Efficacy of a Group Cognitive Behaviour Therapy Program in the Treatment of Young Children with Social Anxiety Disorder and/or Selective Mutism: A Randomized Controlled Trial

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PROBLEM:
Social Anxiety Disorder (SAD) and Selective Mutism (SM) are serious mental health conditions that prevent children from developing appropriate social relationships with peers and adults. Both disorders develop in children during the preschool years; are often co-morbid; and cause significant interference in normative developmental trajectories. Prevalence rates of SAD (0.5 to 4.4 %)[1] and SM (0.71 to 0.76%)[2,3] suggest that in Ontario, respectively 30,988 and 5,352 children under age 14 could have SAD and SM (based upon Health Canada 2011 statistics reporting that 704,265 children are under age 14 in Ontario in 2011).[4] Very limited knowledge of best treatment approaches for these two disorders exists in children younger than eight years of age. Building on previous OMHF funded research that demonstrated the efficacy of the brief, 11-week *"Taming Sneaky Fears"* group Cognitive Behavioural Therapy (CBT) program in treating 5 to 7 year old children with various anxiety disorders, the primary objective of this study is to assess the efficacy of a modified *"Taming Sneaky Fears"* treatment protocol which specifically targets symptoms of SAD and SM in 4 to 7 year old children with SAD and/or SM (thus, expanding the age group to include 4 year old children and examining the efficacy of *"Taming Sneaky Fears"* in SAD and/or SM specifically). In addition, the sample size in this study will allow for the examination of within-the-child and within-the-parent/environmental factors that contribute to treatment outcome and address shortcomings of previous research (e.g., small sample size, non-randomized controlled designs, relatively lengthy interventions).

BACKGROUND:
Anxiety disorders are one of the most prevalent childhood mental health disorders[5,6] with rates as high as 9% found in preschool children.[7] Similar prevalence rates, symptom presentation and co-morbidity patterns are seen in preschool children as in the school-age period.[8-11] Anxiety disorders are debilitating disorders affecting all aspects of a child's life including their social development, academic achievement and family functioning.[6] Most importantly, anxiety disorders are reliable predictors of long-term mental health difficulties.[12,13] Childhood anxiety disorders rarely remit without treatment[6,14,15] and even with remittance, high recurrence rates are evident.[15,16] Low remittance rates are associated with an earlier age of onset, older age at intake, and more severe baseline symptoms.[6,16] Burgeoning evidence suggests that treatment effects may be more robust in early childhood when there is increased neuroplasticity and room for larger developmental changes.[10,17] This highlights the importance for early identification of anxiety disorders and development of effective treatments for young anxious children.

Social Anxiety Disorder (SAD) and Selective Mutism (SM)

a. Diagnosis: SAD and SM are anxiety disorders that develop during the preschool period and appear to share a common developmental diathesis. Children with SAD struggle with social interactions with peers and adults due to elevated anxiety levels; for example, meeting and/or speaking to new people, interacting with peers, being observed by others, or performing in front of others. Symptoms must be present for 6 months.[18] In affected children, the anxiety must be present with peers and not just adults as younger children typically can experience normative anxiety when interacting with adults. As well, in younger children the symptoms may be expressed more behaviourally with crying, tantrums, freezing, or clinging. In SM, significant anxiety prevents children from speaking in social situations. This lack of speech must be present for more than the first month of school[18] as many young children are normatively shy and quiet, especially when placed in new settings with new adults (e.g., new school year with a new teacher and new students). The lack of speech in SM cannot be better accounted for by another psychiatric disorder (e.g. Autism Spectrum Disorder), or communication, learning or language disorders, or be due to a lack of knowledge of the spoken language (e.g., English as a second language).[18]

b. Overlap between SAD and SM: In recent years, an increased understanding that debilitating anxiety is the root of a child's lack of speech in SM has led to the conceptualization of SM as a severe developmental variant of SAD. However, it is only since the Diagnostic and Statistical Manual Fifth Edition (DSM-5)[18] was published in 2013 that SM was actually classified as an anxiety disorder. Originally referred to as Elective

Mutism, due to a belief that children 'stubbornly' refused to speak, it was only with growing understanding that anxiety drove the mutism that the disorder was renamed Selective Mutism. Evidence for the common diathesis for the two disorders comes from the high co-morbidity between SAD and SM, with studies showing from greater than 50%[19-21] to greater than 80% of children with SM also meeting criteria for SAD.[22,23] Further, the presence of SAD symptoms in older children predicts SM symptom severity.[21] Although clinicians rate older children (5.4 to 15 years) with SM as having higher levels of SAD compared to children with only SAD, these children do not rate themselves as more socially anxious on self-reports, compared to children with only SAD.[24-26] In other words, unlike other anxious children, children with SM do not recognize that they are anxious in social situations, which could be a factor contributing to the well-known fact that treating children with SM is particularly difficult.

c. Risk Factors: One widely accepted risk factor for both disorders is temperamental characteristics, specifically *behavioural inhibition (BI)*. Characterized by hypervigilance, especially in novel and unfamiliar social situations, and a reticent stance or withdrawal from social interaction (e.g. looking on rather than interacting with others or playing by themselves),[27] approximately 15% of normatively developing children display BI[28] with higher rates of children with BI developing SAD.[28-30] A *family history* of anxiety disorders is also an important risk factor for SAD and SM, as well as BI. First degree relatives of children with SAD have a 2 to 6 times greater chance of having SAD, while elevated rates of SAD are found in parents of children with SM.[30,31] The common genetic predispositions for both SAD and SM support the current belief of a common underlying diatheses for these two disorders. No twin studies have been conducted in the field. *Speech and language difficulties* are possible risk factors for SM as expressive and receptive language and phonemic awareness deficits[24,33,34] are found more often in children with SM on standardized language measures compared to anxious non-SM children. With the presence of language difficulties potentially contributing to the severity of SM,[21] it is possible that subtle language factors in combination with features of social anxiety contribute to the development of SM. *Family immigration* or situations in which socially anxious children are learning the language of the immigrated country also may be a risk factor for the development of SM.[35,36] Although the aforementioned factors have been independently investigated in small studies, they have not been examined all together in a large sample, which makes it difficult to discern which factors play significant roles in the development, severity, and perpetuation of SAD and/or SM symptoms and affect treatment outcome. In this study, we address some shortcomings from previous research by using a large enough sample size to give the necessary power to concurrently examine the contribution of multiple within-the-child factors (e.g., BI, speech and language skills) and within-the-parent/environment factors (e.g., family history of SAD or SM, immigration status) to the development, severity, and perpetuation of SAD and/or SM and whether and how these factors contribute to treatment outcome.

d. Peak Age of Development: Peak development of both SAD and SM typically occurs in preschool. A first peak of onset for SAD occurs prior to age 5 with a second peak in early adolescence,[37] while typical age of onset of SM is 3 to 5 years old.[38] Until recently, age of referral and diagnosis occurred *years* after age of onset as the child's difficulties were not fully recognized or identified until the child entered situations where verbal communication and social interaction were necessary and expected (e.g. school) and were addressed even later. In the past 5 years, however, increasing awareness and recognition of the two disorders as being more than normative shyness has resulted in our anxiety disorders clinics seeing close to a 5-fold increase in the number of referrals for assessment of SAD and/or SM in 4 to 7 year old children each year, thus highlighting the importance of developing evidence-based treatments.

e. Prevalence: SAD is one of the most common anxiety disorders in preschool children with reported prevalence rates of 0.5 to 4.4%,[1] while prevalence rates of SM are estimated to be 0.71 to 0.76%.[2,3] Greater awareness and understanding that affected young children do not outgrow their mutism has led to teachers and early program educators identifying quiet, excessively shy children and suggesting referrals to mental health clinics for assessment of possible SM, therefore currently reported prevalence rates of SAD and/or SM could be underestimates of true prevalence rates. Nevertheless, current documented prevalence rates suggest that throughout Canada, SAD and SM could respectively affect up to 246,723 and 42,616 children under age 14 (based upon Health Canada 2011 stats that reported 5,607,345 children under age 14 lived in Canada).[4] The 2013 City of Toronto – Population Health Statistics data further

document 30,800 births per year in Toronto, suggesting that 234 new children could be affected by SM and 1,355 with SAD per year in Toronto.[39]

f. Impact and Outcome: The lack of social and/or verbal interaction or communication in the two disorders results in the greatest impact being in the school setting where children with SAD and/or SM do not appropriately interact and engage with teachers and peers. In fact, it is often teachers who first recognize the symptoms and presence of concerns rather than parents who do not have a similar viewpoint of their child's struggles within the context of the home environment. Over time, this lack of interaction and/or verbal communication with peers and important adults such as teachers causes significant interference with academic achievement, social relationships, and normative developmental trajectories.[2,39] Few studies have examined long-term outcomes of SAD and/or SM. However, evidence suggests that even in children who begin to speak, deficits in communication and socialization[38] and psychosocial impairment[33] remain, while various psychiatric difficulties persist into adulthood.[40]

Despite our growing understanding of anxiety disorders in general, SAD and/or SM in early childhood remain poorly understood and under researched anxiety disorders that impact all aspects of a child's psychosocial functioning and normative social development and have negative long-term sequelae. In this study, we tackle the paucity of knowledge on SAD and/or SM by using a strong methodological design and large enough sample to give the necessary power to examine questions not adequately addressed in previous treatment research.

Treatment of Anxiety Disorders in Young Children

There has been increased recognition in recent years of the importance of evaluating treatment approaches for anxiety disorders in young children. Cognitive Behavioural Therapy (CBT), considered a standard treatment modality for anxiety disorders in children older than 8 years, has received increasing support for use in preschool children with anxiety disorders. The basic premise of CBT is for the child to learn a repertoire of skills including behavioural (e.g., relaxation) and cognitive (e.g., self-talk, thinking brave thoughts) strategies that allow for more realistic evaluation of threat and danger, thus allowing the child to function without excess distress. Initially, CBT studies in younger children looked primarily at working with parents, e.g., parent-focused education programs;[15,41] teaching parents how to implement a program of progressive desensitization or gradual exposure to a feared situation;[42] and parent-only CBT groups.[43] More recently, however, innovative approaches for directly teaching CBT strategies to young children have demonstrated that CBT strategies taught to children directly decreased anxiety severity ratings and improved functioning,[44-48] thus confirming that anxious children under 8 years old benefit from CBT. Support for *individual CBT* with young children was shown in an RCT[45] in which children (n=64) aged 4 to 7 years were randomized to individual CBT with their parents or a wait-list control: greater improvements were reported post-treatment in the CBT arm compared to wait-list control. *Group CBT* has also demonstrated efficacy.[46,48] Utilizing a 10 session CBT group program developed for older children, Waters and colleagues[48] randomized children aged 4 to 8 years to either a parent-and-child CBT group (n=24) or parent-only CBT group (n=25) and demonstrated no significant differences between groups on number of primary anxiety diagnoses lost post-intervention, suggesting that direct involvement of children in treatment was not necessary.

Previous Work in Our Lab: In direct contrast to the findings from the Waters et al. study,[48] our recently completed OMHF funded study utilized the 11-week *"Taming Sneaky Fears"* program (10 concurrent parent and child group CBT sessions + 1 introduction session with parents only, specifically designed for 5 to 7 year old children with anxiety disorders) and demonstrated that, in fact, children improve significantly more when *they and their parents* receive CBT, in comparison to when only parents receive CBT. This OMHF funded study compared two treatment arms: (1) children and parents received the child and parent components of the "*Taming Sneaky Fears"* group CBT program separately, but concurrently, and (2) parents received the parent component of "*Taming Sneaky Fears"* while children attended a socialization program where children socialized but were not taught CBT strategies. Findings showed that *children and parents* who received the *"Taming Sneaky Fears"* group CBT program (n=45) had significantly more primary anxiety diagnoses lost, greater decreases in symptom severity, fewer relapses and greater improvements in global functioning immediately post-intervention and at 6- and 12-month follow-up, compared to the treatment arm in which only parents received "*Taming Sneaky Fears"* (n=32).

Both treatment arms demonstrated improvements post-intervention and at 6- and 12-month follow-up; however, significantly greater improvements were noted in the child and parent arm compared to the parent only treatment arm. In this study, we expand on the use of the *"Taming Sneaky Fears"* program by examining its efficacy in the treatment of *4* to 7 year old children with *specific diagnoses of SM and/or SAD*.

Treatment for SAD and/or SM in Children Under Age 8: The treatment literature for children with specific anxiety disorders such as SAD and/or SM is limited with only a few studies conducted on SAD in older adolescents.[49-53] To date, no treatment study has focused specifically on young children with SAD and only a few studies have focused specifically on SM. The SM treatment literature is, however, plagued by the previous lack of a clear understanding of the etiology of SM, preventing a clear rationale for treatments and methodological limitations, such as single case reports and case series,[34,40] making it difficult to assess treatment efficacy or generalize and replicate findings. With the recent recognition of SM as a developmental variant of SAD, the use of treatment approaches similar for both SAD and SM, such as CBT,[54,55] has generated a more focused treatment approach for SM. Most CBT studies in SM to date, however, are case reports or small studies that limit generalizability of findings. Nonetheless, two case series utilizing psychotherapeutic treatment stand out. Sharkey and colleagues[55] (n=5; mean age=6.1 years) conducted an 8-week parent-and-child CBT group program, utilized validated clinical and self-report measures, and showed that 2 of the 5 (40%) children lost their SM diagnosis post-intervention and at 6-month follow-up; while reduced symptom severity and increased functioning were seen in the other 3 children. Utilizing parent psychoeducation and cognitive behavioural techniques over a 6-month period in seven preschoolers with SM aged 3 to 5 years, Oerbeck and colleagues[56] demonstrated improvements in speaking behaviours and in teacher-report of SM symptoms post-treatment. As this case series had no control group, it is impossible to determine whether the reported improvements were due to maturation.

With the exception of a small medication trial,[57] there have been no randomized controlled trials (RCT) for the treatment of SM until recently. The first psychotherapeutic SM-specific RCT was recently published by Bergman and colleagues[58] who randomized children aged 4 to 8 to either a 24-week Integrated Behavior Therapy for Selective Mutism (IBTSM; n=12) in which children and their parents met together with a therapist, or a 12-week Waitlist Control (n=9). Initial sessions focused on rapport development between therapist and child, followed by therapists working with parents on behavioural strategies to increase speech in various social situations. High co-morbidity between SAD and SM was noted as 18/21 (85.7%) children met criteria for both SAD and SM. Sixty seven percent of children who completed the 24-week IBTSM no longer met criteria for SM while no improvements in speaking behaviours were seen at the 12-week waitlist control time. Parents, but not teachers, noted significant improvements in SAD symptoms post-treatment. This study highlights the importance of including both parent and teacher observation of symptom change as we propose to do in the present study.

Although the aforementioned studies provide preliminary support for the use of CBT in the treatment of SAD and/or SM in children 4 to 8 years, further investigation is warranted with larger sample sizes and stronger methodological design. Further, the duration of the Oerbeck[56] and Bergman[58] protocols is onerous for children and families (24 weeks each). The development of brief and efficacious interventions that are less onerous on families would be a significant contribution to the field. In this study, we examine the efficacy of a proven, *brief*, 11-session (vs. other published 24-week programs) *group* (vs. individual) CBT protocol, *"Taming Sneaky Fears,"* in the treatment of 4 to 7 year old children with SAD and/or SM. In addition, we address some of the methodological shortcomings of previous studies by using a randomized controlled design, a manualized treatment program, multiple informants and multiple measures to assess multiple within-the-child and within-the-parent/environment factors contributing to SAD and/or SM and treatment outcome, and a large enough sample size to document statistically and clinically significant short-term and longer-term treatment effects.

Feasibility of the Study: Our previously funded OMHF study demonstrates the efficacy of a group CBT parent and child program (*"Taming Sneaky Fears")* developed specifically for children aged 5 to 7 years with all types of anxiety disorders and their parents and provides an important contribution to the literature on the treatment of anxiety disorders in young children. In this completed RCT, a small sub-sample of children (n=24) had a primary diagnosis of either SAD or SM in the *"Taming Sneaky Fears"* arm, and 10/24 (42%) no longer met diagnostic criteria for SAD or SM post-intervention. At 6-month

follow-up, 6 more children no longer met diagnostic criteria for SM or SAD in that treatment arm, thereby bringing the total 'success' rate of *"Taming Sneaky Fears"* in treating SAD or SM to 67%. These data provide encouraging preliminary evidence for the feasibility of using *"Taming Sneaky Fears"* to treat SAD and/or SM in 4 to 7 year old children as proposed in the present study. The small sub-sample size of the original OMHF study (n=24), however, limits generalizability of findings and does not allow for the examination of factors contributing to SAD and/or SM and treatment outcome. The present study design allows us to assess both the efficacy of the *"Taming Sneaky Fears"* treatment protocol with a larger sample size and the contribution of various within-the-child and within-the-parent/environment factors to SAD and/or SM treatment outcomes.

Since the original OMHF study was completed, we have used *"Taming Sneaky Fears"* in our clinical practice and found that it is useful with the many younger children with SAD and/or SM (as young as 4 years old) who are referred. However, in implementing *"Taming Sneaky Fears"* clinically with young children with SAD and/or SM and their parents, we have found that a more specific focus on progressive desensitization/gradual exposure hierarchies specifically designed around speaking and/or exposure to social situations is needed. As a result, clinical work has allowed us to refine and slightly modify the parent and child components of "*Taming Sneaky Fears"* to make it more specific for children with SAD and/or SM and their parents (by adding psycho-education on SAD and/or SM for the parents and strategies for tackling SAD and/or SM for the children). In order to further assess the feasibility of our study, this modified protocol *("Taming Sneaky Fears for SAD and/or SM"*) was run during the 2014 summer with 7 children aged 4 to 7 who met diagnostic criteria for SAD and/or SM and their parents. The age range was expanded to include children as young as age 4 to meet clinical needs, because studies on SM include such young children, and because in our own clinical experience children as young as 4 years old benefit from *"Taming Sneaky Fears"*. This modified treatment protocol for SAD and/or SM was well received by children and parents and was found to be easy to implement by both parent therapists and child therapists. In this study, we use this modified manualized protocol and formally test its efficacy in the treatment of children with SAD and/or SM, using an RCT study design with a larger sample size in order to adequately power the results as well as to explore the within-the-child and within-the-parent/environment factors affecting treatment.

RESEARCH QUESTIONS AND HYPOTHESES TO BE TESTED: This study builds on our previous OMHF funded work in which we demonstrated that 5 to 7 year old children with anxiety disorders randomized to the "*Taming Sneaky Fears*" group CBT program exhibited greater improvements in global functioning and lost more diagnoses than those randomized to the parent only group CBT program. Starting with a previously proven treatment protocol that is engaging and teaches young children various CBT strategies, we use a slightly revised and refined treatment protocol specifically for children with SAD and/or SM and their parents and expand the age range down to 4 years. The primary objective of this study is to assess the efficacy of the brief (10 concurrent parent and child + 1 parent only), refined, group CBT program *"Taming Sneaky Fears for SAD and/or SM"* in the treatment of 4 to 7 year old children with SAD and/or SM.

Hypothesis #1: The *"Taming Sneaky Fears for SAD and/or SM"* group CBT treatment is more efficacious than a comparison intervention, "Parent Psycho-education and Child Socialization" such that more children in the *"Taming Sneaky Fears for SAD and SM"* group CBT will lose their primary diagnosis of SAD and/or SM, compared to children in the comparison group. Our primary outcome measure will be loss of diagnosis of SAD and/or SM as assessed by an independent clinician blinded to treatment condition and time of assessment using a semi-structured interview, the Anxiety Disorders Interview Schedule for Parents [ADIS-P]),[59] post-intervention and at 6-month follow-up.

Hypothesis #2: In those children who do not lose their primary diagnosis of SAD and/or SM, there will be a 2.0 or greater point improvement in anxiety severity (measured by an independent assessor blinded to treatment condition and time of assessment, using the ADIS-P Clinical Severity Rating [ADIS–CSR]) in more children in the *"Taming Sneaky Fears for SAD and/or SM"* program than children in the comparison group at post-intervention and at 6-month follow-up. This hypothesis is based upon a recent meta-analysis that suggests a 2.0 change in the ADIS-CSR is a clinical meaningful change.[61]

Hypothesis #3: In those children who do not lose their primary diagnosis of SAD and/or SM, there will be a 10.0 or greater point improvement in global functioning (measured by an independent assessor

blinded to treatment condition and time of assessment, using the Clinician Global Assessment Scale [CGAS])[61] in more children in the *"Taming Sneaky Fears for SAD and/or SM"* than children in the comparison group at post-intervention and at 6-month follow-up. A ≥10 point change means change from one category to the next on the CGAS.

A second objective of this study is to evaluate parent and teacher ratings of child symptomatology (SAD and SM) at home and in the classroom, respectively, over the course of the treatment program.

Hypothesis #4: Parents of children who attend the *"Taming Sneaky Fears for SAD and/or SM"* will report significantly fewer symptoms over the course of the study than those in the "Parent Psycho-education and Child Socialization" as measured by the parent Selective Mutism Questionnaire (SMQ)[62] and the Social Anxiety Scale for Children Revised for Parents (SASC-P).[63] Similarly, teachers will report significantly fewer symptoms over the course of this study in children who attend the *"Taming Sneaky Fears for SAD and/or SM"* than those in the "Parent Psycho-education and Child Socialization," as measured by the teacher School Speech Questionnaire (SSQ)[64] and the Social Anxiety Scale for Children Revised for Teachers (SASC-T).[63]

A third objective is to explore factors within the child, parent and environment that predict treatment outcome (i.e., loss of at least one anxiety diagnosis post-treatment; this objective could not be explored in the original OMHF study due to the small sample size and lack of power). Factors hypothesized to predict treatment outcomes include within-the-child factors (age, gender, BI, and speech-language difficulties) and within-the-parent/environment factors (family history of SAD or SM, immigration status, and family stresses).

Hypothesis #5: The most significant factor to predict treatment outcome (i.e. lost diagnosis) at 6 months will be treatment group. The other factors (age, gender, BI, speech-language difficulties, family history of SAD or SM, immigrations status, family stresses) will not be significant in predicting treatment outcome.

METHODS:

Study Design: This study utilizes a repeated measures, longitudinal, randomized controlled trial design to compare the efficacy of two interventions in the treatment of children aged 4 to 7 years with SM and/or SAD. Participants are randomized into either the (1) *"Taming Sneaky Fears for SAD and/or SM"* parent and child group CBT treatment, or (2) the "Parent Psycho-education and Child Socialization" comparison program. Both programs run for 10 consecutive weeks (plus one additional introduction week). To control for the nonspecific factors associated with treatment, such as the support, attention and expectation of improvement, parents and children in both treatment protocols receive comparable levels of attention from therapists (i.e., same duration of group sessions and total number of sessions with a therapist) and comparable opportunities for socialization (e.g., for the children: invitation to discuss how the previous week went, snack time, story time; for the parents: discussion of specific topics at each session). However, parents and children in the comparison group are not taught CBT strategies.

Participants:

Inclusion Criteria: 4 to 7 year old children referred for psychiatric assessment of SM and/or SAD who meet diagnostic criteria for SM and/or SAD as a primary diagnosis, as determined by 1 of the 4 psychiatrists at the 2 sites where the study is conducted. Presence of other anxiety disorders/symptoms is not an exclusion criterion as long as the main concern is SAD and/or SM.

Exclusion Criteria: Presence of autism spectrum disorder, brain injury, or significant developmental delays (based on medical history and clinical assessment). Children and parents not fluent in English.

Sample Size Calculation is based on data from our previous OMHF study, showing that 42% of children in the *"Taming Sneaky Fears"* program lost their primary diagnosis of SAD and/or SM post-intervention vs. none of the children in the comparison group (using the ADIS-P). In the present study, we conservatively estimate that 10% of children will lose their SAD and/or SM diagnosis in the comparison group. Hence using this difference of 32% (42% - 10%), a sample size of 69 (to round up, 35 subjects per treatment protocol) would achieve a power of 81% to detect a difference of 32% between treatment programs using a two-sided Chi-squared test with continuity correction with a significance level set at 0.05.[65] Further, a total of 15/77 children (19%) did not complete the full protocol in the original OMHF study, so we anticipate a 20% (n=18) dropout rate over the course of this study. As a result, 88 participants need to be recruited to ensure a final sample size of 70. In order to obtain a sample size of 88

participants over two years, 2 sites are necessary.

Sites: The 2 sites chosen for recruitment are both tertiary care treatment centers affiliated with the University of Toronto: The Hospital for Sick Children (HSC) and Toronto East General Hospital (TEGH). Both sites house pediatric anxiety disorders clinics and serve large urban/suburban populations. TEGH and HSC are approximately 5 km apart, accept referrals for assessment and treatment from anywhere within the greater Toronto are (GTA), and are easily accessible for families living within the GTA. Respectively 50 and 25 children between the ages of 4 and 7 with SAD and/or SM are referred to HSC and TEGH every year, yielding a total of 75 children assessed per year at the two sites. It is our experience that the majority (approximately 90%) of children attending assessments in our anxiety clinic for either SAD or SM meet criteria for one or both of these diagnoses, thus suggesting that 70 children (.90 x 75 total = 67 eligible patients) will be eligible for study participation per year from the 2 sites. Further, given the academic affiliation of our sites, families attending our clinics are receptive to participation in research studies and conservatively, we find that close to 75 to 80% of families approached are interested and willing to participate in research studies. As a result, we anticipate that 50 to 53 families (.75 x 67 to .80 x 67) from the 2 sites are likely to participate in the study each year. Therefore, it is both feasible and realistic to not only recruit the necessary 88 children, but also to retain the necessary minimum sample size of 70 children over the 2-year study, even when considering attrition over the longer-term follow-up.

Recruitment: Children referred for an assessment of SAD and/or SM at either site are assessed by 1 of the 4 child psychiatrists, who obtains information about presenting problem, its impact on the child's functioning at school, home and with peers, and developmental, medical and family history. Eligible, interested children and families meet with a Clinical Research Project Coordinator (coordinator) who describes the study immediately post-assessment at either HSC or TEGH (depending on site where child was assessed). The coordinator obtains informed consent from parent(s) and assent from child, gives pre-treatment questionnaires to the parent(s), and schedules the first research assessment visit (Time 1) at HSC within 2 to 3 weeks of assessment and start of treatment group. Children and families not eligible for the study or who decline to participate are treated or referred for appropriate treatment as usually done in each clinic.

Measures: A demographic questionnaire (child's age and gender, parent's name, family composition, family history of SAD or SM, and immigration status) is completed by the parent at the start of the study.

A. Clinician Rated Measures:

1) The Anxiety Disorders Interview Schedule for DSM-IV, Parent Version (ADIS-P)[59] is used to assess SAD and/or SM. The ADIS-P has good reliability,[66] is sensitive to treatment effects in child anxiety studies,[66,67] and has been used in a number of studies on preschoolers[45,46,48] and SM treatment.[58] Clinical Severity Rating (ADIS-CSR) uses a 0 to 8 scale to measure clinical severity of diagnosis; a CSR of ≥4 indicates clinically significant symptoms and presence of an anxiety disorder. A trained independent clinician blinded to treatment type and time of assessment completes the CSR.
2) The Children's Global Assessment Scale (CGAS)[61] assesses adaptive functioning during the previous month for children aged 4-16 years. It has high inter-rater and test-retest reliability. A trained independent clinician blinded to treatment type and time of assessment completes the CGAS.
3) The "10 Steps to Talking" has 10 items, each rated as Yes (1 point) or No (0 point), with a total score (ranging from 0 to 10) assigned after a 20 minute period of structured interaction between clinician and child. The "10 Steps to Talking" was developed by our research group to clinically track non-verbal and verbal interactions in which a child engages with a clinician. This measure supports the clinician's assessment of global functioning and provides qualitative information. In the present study, it is completed at each research assessment by the independent clinician blinded to treatment type and time of assessment, but because it is still in development, no specific hypotheses are generated about its use. The 10 items include willingness to stay in the room with examiner, eye contact, nodding, pointing, gesturing, mouthing words (saying words with lips without voice), soft whisper, louder whisper, soft voice, 'normal' voice.
4) National Population Health Survey (NPHS): Household Component Cycle 9 (2010-2012) Questionnaire[69] is a longitudinal survey used to interview Canadians every 2 years and collects health and socio-demographic information. In the present study, NPHS is used to assess socioeconomic status

(household income, education, and number of people living in the household).

B. Parent Report of Child Symptoms:

1) The Selective Mutism Questionnaire (SMQ)[62] is a 17-item parent report of frequency of speech, using a 4-point rating scale ranging from 0 (never) to 3 (always), and yielding a Mean score based on ratings on three subscales (Home, School, Other). SMQ is sensitive to symptom changes.[55,58]

2) The Social Anxiety Scale for Children-Revised (SASC-P/T; Parent and Teacher versions) has 18 items for social anxiety with demonstrated reliability and validity.[63] A higher score indicates higher severity.

3) The Behavioral Inhibition Questionnaire (BIQ)[71] has 30 items that assess BI in 4-15 year old children and discriminates inhibited from uninhibited children.[71,72] Items are rated on a 6-point scale ranging from 1 (hardly ever) to 6 (almost always). Strong psychometric properties have been demonstrated.[72]

4) The Strengths and Weaknesses of ADHD and Normal Behaviour (SWAN) rating scale is a 30-item parent-report that measures a child's ability to attend and control impulsive behaviour (e.g. oppositional behaviours). Items are rated on a 7-point scale from "far below" to "far above". This instrument has been demonstrated to be both reliable and valid. [77,78]

C. Teacher Report of Child Symptoms:

1) The School Speech Questionnaire (SSQ)[64] is a 4-point rating scale of frequency of speaking behaviours at school, ranging from 0 (never) to 3 (always), that is sensitive to teacher-noted symptom improvement.[59,60] A lower score indicates higher severity and impairment. Internal consistency is satisfactory.[59]
2) The Social Anxiety Scale of Children-Revised Teacher version (SASC-T; see above)[63] is adapted by the Bergman group to allow teachers to quantify social anxiety symptoms within the school setting.

D. Parent Measures:

1) The Depression Anxiety Stress Scales short version (DASS-21)[72] is a 21-item self-report of anxiety and depression in adults, using a 4-point scale ranging from 0 ('did not apply to me at all over the last week') to 3 ('most of the time over the past week'). It has excellent psychometric properties[73] including adequate convergent and divergent validity with clinical assessment and the Beck Depression Inventory.[74] Only the anxiety and stress subscales are used in the present study.
2) Parenting Stress Index–Short Form (PSI-SF)[75] has 36 items, measures the magnitude of stress in the parent–child relationship, has good test-retest reliability and internal consistency,[76] and is used as a measure of stress in the present study. Raw scores of ≥90 indicate clinically significant levels of stress.

E. Speech and Language Testing: is completed by a speech language pathologist at the pre-treatment assessment only. Children's speech and language skills are categorized as 1) age appropriate; 2) suspected delay/disorder; 3) confirmed delay/disorder; 4) unable to determine due to lack of compliance in testing, and used as a within-the-child factor.

Research Protocol: The full research protocol takes 9 months for each child and parent to complete and includes a total of 3 research visits (T1, T2, T3) and 11 treatment visits to the HSC Department of Psychiatry. Time between assessment and first research visit is approximately 2-3 weeks.

Pre-treatment Research Assessment (Time 1 [T1]) takes place ~2 weeks prior to group-treatment start. Parent questionnaires are reviewed by a Clinical Research Project Coordinator (CRPC) to ensure completion. The CRPC administers the ADIS-P with the parent and then completes the '10 Steps to Talking' with the child in the presence of the parent (video-recorded). The only speech and language assessment completed as part of the study is conducted (and video-recorded) at this T1 visit. Upon completion of the T1 visit, the CRPC **randomly assigns** each eligible child and parent to either the (1)*"Taming Sneaky Fears for SAD and/or SM"* parent and child group CBT program or (2) the "Parent Psycho-education and Child Socialization" group program, and informs them of group assignment. The online software *Sealed Envelope*^{TM} (https://www.sealedenvelope.com/) is used to randomize. This program is commonly used by hospital research studies because it uses computer-generated sequences to allocate participants to each group. Allocation of participants uses sealed, opaque envelopes and remains concealed until study completion. The CRPC and lead child group and parent group therapists (SM & DB) are not blinded, however, the clinicians completing the post-intervention (T2) and 6-month follow up (T3) assessments are blind to treatment type, previous ratings on all measures, and time of assessment.

Implementation of Treatment Protocols: Both group treatment protocols run concurrently, but on different days. A total of 5 *"Taming Sneaky Fears"* and 5 "Parent Psycho-education and Child Socialization" groups need to run over the course of the 2-year study with 8 - 9 children per group (total of 40 - 45 children per treatment arm over study period). Groups run weekly for 1 hour for nearly 3 months (10 + 1 sessions) starting in September 2015, October 2015, November 2015, March 2016, and April 2016. As the final treatment groups for the study are completed by mid-July 2016, the final 6-month follow-up takes place in mid-January 2017, prior to the end of the study (see Time line of Study p. 10). Regardless of the treatment program, the first treatment visit is for parents only at which time parents are introduced to the therapists and other parents in the group and provided a copy of the "Parent Manual" relevant for each group (either the Parent Manual for "*Taming Sneaky Fears for SAD and SM*" or the one for "*Parent Psycho-education and Child Socialization*" that includes handouts provided as part of the "Improving Parent-Child Relationship" series of videotapes).

In both treatment protocols, parents and children attend weekly, 1-hour group sessions for 10 consecutive weeks at HSC. In order for the 2 treatments to be comparable, each child group follows the same format, i.e., starts with a 'review of the week', followed by a story then craft activity and ends with a snack. At the end of each session, a child therapist drops into the parent group to inform parents about strategies and activities taught to children that day (typically, a 30-second general summary). At the mid-point of both group treatments, a child therapist meets with parent(s) individually to discuss their child's progress. Therefore, children in both treatments receive equal opportunities for interaction with therapists and socialization with peers with the only difference between groups being that children in the *"Taming Sneaky Fears for SAD and/or SM"* group receive CBT while the children in the comparison group do not. Similarly, both parent groups start with a review of homework, then new information is provided and finally, homework is assigned; with the main difference between groups being that in *"Taming Sneaky Fears for SAD and/or SM"* parents receive CBT.

A. *"Taming Sneaky Fears"* Child and Parent Group CBT Protocol: Both children and parents separately, but concurrently, receive CBT in a group format. Using stories, games, and puppets, children are taught a variety of CBT strategies to manage anxiety, especially social anxiety and mutism (e.g., 'use your voice'), and socialization and interaction with peers and group leaders are encouraged. Parents are taught CBT strategies with a strong emphasis on building hierarchies (progressive desensitization) for speech and social situations.

B. "Parent Psycho-education and Child Socialization" Protocol: The parent component of this protocol is made up of a variety of psycho-educational topics, for example, parenting, child behaviour, nutrition, sleep, and normative development. A series of psycho-educational videotapes developed for parents with accompanying parent information handouts (www.improvedparenting.com) is used. Parents view two 30-minute videotapes from the series at each session. In the child group, children listen to stories, play games, complete crafts and have opportunities to interact and socialize with peers and group leaders. Therapists encourage socialization, manage behaviours and interact with children to parallel the *"Taming Sneaky Fears for SAD and/or SM"* group.

Post-group Research Assessment (T2) and Longer-term (6-month) Post-group Research Follow-up (T3): Each post-treatment research visit takes ~2½ hours to complete, is video-taped and is similar to the T1 visit except there is no speech and language assessment. To ensure an unbiased assessment and clinician rating of the ADIS (-P and -CSR) and CGAS, a psychiatrist or graduate (PhD) student trained in the ADIS and blinded to treatment group, previous ratings, and time of assessment, administers the ADIS-P to the parents. This assessor then conducts the "10 Steps to Talking" protocol with the child in the presence of the parent. Parents also complete the same questionnaires used at T1, with the addition of one new questionnaire (the SWAN Rating scale). Parents are provided with teacher questionnaires prior to the end of treatment and bring them back (completed by teachers) at T2,while teacher questionnaires are mailed out to parents a few weeks prior to the 6-month post-intervention (T3) assessment and parents bring the completed questionnaires at the T3 visit. Teacher questionnaires are completed by teachers who know the child well as close to the assessment time as possible (e.g. if a research assessment is in July, the teacher completes the questionnaire prior to the end of school year).

Children receive stickers and parents are reimbursed $20.00 to compensate for expenses such as parking and/or other expenses incurred because of participation in the research assessments at each of the T1, T2, T3 assessments. The 3 research assessments are video-recorded and ≥5% of randomly assigned recordings are reviewed by all assessors (coordinators + assessors at T2 and T3) to establish inter-rater

reliability on ADIS-CSR and CGAS. We acknowledge the difficulty in following families after treatment and to encourage subject retention, 1 of the coordinators contacts families by phone 3 months post-treatment and the need for ongoing monitoring and follow-up to maintain gains made is emphasized to parents**.**

Statistical Analysis and Data Analyses Plan:

Data for demographic variables will be summarized using counts, percentages, measures of central tendency (average, median, mode) and measures of sample variation (standard deviation, range). Parametric statistics (average, standard deviation) will be used for interval and ratio data.

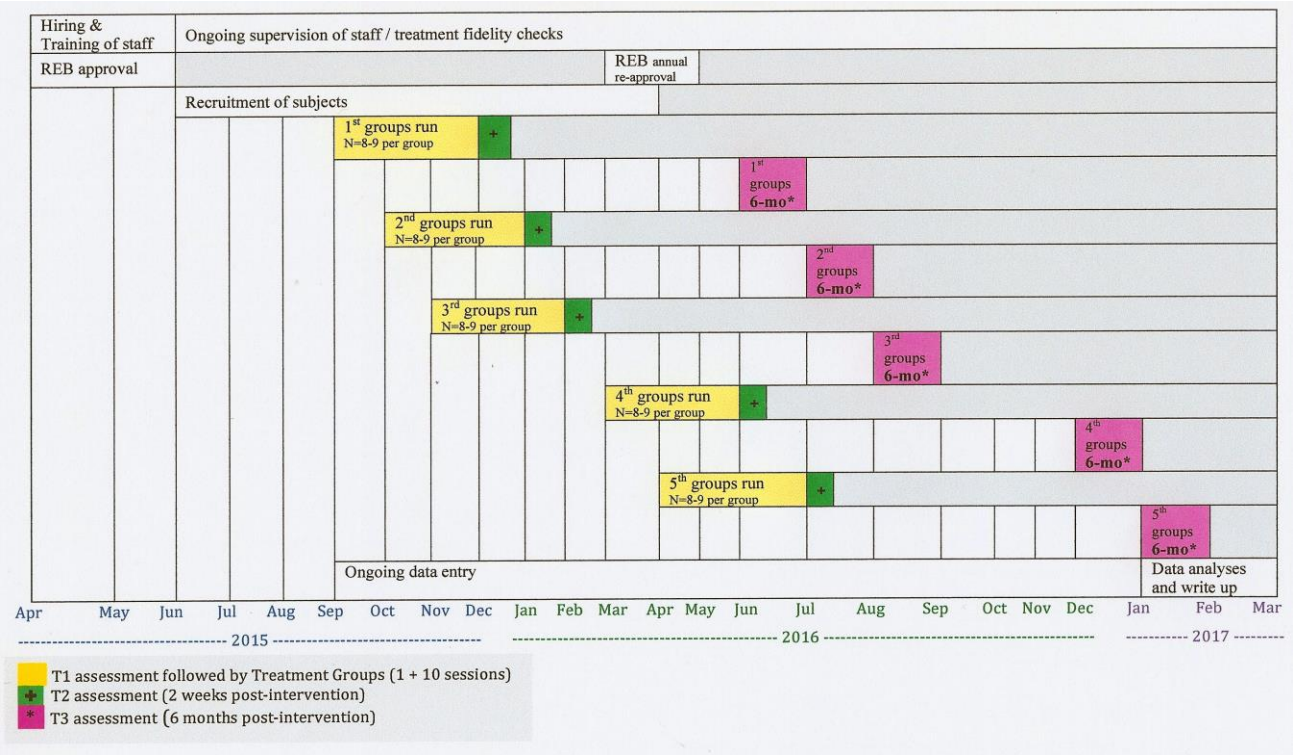
To address Hypothesis 1, we will use a two-sided Chi-Square test with continuity correction to compare the difference between the two 2 groups in the proportion of children who lost diagnoses post-treatment (T2) and 6 months post-treatment (T3).

To test Hypothesis 2, we will use a repeated measures regression model on the ADIS-CSR and compare the two 2 treatment groups from pre-treatment (T1) to 6-month post treatment (T3). An interaction term between time and group will be introduced in the model in order to explore possible differences at different time points between the two groups. The assumptions of the model will be verified using residual analysis and, if necessary, transformations will be used in order to obtain a valid model. This repeated measures regression model will be used for Hypotheses 3 and 4 to assess child global functioning using CGAS and parent and teacher reports of child symptoms on SMQ, SASC-P/T and SSQ.

To examine Hypothesis 5, a logistic regression analysis will be employed. This will allow for the examination of the strength of multiple predictors on the likelihood that a child will lose an anxiety disorder diagnosis 6 months post-intervention (T3). The predictor factors that will be included in this model include group intervention ("*Taming Sneaky Fears for SAD and/or SM*" or "Parent Psycho-education and Child Socialization"), within-the-child factors (child's age, sex, BI, and speech-language difficulties), parent factors (family history of SAD or SM), and environmental factors (family stress, immigration status). All the significant factors will be put into the model and non-significant predictors will be excluded. The model will control for age and sex of the child.

ORIGINALITY AND SIGNIFICANCE/RELEVANCE: This is the first RCT to assess the efficacy of *"Taming Sneaky Fears for SAD and/or SM"*, a group CBT treatment approach to treat 4 to 7 year old children with SM and/or SAD, which are anxiety disorders affecting as many as 36,340 children under age 14 in Ontario. The present study addresses methodological shortcomings of previous studies and builds on OMHF-funded previous work while addressing a significant clinical problem for which little convincing evidence for treatment efficacy exists. The present study represents an innovative treatment method that is brief, CBT-based, and group-focused.

Timeline of the Study:



REFERENCES

1. Franz L, Angold A, Copeland W, Costello EJ, Towe-Goodman N, Egger H. Preschool anxiety disorders in pediatric primary care: prevalence and comorbidity. *J Am Acad Child Adolesc Psychiatry.* **52(12)**,1294-1303 (2013).
2. Bergman RL, Piacentini J, McCracken JT. Prevalence and description of selective mutism in a school-based sample. *J Am Acad Child Adolesc Psychiatry.* **41(8)**, 938-946 (2002).
3. Elizur Y, Perednik R. Prevalence and description of selective mutism in immigrant and native families: a controlled study. *J Am Acad Child Adolesc Psychiatry.* **42(12)**, 1451-1459 (2003).
4. Statistics Canada. Census of Population. In: Catalogue Statistics Canada, ed. Canada 2011 no. 98-312-XCB2011026.
5. Cartwright-Hatton S, McNicol K, Doubleday E. Anxiety in a neglected population: prevalence of anxiety disorders in pre-adolescent children. *Clin Psychol Rev.* **26(7)**, 817-833 (2006).
6. Connolly SD, Bernstein GA. Practice parameter for the assessment and treatment of children and adolescents with anxiety disorders. *J Am Acad Child Adolesc Psychiatry.* **46(2)**, 267-283 (2007).
7. Egger HL, Angold A. Common emotional and behavioral disorders in preschool children: presentation, nosology, and epidemiology. *J Child Psychol Psychiatry.* **47(3-4)**, 313-337 (2006).
8. Eley TC, Bolton D, O'Connor TG, Perrin S, Smith P, Plomin R. A twin study of anxiety-related behaviours in pre-school children. *J Child Psychol Psychiatry.* **44(7)**, 945-960 (2003).
9. Luby JL, Heffelfinger AK, Mrakotsky C, et al. The clinical picture of depression in preschool children. *J Am Acad Child Adolesc Psychiatry.* **42(3)**, 340-348 (2003).
10. Luby JL. Treatment of anxiety and depression in the preschool period. *J Am Acad Child Adolesc Psychiatry.* **52(4)**, 346-358 (2013).
11. Spence SH, Rapee R, McDonald C, Ingram M. The structure of anxiety symptoms among preschoolers. *Behav Res Ther.* **39(11)**, 1293-1316 (2001).
12. Gregory AM, Caspi A, Moffitt TE, Koenen K, Eley TC, Poulton R. Juvenile mental health histories of adults with anxiety disorders. *Am J Psychiatry.* **164(2)**, 301-308 (2007).
13. Otto MW, Pollack MH, Maki KM, et al. Childhood history of anxiety disorders among adults with social phobia: rates, correlates, and comparisons with patients with panic disorder. *Depress Anxiety.* **14(4)**, 209-213 (2001).
14. Hirshfeld-Becker DR, Micco JA, Mazursky H, Bruett L, Henin A. Applying cognitive-behavioral therapy for anxiety to the younger child. *Child Adolesc Psychiatr Clin N Am.* **20(2)**, 349-368 (2011).
15. Rapee RM, Kennedy S, Ingram M, Edwards S, Sweeney L. Prevention and early intervention of anxiety disorders in inhibited preschool children. *J Consult Clin Psychol.* **73(3)**, 488-497 (2005).
16. Cohen P, Cohen J, Brook J. An epidemiological study of disorders in late childhood and adolescence--II. Persistence of disorders. *J Child Psychol Psychiatry.* **34(6)**, 869-877 (1993).
17. Shonkoff JP, Phillips D. *From Neurons to Neighborhoods: The Science of Early Childhood Development.* Washington DC. : National Academy Press; 2000.
18. American Psychiatric Association, ed *Diagnostic and Statistical Manual of Mental Disorders.* Fifth Edition ed. Arlington, VA: American Psychiatric Publishing; 2013.
19. Alyanak B, Kilincaslan A, Harmanci HS, Demirkaya SK, Yurtbay T, Vehid HE. Parental adjustment, parenting attitudes and emotional and behavioral problems in children with selective mutism. *J Anxiety Disord.* **27(1)**, 9-15 (2012).
20. Arie M, Henkin Y, Lamy D, et al. Reduced auditory processing capacity during vocalization in children with Selective Mutism. *Biol Psychiatry.* **61(3)**, 419-421 (2007).
21. Manassis K, Tannock R, Garland EJ, Minde K, McInnes A, and Clark S. The sounds of silence: language, cognition, and anxiety in selective mutism. *J Am Acad Child Adolesc Psychiatry.* (2007): **46(9)**, 1187-1195 (2007).
22. Dummit ES, Klein RG, Tancer NK, Asche B, Martin J, Fairbanks JA. Systematic assessment of 50 children with selective mutism. *J Am Acad Child Adolesc Psychiatry.* **36(5)**, 653-660 (1997).
23. Vecchio J, and Kearney CA. Selective mutsim in children: comparison to youths with and without anxiety disorders. (2007); *J Psychopath Behav Assessment*. **26**, 31-37 (2007).
24. Manassis K, Fung D, Tannock R, Sloman L, Fiksenbaum L, McInnes A. Characterizing selective mutism: is it more than social anxiety? *Depress Anxiety.* **18(3)**, 153-161 (2003).

25. Yeganeh R, Beidel DC, Turner SM, Pina AA, Silverman WK. Clinical distinctions between selective mutism and social phobia: an investigation of childhood psychopathology. *J Am Acad Child Adolesc Psychiatry.* **42(9)**, 1069-1075 (2003).
26. Yeganeh R, Beidel DC, Turner SM. Selective mutism: more than social anxiety? *Depress Anxiety.* **23(3)**, 117-123 (2006).
27. Kagan J, Reznick JS, Snidman N. Biological bases of childhood shyness. *Science*. **240**, 167-71. (1988).
28. Fox NA, Henderson HA, Marshall PJ, Nichols KE, Ghera MM. Behavioral inhibition: linking biology and behavior within a developmental framework. *An Rev Psychology.* **56**, 235-262 (2005).
29. Hirshfeld-Becker DR, Biderman J, Henin A, Faraone SV, Davis S, Harrington K, Rosenbaum JF. Behvaioral inhibition in preschool children at risk is a specific predictor of middle childhood social anxiety: a five year follow-up. *J Dev Behav Pediatr* **28(3)**, 225-233 (2007).
30. Hayward C, Killen JD, Kraemer HC, Taylor CB. Linking self-reported childhood behavioral inhibition to adolescent social phobia. *J Am Acad Child Adolesc Psychiatry.* **37**, 1308-1316 (1988).
31. Black B, Uhde TW. Elective mutism as a variant of social phobia. *J Am Acad Child Adolesc Psychiatry.* **31(6)**, 1090-1094 (1992).
32. Chavira DA, Shipon-Blum E, Hitchcock C, Cohan S, Stein MB. Selective mutism and social anxiety disorder: all in the family? *J Am Acad Child Adolesc Psychiatry.* **46(11)**, 1464-1472 (2007).
33. Steinhausen HC, Wachter M, Laimbock K, Metzke CW. A long-term outcome study of selective mutism in childhood. *J Child Psychol Psych Allied Disciplines.* **47(7)**, 751-756 (2006).
34. Viana AG, Beidel DC, Rabian B. Selective mutism: a review and integration of the last 15 years. *Clin Psychol Rev.* **29(1)**, 57-67 (2009)
35. Bradley S, Sloman L. Elective mutism in immigrant families. *J Am Acad Child Psychiatry.* **14(3)**, 510-514 (1975).
36. Toppelberg CO, Tabors P, Coggins A, Lum K, Burger C. Differential diagnosis of selective mutism in bilingual children. *J Am Acad Child Adolesc Psychiatry.* **44(6)**, 592-595 (2005).
37. Schneider S, Blatter-Meunier J, Herren C, Adornetto C, In-Albon T, Lavallee K. Disorder-specific cognitive-behavioral therapy for separation anxiety disorder in young children: a randomized waiting-list-controlled trial. *Psychother Psychosom.* **80(4)**, 206-215. (2011).
38. Cunningham CE, McHolm A, Boyle MH, Patel S. Behavioral and emotional adjustment, family functioning, academic performance, and social relationships in children with selective mutism. *J Child Psychol Psych Allied Disciplines.* **45(8)**, 1363-1372 (2004).
38. City of Toronto. Population Health Statistics: Summary Tables 2013; http://www.toronto.ca/health/statistics/, 2014.
39. Carbone D, Schmidt LA, Cunningham CC, et al. Behavioral and socio-emotional functioning in children with selective mutism: a comparison with anxious and typically developing children across multiple informants. *J Abnorm Child Psychol.* **38(8)**, 1057-1067 (2010).
40. Cohan SL, Chavira DA, Stein MB. Practitioner review: Psychosocial interventions for children with selective mutism: a critical evaluation of the literature from 1990-2005. *J Child Psychol Psych Allied Disciplines.* **47(11)**, 1085-1097 (2006).
41. Rapee RM, Kennedy SJ, Ingram M, Edwards SL, Sweeney L. Altering the trajectory of anxiety in at-risk young children. *Am J Psychiatry.* **167(12)**, 1518-1525 (2010).
42. Santacruz I, Mendez FJ, Sanchez-Meca J. Play Therapy Applied by Parents for Children with Darkness Phobia: Comparison of Two Programmes. *Child Fam Behav Ther.* **28(1)**, 19-35 (2006).
43. Kennedy SJ. A Selective Intervention Program for Inhibited Preschool-Aged Children of Parents With an Anxiety Disorder: Effects on Current Anxiety Disorders and Temperament. *J Am Acad Child Adolesc Psychiatry.* **48(6)**, 602-9 (2009).
44. Hirshfeld-Becker DR, Masek B, Henin A, et al. Cognitive-behavioral intervention with young anxious children. *Harv Rev Psychiatry.* **16(2)**,113-125 (2008).
45. Hirshfeld-Becker DR, Masek B, Henin A, et al. Cognitive behavioral therapy for 4- to 7-year-old children with anxiety disorders: a randomized clinical trial. *J Consult Clin Psychol.* **78(4)**, 498-510 (2010).

46. Monga S, Young A, Owens M. Evaluating a cognitive behavioral therapy group program for anxious five to seven year old children: a pilot study. *Depress Anxiety.* **26(3)**, 243-250 (2009).
47. Pahl KM, Barrett PM. The development of social-emotional competence in preschool-aged children: An introduction to the Fun FRIENDS program. *Aust J Guid Counsell.* **17(1)**, 81-90 (2007).
48. Waters AM, Ford LA, Wharton TA, Cobham VE. Cognitive-behavioural therapy for young children with anxiety disorders: Comparison of a child + parent condition versus a parent pnly condition. *Behav Res Ther.* **47(8)**, 654-662 (2009).
49. Albano AM, Marten PA, Holt CS, Heimberg RG, Barlow DH. Cognitive-behavioral group treatment for social phobia in adolescents: a preliminary study. *J Nerv Ment Dis.***183(10)**, 649-656 (1995).
50. Hayward C, Varady S, Albano AM, Thienemann M, Henderson L, Schatzberg AF. Cognitive-behavioral group therapy for social phobia in female adolescents: results of a pilot study. *J Am Acad Child Adolesc Psychiatry.* **39(6)**, 721-726 (2000).
51. Spence SH, Holmes JM, March S, Lipp OV. The feasibility and outcome of clinic plus internet delivery of cognitive-behavior therapy for childhood anxiety. *J Consult Clin Psychol.* **74(3):**614-621 (2006).
52. Beidel DC, Turner SM, Morris TL. Behavioral treatment of childhood social phobia. *J Consult Clin Psychol.* **68(6)**, 1072-1080 (2000).
53. Baer S, Garland EJ. Pilot study of community-based cognitive behavioral group therapy for adolescents with social phobia. *J Am Acad Child Adolesc Psychiatry.* **44(3)**, 258-264 (2005).
54. Reuther ET, Davis TE, 3rd, Moree BN, Matson JL. Treating selective mutism using modular CBT for child anxiety: a case study. *J Clin Child Adolesc Psychology.* **40(1)**,156-163 (2011).
55. Sharkey L, Mc Nicholas F, Barry E, Begley M, Ahern S. Group therapy for selective mutism - a parents' and children's treatment group. *J Behav Ther Exp Psychiatry.* **39(4)**, 538-545 (2008).
56. Oerbeck B, Johansen J, Lundahl K, Kristensen H. Selective mutism: A home-and kindergarten-based intervention for children 3-5 Years: A pilot study. *Clin Child Psychol Psychiatry.* **17(3)**, 370-383 (2011).
57. Black B, Uhde TW. Treatment of elective mutism with fluoxetine: a double-blind, placebo-controlled study. *J Am Acad Child Adolesc Psychiatry.* **33(7)**, 1000-1006 (1994).
58. Bergman RL, Gonzalez A, Piacentini J, Keller ML. Integrated Behavior Therapy for Selective Mutism: a randomized controlled pilot study. *Behav Res Ther.* **51(10)**, 680-689 (2013).
59. Silverman WK, Albano AM. The Anxiety Disorders Interview Schedule for children for DSM-IV: Clinician manual (Child and parent versions). San Antonio, TX: Psychological Corporation; 1996.
60. Bennett K, Manassis K, Walter SD, et al. Cognitive behavioral therapy age effects in child and adolescent anxiety: an individual patient data metaanalysis. *Depress Anxiety.* **30(9)**, 829-841 (2013).
61. Shaffer D, Gould MS, Brasic J, et al. A children's global assessment scale (CGAS). Arch Gen Psychiatry. **40(11)**, 1228-31 (1983).
62. Bergman RL, Keller ML, Piacentini J, & Bergman AJ. The development and psychometric properties of the selective mutism questionnaire. *J Clin Child Adolesc Psychology*. **37(2)**, 456-464 (2008).
63. LaGreca AM, and Stone WL. The social anxiety scale for children-revised: factor structure and concurrent validity. *J Clin Child Psychology*. **22**,17-27 (1993).
64. Bergman RL, Keller M, Wood J, Piacentini J, and McCracken J. Selective mutism questionnaire: development and findings. In *Proceedings of the American Academy of child and adolescent psychiatry meeting*. **48**; pp.163 (2001).
65. Fleiss JL. In *Statistical Methods for Rates and Proportions*. 1981. Chp. 4 John Wiley & Sons. NY
66. Silverman WK, Saavedra LM, & Pina AA. Test-retest reliability of anxiety symptoms and diagnoses with the Anxiety Disorders Interview Schedule for DSM-IV: child and parent versions. *J Am Acad Child Adolesc Psychiatry* 2**40**, 937-944 (2001).
67. Walkup JT, Albano AM, Piacentini J, Birmaher B, Compton SN, Sherrill JT, et al. Cognitive behavioral therapy, sertraline, or a combination in childhood anxiety. *New Eng J Medicine* **359**, 2753-2766 (2008)

68. National Population Health Survey (NPHS): Household Component Cycle 9 (2010-2012) questionnaire (http://www.statcan.gc.ca/eng/survey/household/3225).
70. Bishop G, Spence SH, & McDonald C. Can parents and teachers provide a reliable and valid report of behavioral inhibition? *Child Devel*. **74**,1899-1917 (2003).
71. Broeren S. & Muris P. A Psychometric Evaluation of the Behavioral Inhibition Questionnaire in a Non-Clinical Sample of Dutch Children and Adolescents. *Child Psychiatry Hum Dev* **41**, 214-229 (2010).
72. Lovibond SH, & Lovibond PF *Manual for the Depression Anxiety Stress Scales*. *(2nd. Ed.)* Sydney: Psychology Foundation (1995).
73. Brown, TA, Korotitsch W, Chorpita BF, & Barlow DH. Psychometric properties of the Depression Anxiety Stress Scales (DASS) in clinical samples. *Behav Res Therapy* **35**, 79-89 (1997).
74. Lovibond SH & Lovibond PF The structure of negative emotional states: comparison of the Depression Anxiety Stress Scale (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Therapy* **33**, 335-343 (1995).
75. Abidin RR The Parenting Stress Index (PSI) manual (3rd ed.). Pediatric Psychology Press: Charlottesville VA (1995).
76. Haskett ME, Ahern LS, Ward CS & Allaire JC. Factor structure and validiaty of the Parenting Stress Index-Short From. *J Clin Child Adolesc Psychology* **35**, 302-312 (2006).
77. Lakes KD, Swanson JM, & Riggs M. The reliability and validity of the English and Spanish Strengths and Weaknesses of ADHD and Normal behavior rating scales in a preschool sample: continuum measures of hyperactivity and inattention. *J Atten Disord*, **16(6)**, 510–6 (2012).
78. Normand, S, Flora DB, Toplak ME, & Tannock, R. Evidence for a general ADHD factor from a longitudinal general school population study. *J Abnorm Child Psych*, **40(4)**, 555–67 (2012).