequently irritable to point of being rude or withdrawn
   E. Hostile and uncooperative about all the time

5. **Speech (rate and amount) –** ***Is your child talking more quickly or more than usual?***

   A. No Change
   B. Seems more talkative
   C. Talking faster or more to say at times
   D. Talking more or faster to point he/she is difficult to interrupt
   E. Continuous speech; unable to interrupt

6. **Thoughts –** ***Has your child shown changes in his/her thought patterns?***

   A. No
   B. Thinking faster; some decrease in concentration; talking "around the issue"
   C. Distractible; loses track of the point; changes topics frequently; thoughts racing
   D. Difficult to follow; goes from one idea to the next; topics do not relate; makes rhymes or repeats words
   E. Not understandable; he/she doesn't seem to make any sense

7. **Content –** ***Is your child talking about different things than usual?***

   A. No
   B. He/she has new interests and is making more plans
   C. Making special projects; more religious or interested in God
   D. Thinks more of him/herself; believes he/she has special powers; believes he/she is receiving special messages
   E. Is hearing unreal noises/voices; detects odors no one else smells; feels unusual sensations; has unreal beliefs

8. **Disruptive-Aggressive Behavior –** ***Has your child been more disruptive or aggressive?***

   A. No; he/she is cooperative
   B. Sarcastic; loud; defensive
   C. More demanding; making threats
   D. Has threatened a family member or teacher; shouting; knocking over possessions/furniture or hitting a wall
   E. Has attacked a family member, teacher, or peer; destroyed property; cannot be spoken to without violence

Appendix P
Treatment Evaluation Questionnaire, parent version

Treatment Evaluation Questionnaire – Parent

You recently participated in a research study that is investigating the treatment of selective mutism. Please evaluate this intervention (treatment) by circling the number which best describes your agreement or disagreement with each statement. Please answer each question.

		Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree		Strongly Agree
1.	This was an acceptable intervention for my child's problem behavior.	1	2	3	4	5	6
2.	Most parents would find this intervention appropriate for behavior problems in addition to the one described.	1	2	3	4	5	6
3.	This intervention was effective in changing my problem behavior.	1	2	3	4	5	6
4.	I would suggest the use of this intervention to other parents.	1	2	3	4	5	6
5.	My child's behavior problem was severe enough to warrant use of this intervention.	1	2	3	4	5	6
6.	Most parents would find this intervention suitable for the behavior problem described.	1	2	3	4	5	6
7.	The intervention did not result in negative side effects for my child.	1	2	3	4	5	6
8.	The intervention would be appropriate for a variety of children.	1	2	3	4	5	6
9.	The intervention was a fair way to handle my child's problem behavior.	1	2	3	4	5	6
10.	I liked the procedures used in the intervention.	1	2	3	4	5	6
11.	The intervention was a good way to handle my child's behavior problem.	1	2	3	4	5	6

Appendix Q
Consent Forms and Assent Procedures for Participation (Parent, Teacher, Child)

EVALUATING THE RESULTS OF PHYSICIAN AND PARENT DECISIONS TO TREAT SELECTIVE MUTISM WITH FLUOXETINE

PARENT INFORMATION AND CONSENT FORM

YOU ARE INVITED TO GIVE PERMISSION FOR YOUR CHILD TO PARTICIPATE IN A RESEARCH STUDY ON THE TREATMENT OF SELECTIVE MUTISM.

Researchers and Titles: 1) Justin Barterian M.A., Doctoral Candidate in School Psychology
2) John Carlson Ph.D., Professor and Psychologist
3) Jed Magen D.O., Professor and Psychiatrist

Institution: Michigan State University

Departments: 1) Department of Counseling, Educational Psychology, and Special Education
2) Department of Psychiatry

Contact Information: Mr. Justin Barterian
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PURPOSE OF RESEARCH

The purpose of this research study is to see if a medication called fluoxetine sometimes called Prozac can help your child talk with others. Fluoxetine is a medication approved by the U.S. Food and Drug Administration for anxiety (Obsessive-Compulsive Disorder) in children ages 7 to 18 years old. You and your child have been asked to be in this research study because your child has had trouble talking to others. Many families will be interviewed to see if their child is a good candidate for the treatment. Only five families, who have children ages 5 to 17 years old, will be selected to come to the MSU Psychiatry Clinic to receive treatment.

ALTERNATIVE OPTIONS

If you decide not to take part in this research study, you should know that there are other treatments that may be helpful for selective mutism. Other medications, like Zoloft, and behavior therapy have been helpful for some children. Behavior therapy often is used to increase how much a child talks. Your child's doctor may be willing to talk about the good and bad sides of these other treatments.

If you leave the study, there are two different choices the project coordinator will offer you to get treatment for selective mutism. First, you may be sent to the school psychologist of your child's school. Second, you may be sent to a mental health worker in the community. The payment for this treatment will be your responsibility.

WHAT WILL YOU DO

Overview

This research study occurs in two phases. First, we will conduct a phone interview to see if your child is a good fit for the medication treatment. You will be asked questions about your child's symptoms, the mental health history of family members, and your child's treatment history. We may also ask if you are comfortable with us contacting your child's teacher to help collect data for us. After the interview, you may be sent a screening packet in the mail that will contain forms for you to complete, including release of information permission forms, questionnaires about your child's symptoms, and a form about your child's developmental history.

If your child is invited to the clinic, you and your child will be enrolled in the treatment part of the study for approximately 15 weeks. You and your child will come to the clinic about once every two weeks (you can come sooner if needed). You will come to the clinic 9 times. These visits will take about one hour. The researchers will examine your child's symptoms throughout the study to see if the symptoms are getting better and to make sure your child is not feeling worse. You should feel free to contact the psychiatrist if you have questions about the medication.

Randomization

During the first week of the study, you will be asked to fill out forms about your child's behaviors. During this week, your child will not receive any treatment. After the first week, your child will receive the medication (fluoxetine) or syrup that looks and tastes like the medication, but has no medication in it. This is done to see if the real medication is helping your child. This means your child will not get the real medication during some weeks of the study. However, your child will get the real medication at some point in the study. While you, your child, and your child's teacher will not know if your child is getting the real medication, your psychiatrist will know. The time your child gets the real medication is decided by chance and is not determined by any information you give us. Since you will not know if your child is getting the real medication you will not know how the medication worked for your child until the end of the research study.

School and Home Involvement

Information about your child's behavior at home, in the community, and at school will be collected. You and your child's teacher will be asked to watch your child's behaviors at many times during this research study. This information will help the researchers know if the medication is helping your child.

Clinic Visits

You will have to come to the Michigan State University Psychiatry Clinic in East Lansing, MI nine times during this study. During these visits, you and your child will meet with the project coordinator or one of his assistants. The project coordinator and assistants have Masters degrees in psychology. You and your child will also met with the psychiatrist who will prescribe the medication. During these meetings you may be asked complete forms and talk about how your child is doing with project coordinator, project assistants, and psychiatrist. This will help us know how the medication may be helping your child.

Information about your child's progress throughout the study will be shared with you. At the end of the study, the staff will help you chose other treatments or help you secure treatment for your child with a professional in your community. Fluoxetine treatment may be continued after the study; however, you would have to pay for the treatment.

More information about your visits to the MSU psychiatry clinic is give below.

Visit 1— You will meet with a researcher who will get you ready for your meeting with the psychiatrist. He or she will answer any questions you have about the research study. The researcher will also talk to your child to make sure they agree to be in the study. After this, you will meet with the psychiatrist. The psychiatrist will go over your child's treatment, medical, family, and psychiatric history. The psychiatrist will physically examine your child to make sure they are healthy and meet the requirements for treatment. The psychiatrist may ask other questions to make sure your child is a good fit for the study. Next, if your child is still thought to be a good fit for the study, the researcher will meet with you again for about one hour to give you training on the forms you will be asked to complete every week. You will be asked to complete several forms during the week and asked to come back next week.

Visits 2-8 – During these visits, your child will be prescribed the medication or syrup that tastes and looks like the medication. When your child is given the medication, s/he will be prescribed a lower dose for two weeks, which will be raised to a higher dose after those two weeks. The psychiatrist will decide the dose for your child, because each child is different and may need different doses than other children. When your child receives the syrup that does not contain the medication, the dose might also look to change so you cannot tell if your child is on the medication or the syrup.

During these visits you and your child will meet with the psychiatrist to discuss how your child is doing. You and your child may be asked to complete forms about your child's behavior. The psychiatrist will also ask questions regarding your child's speaking and anxiety.

Visit 9 – During the last visit, you and your child will do the same things as visits two through eight. However, the study psychiatrist will also complete a physical examination with your child and will discuss ending the research study.

POTENTIAL BENEFITS

It is possible the medication may help our child talk. It may also help your child feel more comfortable in social situations. However, it is also possible that your child may not improve after taking the medication. The data from this study may help to better understand your child's behavior, which may help you decide how to best help your child.

You and your child's participation in this research study may also help other children who also have trouble speaking in public. For example, the information from this study may add to help doctors and psychologists better treat selective mutism. The results of the study may also benefit other children who might later be treated with the same medication.

POTENTIAL RISKS

Medical Risks

The side effects of fluoxetine have not been studied fully in children, especially in children younger than 7 years of age. Because of this, the Food and Drug Administration (FDA) has not approved the use of fluoxetine for children younger than age seven for any disorder. In addition, the FDA has not approved the use of fluoxetine for the treatment of selective mutism in children. It is possible that unexpected immediate and long-term side effects may occur if your child is below the age of 7. Some of these unexpected side effects may include headaches, stomachaches, and behavior changes. In children who are older than 7 who have taken the medication for other anxiety disorders and depression, most children have not had bad side effects. However, sometimes people do experience side effects when taking fluoxetine. These side effects are listed below:

- Asthenia (loss of strength)
- Flu Syndrome
- Vasodilation (Widening of Blood Vessels)
- Nausea
- Diarrhea
- Anorexia
- Dry Mouth
- Dyspepsia (Upset Stomach/Indigestion)
- Insomnia
- Constipation
- Flatulence
- Vomiting
- Weight Loss
- Thinking Abnormal
- Mania/Hypomania
- Thirst
- Hyperkinesia (Abnormal Movements)

- Agitation
- Personality Disorder
- Epistaxis (Nose bleeds)
- Anxiety
- Nervousness
- Somnolence (Drowsiness)
- Tremor
- Libido Decreased (decreased sex drive)
- Urinary Frequency
- Mennorrhagia (Vaginal Bleeding)
- Abnormal Dreams
- Pharyngitis (Inflammation of the Throat)
- Sinusitis (Inflammation of the Sinuses)
- Yawn
- Sweating
- Rash
- Pruritus (Itching)
- Abnormal Vision
- Impotence
- Abormal Ejaculation

Some uncommon but serious side effects have been linked to the use of fluoxetine. For example, other medications like fluoxetine have been connected to an increase in suicide in children, adolescents, and young adult patients. However, this is rare. Also, in some patients, serotonin syndrome, which is an uncommon condition that happens when there is too much serotonin in the brain can develop and be life threatening. However, serotonin syndrome is very uncommon in children receiving normal doses of this type of medication.

As with any medication, some unexpected side effects may come about. If the researchers learn of any information that might change your mind about allowing your child to stay in this study, the research staff will tell you. We encourage you and your child to tell us about any side effects he or she is experiencing or if he or she is feeling worse.

Although research has shown no effects of fluoxetine on mental or physical performance, medications like fluoxetine have been shown to weaken the mental and physical skills needed to do dangerous activities like driving a car or using heavy machinery. Since this may happen with fluoxetine, it is important to be careful.

Any other medications used during the study should be discussed with the study psychiatrist, who will inform you if this additional medication is safe to use during the research study.

PRIVACY AND CONFIDENTIALITY

As with any psychiatric/medical treatment, there is a small risk that confidentiality will be broken. However, your confidentiality will be protected to the maximum extent allowable by

law. Only the investigators, the study coordinator, the MSU Human Research Protection Program (HRPP), and under certain circumstances, the U.S. Food and Drug Administration will have access to your child's clinical records. Otherwise, your child's identity will be kept confidential. Confidentiality is also insured by the use of patient initials on case records, instead of patient names. Identification numbers will be used when entering information into a database and the codebook will remain in a locked file. The locked file will be located on Michigan State University's campus. These records will be destroyed five years after the study is completed. If the study results are published or presented at a professional meeting, your child's name will not be used. Your child's treatment plan and progress (for example, improvements and side effects) may be shared with a safety committee of medical professionals. No identifying information (for example, names, birthdates, addresses) will be provided to the committee.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

Participation in this study is voluntary, and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you or your child are otherwise entitled. You have the right to say no. You may choose not to answer specific questions.

Under certain circumstances, patients may be withdrawn from the study without their consent if the psychiatrist decides that it is not in their best interest, or if they fail follow the procedures.

COSTS AND COMPENSATION FOR BEING IN THE STUDY

All assessment and treatment procedures (including medication) will be provided at no cost to you or your child and your health insurance (if applicable) will not be charged. In addition, you will receive financial assistance at the end of the study for your trips to the clinic based on the distance from your residence to Michigan State University, using the following criteria:

Distance	**Reimbursement**
25 miles	$100
26 miles to 50 miles	$150
51 miles to 90 miles	$270

THE RIGHT TO GET HELP IF INJURED

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact Dr. John Carlson at 517-432-0843 with any questions or to report an injury.

CONTACT INFORMATION

If you have any questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please feel free to contact Justin Barterian, MA at (586) 899-3715 or barteria@msu.edu, John Carlson, PhD at (517) 432-4856 or carlsoj@msu.edu, or Jed Magen, DO at (517) 353-4363 or jed.magen@hc.msu.edu. Additionally, you can contact Mr. Barterian by mail at Michigan State University, 620 Farm Lane, 401c Erickson Hall, East Lansing, MI 48823.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or email irb@msu.edu or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI, 48824.

DOCUMENTATION OF INFORMED CONSENT

Your signature below means you voluntarily agree to participate in this research study.

Signature of Parent or Guardian: _____ Date: _____

Signature of Child/Adolescent: _____ Date: _____
(Ages 13-18)

Signature of Investigator: _____ Date: _____

EVALUATING THE RESULTS OF PHYSICIAN AND PARENT DECISIONS TO TREAT SELECTIVE MUTISM WITH FLUOXETINE

Project Overview and Teacher Consent Form

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask researchers any questions you may have.

Study Title: Evaluating the results of physician and parent decisions to treat selective mutism with fluoxetine.

Researchers and Titles: 1) Justin Barterian M.A., Doctoral Candidate in School Psychology
2) John Carlson Ph.D., Professor and Psychologist
3) Jed Magen D.O., Professor and Psychiatrist

Institution: Michigan State University

Departments: 1) Department of Counseling, Educational Psychology, and Special Education
2) Department of Psychiatry

Contact Information: Mr. Justin Barterian
Michigan State University
620 Farm Lane
401 C Erickson Hall
East Lansing, MI 48823
Phone: 586-899-3715
Email: barteria@msu.edu

Purpose of the Research

A research study concerning the treatment of children who have selective mutism is being conducted, and we would appreciate your participation. Many teachers of children who exhibit characteristics of selective mutism often wonder what can be done to help the child feel more comfortable speaking in certain situations. In order to help address these concerns, this research study will provide evaluation and treatment to children, ages five to eighteen, who exhibit the characteristics of selective mutism. The treatment will consist of a medication (fluoxetine).

The families and teachers of children who meet the study criteria will be invited to participate in this study. Since selective mutism is a disorder that results in the withholding of speech within the school context, it is important to understand teacher viewpoints regarding an improvement in functioning that has occurred for the child. Children will be assessed on various measures over

the course of the study, in which teachers, if willing, will play an important role. The length of this research study is approximately 15 weeks. Your participation in this study will include a 1-hour training on data collection. In addition, you will be asked to complete rating scales that will take approximately 20 to 30 minutes per week.

In addition to examining a treatment for selective mutism, this study will, in part, fulfill requirements for a graduate degree at Michigan State University for the project coordinator, Mr. Justin Barterian.

What You Will Do

You have been selected to participate in this study, as a child in your classroom meets criteria for enrollment. The role of the teachers who decide to participate will be to complete rating scales of the child's behavior during all phases of the study keeping all information regarding the child confidential. Teachers will be asked to provide overall ratings of the child's functioning within the classroom on a measure twice a week. It is estimated that the completion of this measure will take no longer than 10 to 20 minutes per week. In addition, teachers will be asked to provide a brief rating of the child's behavior on a daily basis. It is estimated that completion of the daily rating will take no longer than 2 minutes per day.

Potential Risks and Benefits

This study will examine a medication treatment for children with selective mutism. Therefore, there are potential medical risks involved for the child. However, there are no known risks to teachers who are involved in this project. While there is no anticipated direct benefit for teachers in this study, they may find they are better able to communicate with the child in the classroom setting if the medication treatment is successful.

Privacy and Confidentiality

All information will be held strictly confidential, and no identifying information will be used in any discussions or reports. The data you provide for this study will be kept confidential to the maximum extent of the law; however, parents' of the participant will see your behavior ratings in an attempt to give them a better understanding of how the fluoxetine treatment is affecting their child's behavior in the classroom. Additional individuals who will have access to the data you provide include researchers and research staff and the MSU Institutional Review Board. In addition, there is a possibility that the U.S. Food and Drug Administration may inspect the records.

All data provided by you will be kept in a locked file on the MSU campus. Identification numbers will be used when entering information into a computer database and the codebook will remain in a locked file. All records collected during this study will be destroyed five years after the completion of the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your Rights to Participate, Say No, or Withdraw

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Costs and Compensation for Participation

There is no cost for you to participate in this study and you will receive a $50 gift card for school supplies at the end of the study for your participation.

Contact Information

If you have any questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please feel free to contact Justin Barterian, MA at (586) 899-3715 or barteria@msu.edu, John Carlson, PhD at (517) 432-4856 or carlsoj@msu.edu, or Jed Magen, DO at (517) 353-4363 or jed.magen@hc.msu.edu. Additionally, you can contact Mr. Barterian by mail at Michigan State University, 620 Farm Lane, 401c Erickson Hall, East Lansing, MI 48823.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or email irb@msu.edu or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI, 48824.

Documentation of Informed Consent

Your signature below means that you voluntarily agree to participate in this research study.

_____ _____

Signature Date

You will be given a copy of this form to keep.

Informed Assent Script for Minors (Ages 5 to 7)

We wanted you to come here today because you sometimes have a hard time talking to children and grown ups. At this doctor's office, we are trying to see what will help kids like you who may be too shy to talk sometimes. We are trying a medicine called "fluoxetine", which might help children talk more.

Before getting the medicine, you'll get a check-up from the doctor. He will do things like listen to your heart. Also, your mom/dad and you will be asked about how you have been feeling and what you have been thinking and doing.

To help us know if the medicine we are going to give you works, we will sometimes give you "real" medicine and sometimes give you "pretend" medicine. The pretend medicine will look and taste just like the real medicine, but it won't have in it any of the stuff that makes the real medicine work. You won't know if we are giving you the real medicine or the pretend medicine. This helps us know if the real medicine helps kids like you. You will be given real medicine or pretend medicine for 15 weeks, and you will be given the real or pretend medicine once a day. Also, you will come visit us here at the MSU doctor's office 8 times and you, your mom and dad, and teacher will be asked how you are feeling.

Sometimes, but not all of the time, the medicine might make you feel funny and it may make your stomach or head hurt, or might make you feel weird in other ways. If this happens, you can tell your mom and dad who can tell us. We will fix it right away so you do not have to feel bad for long. If the medicine doesn't help, we will have your parents stop giving you the medicine.

Do you have any questions?

Do you want to help us see if this medicine will help you and other kids talk more by taking the medicine and visiting our doctor's office?

Informed Consent for Minors (Ages 8 +)

We asked you to be in a research study because you have a hard time talking sometimes. A research study means that we want to try something new and see if it helps kids. At this doctor's office, we would like to find out if a medicine called fluoxetine helps kids who sometimes can't talk. Medicine can't make kids talk, but this medicine may help kids who want to talk more. There are other types of help for kids who can't talk sometimes and your doctor can tell you more about these if you want him/her to.

Before we start, you will get a check-up from our doctor. You and your mom/dad will be asked questions about how you have been feeling and what you have been thinking and doing.

If you want to take the medicine, you will take the medicine for about 15 weeks. You will be asked to take medicine every day and to come here for visits sometimes. We might give you real medicine or a pretend medicine that tastes and looks like the real medicine, but does not have any of the real medicine that may help you talk. This is to help us know if the real medicine is helping you.

You will come to this doctor's office eight times. When you come, you will be asked to meet with the doctor to find out how you have been doing. Your mother/father and teacher will also fill out forms to help us know how you are doing. At the end of the study, you will get another check-up from the doctor.

Sometimes, but not always, this medicine may make kids feel a little uncomfortable. You might get an upset stomach or get diarrhea; your mouth might feel dry; you might have problems sleeping or feel dizzy. If you feel sick, let us know so we can change it right away. If we can't change it, you do not have to keep taking the medicine. If the doctor thinks the medicine is not helping you then the doctor may stop giving it to you.

If you want to be in the study and try the medicine, write your name on the line below. Writing your name on the line means that I told you about the study and the medicine. It also means what I told you makes sense and that I told you that you could ask questions. Writing your name on the line means you don't have to take the medicine or be in the study if you don't want to, and you do not have to say why you don't want to. We now want you to write your name to let us know that what we said about the study makes sense.

When I write my name it means that I agree to do the study. My parents will also have to agree to have me in the study.

Signature of the patient: _____ Date: _____

Signature of Investigator: _____ Date: _____
Investigator: Justin Barterian, MA

Appendix R
Medical, Developmental, Psychosocial, Family, Substance Abuse, and Legal History Form—
MSU Psychiatry Clinic

Michigan State University
Department of Psychiatry

PSYCHIATRIC ASSESSMENT SERVICES FOR CHILDREN AND ADOLESCENTS

For Office Use Only

BP: _____

Height: _____

Weight: _____

IDENTIFYING INFORMATION

Child's Name		Sex □ Male □ Female	Date
Date of Birth	Place of Birth	School Grade	
Address	Telephone	School	
	Religion (optional)	Pediatrician or Family Doctor	
		Address & Phone Number	
	Referral Source or how did you learn of program?		
Your Name		Relationship to Patient □ Father □ Mother □ Guardian □ Grandparent	
Chief Complaint:			

1

PAST PSYCHIATRIC TREATMENT

Has the child been seen by a Psychiatrist or Psychologist before? ☐ Yes ☐ No

If yes, please list below:

Psychiatrist/Psychologist	Dates Seen	Reason Seen	Medications Prescribed

Has the child been hospitalized for emotional or behavior problems? ☐ Yes ☐ No

If yes, please list below:

Hospital	City, State	Dates

MEDICAL HISTORY

Is the child up to date with his/her vaccinations? ☐ Yes ☐ No ☐ I don't know

Has the child had any of the following childhood diseases?

☐ Measles ☐ Chickenpox ☐ Whooping Cough ☐ Mumps

When was the child last seen by his/her physician?_____

What was the purpose of that visit?_____

_____

_____

Has the child ever been treated for an emergency? ☐ Yes ☐ No

If yes, please describe: _____

_____

_____

Has the child had any surgeries? ☐ Yes ☐ No

If yes, please describe: _____

_____

Is the child taking any medications at this time? ☐ Yes ☐ No

If yes, please list the medications and dose: _____

_____

_____

Has the child taken any medications for hyperactivity, attention problems, behavior problems or mood problems? ☐ Yes ☐ No

If yes, please list the medications and dose: _____

_____

_____

Is the child allergic to any medications? ☐ Yes ☐ No

If yes, please describe:_____

Has the child suffered any accidents? ☐ Yes ☐ No

If yes, please describe: _____

_____

_____

Has the child ever suffered with any of the following?

☐ Allergies	☐ Anemia	☐ Arm Problems	☐ Poor Appetite
☐ Arthritis	☐ Asthma	☐ Backaches	☐ Sinus Trouble
☐ Broken Bones	☐ Colds or Flu	☐ Colic	☐ Rheumatic Fever
☐ Constipation	☐ Convulsions	☐ Diabetes	☐ Sugar Levels
☐ Diarrhea	☐ Digestive Problems	☐ Dizziness	☐ Ruptures or Hernias
☐ Earaches	☐ Ear Infections	☐ Fainting	☐ Tuberculosis
☐ Growing Pains	☐ Headaches	☐ Heart Trouble	☐ Walking Problems
☐ Hypertension	☐ Joint Problems	☐ Leg Problems	☐ Strep Throat
☐ Muscle Jerking	☐ Neck Problems	☐ Paralysis	☐ Head Injury

☐ Other: _____

DEVELOPMENTAL HISTORY

Birth

Normal pregnancy? ☐ Yes ☐ No

If mother ill during pregnancy, please explain _____

_____

Length of active labor _____ hrs ☐ Easy ☐ Difficult

Full term? □ Yes □ No

If premature, how early? _____

If overdue, how late? _____

Birth weight: _____ lbs _____ oz

Type of delivery? □ spontaneous □ cesarean □ with instruments □ head first □ breech

Was it necessary to give the infant oxygen? □ Yes □ No If yes, how long: _____

Did the infant require blood transfusion? □ Yes □ No

Did the infant require X-ray, CT or MRI? □ Yes □ No

Physical condition of infant at birth: (if yes, please explain)

Trauma □ Yes □ No _____

Other complications □ Yes □ No _____

Did mother use substances during pregnancy?

Alcohol: □ Yes □ No _____

Tobacco: □ Yes □ No _____

Drugs: □ Yes □ No _____

Newborn Period

			How Long
Irritability	□ yes	□ no	_____
Vomiting	□ yes	□ no	_____
Difficulty breathing	□ yes	□ no	_____
Convulsions/Twitching	□ yes	□ no	_____
Colic	□ yes	□ no	_____
Normal weight gain	□ yes	□ no	_____
Was child breast fed	□ yes	□ no	_____

Developmental Milestones

	Age		Age		Age
Sat up		Crawled		Walked	
Spoke single words		Sentences		Weaned	
Bladder Trained		Bowel Trained			

Describe the manner in which toilet training was accomplished _____

_____

Early Social Development

Relationship to siblings and peers: □ Plays Individually □ Plays in Groups
□ Competitive □ Cooperative
□ Leadership Role □ Follower

Describe special habits, fears or idiosyncrasies of the child: _____

_____

Educational History

	Name of School	City/State	Dates Attended Begin	End	Grades completed at this school
Preschool					
Elementary					
Junior High					
High School					

Type of Classes: □ Regular □ Home School □ Emotionally Impaired □ Other_____
□ Alternative HS □ Resource Room □ Learning Impaired _____

Did the child skip a grade? □ Yes □ No Repeat a grade? □ Yes □ No
If yes, when and how many years _____

_____

Did the child have any specific learning difficulties? □ Yes □ No
If yes, has any testing been done? Describe (please enclose copies of these reports) _____

_____

Please give the name and telephone number of someone at school who is familiar with your child's behavior and academic performance _____

PSYCHOSOCIAL HISTORY

Current Family Situation:

Mother's Name	Age	Birth date
Relationship to Child □ natural parent □ step-parent □ adoptive parent □ relative _____		Birthplace
Occupation	Education	Religion
Father's Name	Age	Birth date
Relationship to Child □ natural parent □ step-parent □ adoptive parent□ relative _____		Birthplace
Occupation	Education	Religion

Marital History of Parents:

Natural Parents: □ Married when _____ age _____
□ Separated when _____
□ Divorced when _____
□ Deceased Mother when _____ Father when _____

Step Parents: □ Married when _____

Living Arrangements: Places Dates

Number of moves in child's life ____ _____ _____

Present home □ house □ apartment _____ _____
□ Rent □ own _____ _____

Does child share a room? □ Yes □ No _____ _____

If yes with whom & relationship _____

If no, how long with own room _____

Others living in the home (and their relationship:)

1. _____
2. _____
3. _____

Has the child ever lived away from the family? □ Yes □ No

Explain _____

What are the major family stresses at the present time, if any? _____

_____

What are the sources of family income? _____

_____

Brothers & sisters (indicate if stepbrothers or stepsisters)

Name	Age	Sex	School or Occupation	Present Grade	Living at Home	Use drugs or alcohol	Treated for Drug abuse	Treated for mental illness
1.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No
2.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No
3.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No
4.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No
5.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No
6.		□ M □ F			□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No

If child is adopted, adoption source _____

Reason and circumstance _____

Age when child first in home _____ Date of legal adoption _____

What has the child been told? _____

Others living in the home (and their relationship):

1. _____
2. _____
3. _____

Does or did any member of the child's family have any problems with: ☐ reading ☐ spelling ☐ math ☐ speech (if yes, please explain) _____

_____

FAMILY HISTORY

Please indicate any history in each of the child's biological relatives with an 'X' under the correct column:

Is there family history for one or more of the following problems in any blood relative listed to the right?	Mark One 'X' for each Blood/Biological Relative with the Problem						
	Father	Mother	Siblings	Uncles	Aunts	Grand-parents	Other
Depression:							
Anxiety:							
Obsessive or Compulsive:							
Bipolar or Manic:							
Attention Problems:							
Hyperactivity Problems:							
Mental Retardation:							
Schizophrenia Or Psychosis:							
Alcohol Use Problems:							
Drug Use Problems:							
Learning Problems:							
In trouble with the Law:							
Abused or neglected:							
Has been prescribed medication for psychiatric problems:							
History of attempting suicide:							
History of aggression toward self or others:							

Has any member of the family been on psychiatric medication?_____

Other Problems: _____

_____

_____

SUBSTANCE ABUSE

Do you have any concerns about your child using drugs or alcohol? ☐ Yes ☐ No

If yes, please explain_____

_____

LEGAL HISTORY

Has the child ever been arrested? ☐ Yes ☐ No

If yes, describe_____

_____

Has the child ever been in trouble with the police? ☐ Yes ☐ No

If yes, describe_____

_____

Has the child ever been involved with the juvenile court? ☐ Yes ☐ No

If yes, describe_____

_____

Name of Probation Agent_____

Name of Attorney (if any)_____

Has the child ever been involved with the circuit or district courts? ☐ Yes ☐ No

If yes, describe_____

_____

Name of Probation Agent_____

Name of Attorney (if any)_____

Your Name:_____ Date:_____

Appendix S
Consent for Release of Confidential Medical, Treatment, and School Records

PATIENT AUTHORIZATION FOR DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

Patient Name: _____

Address: _____

Date of Birth: _____

I AUTHORIZE THE DISCLOSURE OF MY HEALTH INFORMATION

FROM: _____
Name of hospital or health care system or provider

_____
Address

_____

_____
Phone/Fax Number

TO: Mr. Justin Barterian/Selective Mutism Study
401C Erickson Hall
620 Farm Lane
East Lansing, MI 48823
Phone: 586-899-3715
Fax: 517-353-6393

DESCRIPTION OF INFORMATION TO BE DISCLOSED (select one of the following):
___ ALL information contained in my medical and academic records.

OR

___ ONLY disclose the following information:

RESEARCH STUDY FOR THIS DISCLOSURE:
Title of Study: Evaluating the Results of Physician and Parent Decisions to Treat Selective Mutism with Fluoxetine
Name of Research Leader: John Carlson Ph.D., Justin Barterian, M.A., and Jed Magen D.O.
Affiliation of Researchers: Michigan State University
IRB#_____ Name of IRB: Michigan State University
Biomedical and Health Institutional Review Board

EXPIRATION (fill in one of the following):
Your Authorization to disclose the above information expires on August 31st, 2014 _____; or
Expires at the end of the research study _____.

REVOCATION, REFUSAL, REDISCLOSURE:
You may revoke this Authorization in writing at any time by contacting Mr. Justin Barterian/Selective Mutism Study, but it will not affect any information already released to the researcher(s).

You may refuse to sign this authorization and your refusal will not affect your ability to obtain treatment, however, it may affect your ability to participate in this research study.

Your information that is disclosed to the researcher(s) may no longer be protected by Federal privacy regulations if the researcher(s) is not a health care provider covered by the regulations, however the researcher(s) agrees to protect your information as required by law.

_____ _____
Signature of Patient or Personal Representative Date

_____
Name of Personal Representative and Relationship to Patient (or description of authority to act on behalf of the patient)

PROVIDE COPY TO PATIENT

MSU Research Privacy Board Template – Authorization for Disclosure of Protected Health Information for Research – 2/16/06

Appendix T
History of Treatment Form for Previous Treating Professional

Dear Professional,

In the recent past, you treated _____ for symptoms associated with a diagnosis of selective mutism. Currently, this child is enrolled in a selective mutism treatment study at Michigan State University to examine the effectiveness of fluoxetine in the treatment of selective mutism. In order to determine if _____ is eligible for participation in the selective mutism study at Michigan State University, it is essential to obtain information regarding the previous types of treatment that child has received under your care. Please check the following boxes that apply to the types of treatments that were provided to the child:

A. Behavioral Treatments

_____ Contingency Management
_____ Shaping
_____ Positive reinforcement program
_____ Stimulus fading
_____ Response initiating
_____ Response Cost
_____ Systematic desensitization
_____ Behavioral Play therapy

B. Psychodynamic Treatments

_____ Psychoanalysis
_____ Affect Sharing
_____ Play therapy
_____ Art therapy

C. Cognitive-Behavioral

_____ Cognitive restructuring
_____ Anxiety Management
_____ Social skills training
_____ Self-Modeling
_____ Relaxation training

D. Family Therapy

_____ General Family Therapy
_____ Structural family therapy

E. Psychoeducation

_____ Parent Training
_____ Teacher Training

Please provide the number of sessions and the length of each session in which you worked with the participant:

_____
_____
_____
_____
_____

Please provide a brief paragraph regarding the scope and goals of treatment:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Please list any treatment manuals that were used in whole or in part during treatment:

_____
_____
_____

Please provide any additional information about the treatment that was not accounted for in the previous questions:

_____
_____
_____
_____
_____
_____

Appendix U
Physical Exam

To be completed by the study psychiatrist on the participants first/last clinic visit

DATE: _____

COMPLETED BY: _____

CHILD'S NAME: _____

PROCEDURES TO BE COMPLETED

HEIGHT: _____

WEIGHT: _____

BLOOD PRESSURE: _____

PULSE: _____

OTHER:

Taken from Carlson (1997)

Appendix V
Visual Analysis Decision Tree

Complete the following decision tree for each graph for each participant:

1) Is there evidence of the problem behavior (e.g., lack of speech)? Is there a stable baseline (i.e. no medication and placebo) pattern of data? :

_____ Yes to all (Go to question 2)
_____ No to any (Discontinue Participant)

2) Compare the level (mean) of the data form the baseline phase to the level (mean) of the treatment phase. Is the level of the treatment phase visually higher than the level for the baseline phase?

_____ Yes (Go to question 3)
_____ No (Skip to step X and list "No observable effect of treatment")

3) Compare the baseline phase trend (slope) to the treatment phase trend (slope). Is the treatment phase slope significantly more pronounced in the hypothesized direction than the baseline slope?

_____ Yes (Go to question 4)
_____ No (Skip to step X and list "No observable effect of treatment")

4) Does the change in level and trend occur within the expected time frame of treatment effects (i.e. during the acquisition period or during the first three time points after the acquisition period).

_____ Yes (there is an observable treatment effect)
_____ No (there is not "No observable effect of treatment")

_____ Observable Treatment Effect _____ No Observable Treatment Effect

Overall Change

Complete the following analysis after examining all of the participants' data.

When examining all of the baseline and treatment phase replications together, does the data consistently indicate that there is a significant change in the treatment phase?

_____ Replicated Effect _____No Replicated Effect _____ Mixed Data*

*If mixed data, please explain how many replications were observed and how many participants did not show a predicted treatment effect:

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REFERENCES

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