ORIGINAL ARTICLE

A Model and Treatment for Autism at the Convergence of Chinese Medicine and Western Science: First 130 Cases*

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ABSTRACT **Objective**: To present a model for autism showing that impairment of sensory and self-regulation is the core deficit that underlies delays in social/language skills and abnormal behavior in autism; and to demonstrate the efficacy of a treatment for autism based on Chinese medicine. **Methods**: Children with autism under 6 years of age were assigned to treatment or wait-list conditions. A total of 130 children were treated and the results compared with 45 wait-list controls. Treatment is a tuina methodology directed at sensory impairment——Kai Qiao Tuina. The treatment was a five-month protocol that was implemented daily by trained parents via trained support staff. The effects of treatment on the main symptoms, autistic behavior, social/language delay, sensory and self-regulatory impairment, as well as on parenting stress, were observed and compared. **Results**: The treatment had a large effect size (P<0.0001) on measures of sensory and self-regulation. The evaluations done by pre-school teachers demonstrated improvement in the measures of autism (P<0.003), and were confirmed by evaluations done by parents (P<0.0001). There was a large decrease (P<0.0001) in parenting stress. **Conclusions**: Sensory and self-regulatory impairment is a main factor in the development and severity of autism. Treatment of young children with autism with Kai Qiao Tuina resulted in a decrease in sensory and self-regulatory impairment and a reduction in severity of measures of autism.

KEYWORDS Kai Qiao Tuina, Qigong sensory training, autism treatment for children, sensory impairment, abnormal sensory responses, autism, early intervention for autism

Two recent randomized controlled trials (RCTs) of a tuina intervention for pre-school children with autism, based on concepts of Chinese medicine, showed significant improvement of behavioral and social measures of autism in treated children[1,2]. The intervention is called Kai Qiao Tuina in China, or Qigong sensory training (QST) in the U.S. These two studies are the most recent in a nine-year research stream during which the intervention was adapted and training materials developed and refined for implementation by parents with support by early intervention specialists. During this process, a series of pre-post design studies were conducted in conjunction with training staff from early intervention programs, and continuously evaluated for efficacy against measures of autism.

To date, outcomes data has been collected on 130 treated children and on 45 of whom served as wait-list controls. In this paper, we present a model for the patho-physiology and treatment of autism based on the concepts of Chinese medicine: that autism results from a partial closure of the sensory orifices due to toxicity, deficiency or block. As a result, the senses inappropriately under or over-react to incoming stimuli and do not work together, such that the brain does not receive the sensory information from the outside world required for normal learning and development. In Western medical terms, an impairment of sensory regulation underlies the abnormal behaviors and learning delays seen in autism. Treatment with a tuina methodology directed at sensory regulation results in normalization of behavior and improvement in developmental learning (Figure 1).

In presenting the model and providing preliminary support with pooled data, we have three principal objectives: (1) to summarize data which shows that this five-month early intervention methodology is significantly effective in reducing both the severity of autism and the intensity of parenting stress experienced by parents of young children with autism, we will compare pooled treatment data to pooled wait-

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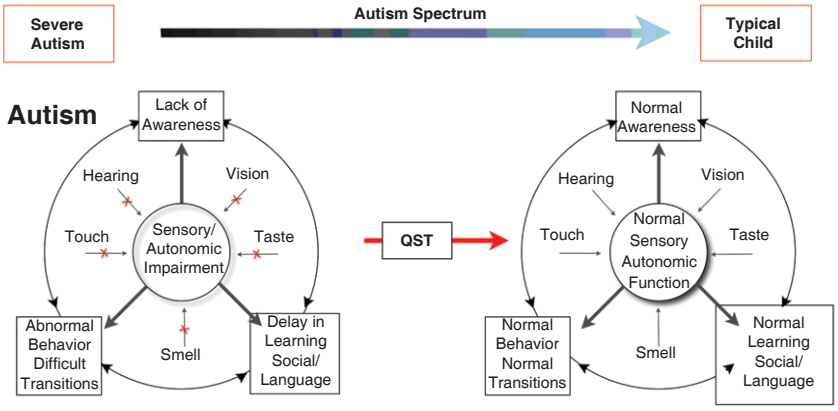

Figure 1. Mode for Autism

list control data; (2) to emphasize that this intervention is able to target sensory regulation regardless of the severity of autism, we will present an analysis showing no statistical difference in treatment outcome between high and low functioning children and discuss the limitations of our analysis; (3) to demonstrate that improvement in sensory function occurs with a decrease in severity of autism symptoms, and that there is still more improvement to be had after five months of treatment, we will present an analysis of the correlations between parent measures of sensory regulation and autism composite scores as a result of the following treatment. In contrast, attempts to correlate severity of autism with a proposed measure of regulation, vagal tone[3], proved unsuccessful in the age group of children we studied.

METHODS

Clinical Materials

Outcomes data from ten studies that took place in Oregon, USA between 2005 and 2009 is presented here. Studies shared a common method of recruitment of children (invitation letter to families receiving local early intervention services), common eligibility criteria for children (age under six, receiving services for autism, no complicating medical diagnoses, not planning on starting new therapies for the duration of the study), a common treatment procedure (the QST intervention) and two common hypotheses (an impairment of sensory regulation is a primary cause of autism, and the QST intervention is an effective treatment for autism). Studies differed in design (RCT versus single group pre-post design), in educational background of QST trainers, and in degree of support offered parents by trained support personnel. Outcome data was collected from both teachers and parents. In the RCT, teachers were blind to group. In the single group design, it was not possible for teachers to be blind; however no expectations were communicated relative to the study. The studies are summarized briefly below.

Study 1: A small RCT study of 15 children done in 2005, for which treatment was delivered by a physician trained in Chinese medicine[4]. Initially eight children were in the treatment group and an additional five wait-list control children were subsequently treated, and outcome data gathered.

Study 2: A study in 2006 piloting a five-month, skill-based QST program for early intervention (EI) staff and evaluating outcomes for 26 children with autism. Treatment was delivered by EI staff that was being trained on QST[5]. One aim of this study was to see if persons not fully trained in Chinese medicine could be trained to use the methodology effectively. The study proved successful, and from this point forward, studies were conducted in conjunction with trainings for EI staff.

Study 3: A RCT design study in 2007 to replicate and extend Study 2 with a larger sample of 46 children, of which 23 were in the initial treatment group. Outcome data was collected from preschool teachers who were blind to the treatment group, and by parents[1]. The wait-list control group was subsequently treated, and outcome data gathered on an additional 22 children.

Studies 4, 5, 6 and 7: Pre-post single group design studies in 2008 and 2009 evaluated outcomes of four additional five-month trainings conducted

in Oregon, USA with each therapist-in-training providing treatment to one or two children. Numbers of children in these studies were 10, 14, 10 and 15, respectively. During these studies, training materials and procedures for parents and QST therapists were further developed and refined. Starting with Study 5, cardiac vagal tone data was collected[3].

Studies 8 and 9: RCTs evaluated the impact of a less intensive version of QST where only parents give the Qigong treatment while being coached by a QST therapist. This treatment outcome data will be reported[2] but the wait-list control data is included here. In both of these studies, there were 8 children in the initial treatment group. The wait-list control groups were subsequently treated, and outcome data gathered on an additional 10 children in Study 8 and eight children in Study 9.

Study 10: A pre-post single group design with eight children evaluated treatment outcomes as a result of a single three-hour parent training followed by online support.

The QST Dual Intervention

Procedures involved in training parents and therapists to deliver the intervention and the methodology itself have been previously described in detail[4]. The QST intervention is a dual intervention delivered by parents and trained staff. The parent version is designed to calm and balance the child on a daily basis. The trainer version is designed to advance the progress of the child from week to week. The parent protocol is given every day, takes about 15 min to deliver, and consists of a sequence of 12 patting, shaking or pressing movements with the following actions according to Chinese medicine: movements 1, 2, 3: open and clear the channels to the brain and senses; movement 4: clear additional functional impediments of the ear; movements 5, 6, 7: promote social interaction and speech, open and nourish the middle Dantien; movements 8, 9: strengthen digestion and elimination, nourish the lower Dantien (丹田): movements 10, 11, 12: calm and quiet the child, improve sleep, nourish the upper Dantien.

Timetable for Delivery of the QST Dual Intervention

After the children were pre-tested, parents received training in the methodology from an EI staff person who had been trained in the QST methodology (QST trainer). Following this, the QST trainer met with families for twenty, half-hour visits over the five-month intervention. At each visit trainers gave the child a treatment, and provided additional training and support to the parent in the methodology. Five months later, outcome data was gathered, and shared with the parents at an exit interview that included a recommendation for length of time the treatment should be continued.

Items and Methods of Observation

Over the course of this research, our work has been with autistic children under six years of age. Consequently, our search for reliable and sensitive assessment tools in that age group has led us to try several different assessment tools, and in the cases where evaluative tools were not available, to design and validate the desired tools. This process of change and development is reflected in the data sets presented. The measures we have employed are briefly described below in chronological order of their use.

The Vineland (and Vineland-Ⅱ) Adaptive Behavior Scales[6] were used to measure self-help and motor skills. The Autism Behavior Checklist (ABC)[7,8] was chosen to evaluate autistic behavior in the classroom. The Sensory Profile[9] was initially used to measure sensory impairment. The Pervasive Developmental Disorders Behavior Inventory[10] (PDDBI) Teacher and Parent Versions were used to measure social/language abilities and maladaptive behavior in the school and home settings. The Autism Parenting Stress Index was developed to measure parent stress in 14 aspects of autism of concern to parents. Current validation data indicate reasonable levels of internal consistency (0.785) and test-retest stability (0.772)[a]. Cardiac vagal tone: measurements were taken with an ambulatory heart rate monitor (EZ-IBI-3, UFI, Morro Bay, CA, USA). The ECG electrodes were placed in a standard configuration on the chest. With the child seated between the parent and the technician, two-minute recordings were made. Vagal tone was quantified using the respiratory sinus arrhythmia editing program

[a]The Autism Parenting Stress Index is available online at www.qsti.org. Based on current validation data, it has been slightly modified to omit the first item. With this the internal consistency is 0.827, and test-retest stability is 0.772.

from Brain-Body Center, University of Illinois at Chicago[11]. The Sense and Self-Regulation Checklist (SSC) was developed to measure sensory and self-regulatory symptoms reported by parents[12]. The choice, grouping, and weighting of the questions on the questionnaire derive from the Five Phase Theory of Chinese medicine whereby the five senses are related to five physiological systems that support growth and development, and regulate one another. For the original SSC, scores were divisible into Sense scores (ranging from 0–40) and Self-Regulation scores (ranging from 0–27). An internal consistency alpha coefficient of 0.826 has been demonstrated in studies to date. The SSC has recently been updated to better reflect important items and the response scale has been refined to more accurately assess behaviors. Sense scores now range from 0–75 and Self-Regulation scores now range from 0–132. This updated SSC has also demonstrated relatively high levels of internal consistency (0.909) and test-retest (0.755) in a smaller sample of children[b].

Statistical Analysis

An analysis of the parent and teacher generated pre-assessment data and severity of autism for participants from the pooled studies was conducted to determine equivalence using univariate and multivariate analysis of variance using group as the independent variable.

Pre- to post-treatment effect analyses were conducted in several sequences. Initially, pre-assessment scores for treatment and control groups were analyzed to determine equivalence. The next set of analyses tested the changes that occurred in the scores from pre- to post-intervention assessments. These analyses were conducted to document any changes exhibited from pre to post in both treatment and control groups and to determine whether these changes were statistically significant. Paired *t*-tests were used to conduct these analyses.

To test the hypothesis that the QST intervention has a significant main effect, the multivariate analysis of covariance (MANCOVA) and analysis of covariance (ANCOVA) were conducted separately on parent and teacher generated data using post assessment scores as the dependent variable, treatment as the independent variable and pre-assessment scores as covariates. Parent and teacher data were treated separately to reflect the different contexts with which observations were conducted: the home and the classroom. MANCOVA/ANCOVA were employed due to the deviations from full random assignment as discussed previously. Univariate ANCOVA and follow-up *t*-tests with Bonferroni adjustments were employed when overall MANCOVA/ANCOVA tests were significant to identify specific differences in outcomes by group. SPSS generates partial eta-squared as an effect size estimate in the general linear model[13]. Partial eta-squared is equivalent to r^2. Using the formula for deriving r from Cohen's d[14], it is possible to establish ranges in partial eta^2 that coincide with Cohen's original small, medium and large classifications[15] with numbers in the range from 0.01–0.06 indicating a small effect size, numbers in the range of 0.06 and 0.14 indicating medium size effect and numbers >0.14 indicating a large effect size.

To determine whether there was a differential effect of the treatment by severity of autism as measured by the teacher ABC at pre-treatment, a two-stage analytic approach was taken when analyzing parent data. First, a data analytic approach similar to that described above was used. However, a failure to reject the null hypothesis in the approach does not signify equivalence. To test for equivalence in outcomes, the confidence interval approach for equivalence testing[16] was used, setting the theoretical/clinical boundary of equivalence of +20% of mean gain of the lower severity group.

A Pearson correlation analysis was conducted to determine the relationship between changes in measures of sense/self-regulation impairment, autism outcomes, and vagal tone. The r^2 value is an appropriate measure of association effect size estimate[17] and can be interpreted as the percent of variance in the correlational variable accounted for. For example, if the r^2=0.64, 64% of the change in the outcome is accounted for by changes in the sense/self-regulation impairment scoring tool.

RESULTS

Pre-Intervention Equivalence

The analysis of the parent generated pre-treatment data for participants from the pooled studies

[b]The SSC is available online at www.qsti.org

revealed no overall statistical differences between groups. The Pillai's trace criterion was adopted as the most conservative test statistic[18]. For the parent generated data, Pillai's trace=0.015, $F(2,125)=0.923$, $P=0.400$.

For the teacher generated data, the analysis of variance (ANOVA) revealed no overall statistical differences between groups at pre-assessment, $F(1,164)=2.90$, $P=0.090$. Though there were no significant pre-treatment differences in parent and teacher data, the pooling of data across studies deviates from full random assignment and indicated the ANCOVA would be preferable to test for main treatment effects and control for initial differences.

The analysis of the parent and teacher generated pre-assessment data for participants from the pooled studies was also conducted using the multivariate analysis of variance (MANOVA) using severity of autism as the dependent variable. For the parent generated data, this analysis revealed an overall statistical differences between groups at pre-assessment, Pillai's trace=0.222, $F(2,117)=16.70$, $P<0.0001$. Bonferroni adjusted post-hoc univariate analysis of variance identified significant differences on both parent variables. Significant pre-treatment differences in parent and teacher data and the pooling of data across studies deviating from full random assignment, the MANCOVA is needed to test for main treatment effects and control for initial differences.

Pre-Post Intervention Effects (Hypothesis 1)

ANCOVA/MANCOVA were used to test for the intervention effects in the classroom and home settings related to measures on autism and sensory and self-regulation impairment. Results for teacher data indicate a small overall treatment effect on the ABC. This is equivalent to a difference of 10 points on the 167 point scale. With items on the ABC having different weights from 1–4, an improvement of 10 points could be achieved with improvement of between 3 to 10 of the 57 items on the ABC. For example, "actively avoids eye contact" is worth four points, and "does not respond to own name" and "does not follow simple commands (come here, sit down)" are worth one point each. Improvement in each of these items would improve the overall score by 6 points. Improvement of 10 points would represent somewhat greater improvement.

The results for parent data indicate a large overall treatment effect on the Parent PDDBI Autism Composite, Autism Parenting Stress Index, and the Sense and Self-Regulation Checklist. Bonferroni adjusted post-hoc univariate ANCOVA found significant treatment effects for the PDDBI Autism Composite, Parental Stress; and, the Sense and Self-Regulation Checklist (Table 1).

Differential Effects by Severity of Autism (Hypothesis 2)

MANCOVA/ANCOVA were also used to test for severity of autism effects in the classroom and home settings related to measures of autism and sensory regulation impairment. Results for parent data failed to identify any severity of autism effects on outcomes. Bonferroni adjusted post-hoc univariate ANCOVA did not find significant severity effects for the Sensory and Self-Regulation Checklist, nor the PDDBI Autism Composite (Table 2).

Because lack of difference does not necessarily mean equivalence, the confidence interval approach

Table 1. Treatment Effects

Variable	Main intervention effect			
	d.f.	*F*	*P*	Partial eta^2
Teacher data				
ANCOVA				
Autism Behavior Checklist	1,151	8.9	0.003	0.056
Parent Data				
MANCOVA	3,108	10.6	0.0001	0.316
ANCOVA				
Parent PDDBI Autism Composite	1,110	20.6	0.0001	0.225
Sense & Self-Regulation Checklist	1,110	23.9	0.0001	0.251
Autism Parenting Stress Index	1,110	17.2	0.0001	0.195

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to equivalence testing was also conducted. Two means (in this case mean gain scores) can be defined to be equivalent if the 95% confidence interval (95% CI) of the mean difference is wholly contained within the tolerance limits set. This condition was not met, which is not surprising given the large standard deviations. We are unable at this point to determine whether the treatment is truly equivalent across the severity of the autism spectrum.

Relationships between Changes in Measures of Sensory Regulation, Composite Autism Scores and Vagal Tone (Hypothesis 3)

Pearson point-biserial correlations were conducted between pre-post difference scores on measures of autism, sensory and self-regulation impairment, vagal tone and parenting stress to examine the relationships between sensory regulation, autism and vagal tone. As hypothesized, there was a significant positive correlation found between changes in autism and sensory and self-regulation impairment (0.597, with a 95%CI of between 0.46 and 0.71). The r^2 value is 0.356, with a 95%CI of between 0.21 and 0.50. This is equivalent to a large effect size. Significant correlations between vagal tone, sensory regulation and autism were not found. The correlations between vagal tone and parental measures of changes in autism and sensory regulation impairment were 0.030 and 0.048 respectively. Changes in parenting stress were also significantly correlated with changes in sensory regulation (Table 3).

In Table 4, we examine the correlations between sensory impairment and parent measures of autism after the first five months of treatment. There was still a significant positive correlation found between sensory and self-regulation impairment (0.782), with a 95% CI of between 0.70 and 0.85 indicating that

Table 2. Severity of Autism Effects

Variable	Main intervention effect			
	d.f.	*F*	*P*	Partial eta^2
Parent data				
MANCOVA	2,102	2.27	0.108	0.043
Post-Hoc ANCOVA				
Parent PDDBI Autism Composite	1,103	3.69	0.057	0.035
Sense & Self-Regulation Checklist	1,103	0.353	0.554	0.003

Table 3. Correlations between Changes in Measures of Autism, Sensory and Self-Regulatory Impairment, Vagal Tone and Parenting Stress

Variable	Changes in vagal tone	Changes in sensory and self-regulatory impairment	Changes in parent measure of autism	Changes in parenting stress	Changes in teacher measure of autism
Changes in vagal tone	–	0.030 (*n*=44)	0.048 (*n*=31)	−0.233 (*n*=40)	−0.106 (*n*=36)
Changes in sensory and self-regulatory impairment			0.597** (*n*=114)	0.485** (*n*=89)	0.241* (*n*=104)
Changes in parent measure of autism				0.327** (*n*=76)	0.392** (*n*=90)
Changes in parenting stress					0.252* (*n*=69)
Changes in teacher measure of autism					–

Notes: *correlation is significant at the 0.05 level (2-tailed); **correlation is significant at the 0.01 level (2-tailed); the same below

Table 4. Correlations between Post-Treatment Measures of Autism, Sensory and Self-Regulatory Impairment, Vagal Tone and Parenting Stress

Variable	Vagal tone	Sensory and self-regulation impairment	Parent measure of autism	Parenting stress	Teacher measure of autism
Vagal tone	–	−0.139 (*n*=44)	−0.136 (*n*=31)	−0.068 (*n*=40)	−0.108 (*n*=30)
Sensory and self-regulation impairment			0.782** (*n*=114)	0.585** (*n*=105)	0.326** (*n*=82)
Parent measure of autism				0.559** (*n*=92)	0.485** (*n*=94)
Parenting stress					0.401** (*n*=86)
Teacher measure of autism					–

impairment of sensory regulation still accounted for between 49% and 72% of the severity of autism (P<0.001). The r^2 value is 61%. This is equivalent to a large effect size.

Treatment Effects on Measures of Autism and Sensory Regulation Impairment

The scores from the Teacher ABC, the parent PDDBI Autism Composite, the Sense and Self-Regulation Checklist, and Autism Parenting Stress Index were used in the analysis. Significant intervention effects were found on all four measures. The effect sizes (partial eta^2) are in the small range for the teacher measures and in the large range for parent measures.

Severity of Autism Effects on Autistic Behavior and Sensory Regulation Impairment

Teacher ABC scores were used to divide the group into lower and higher functioning. Scores from the parent PDDBI Autism Composite and the Sense and Self-Regulation Checklist were used in the analysis. There were no significant outcome differences between higher and lower functioning children for any of the measures — both groups improved.

Relationship between Severity of Sensory Regulation Impairment and Severity of Autism

Correlation analysis indicated that improvements in sensory regulation accounted for 36% of the improvements in total autism scores at five months of the intervention with significant difference (P<0.001). Correlations between post-treatment sensory regulation scores and total autism scores indicated that impairment of sensory regulation still accounted for over 50% of the severity of autism (P<0.001). In contrast, there was no significant correlation between changes in vagal tone measurements and changes in severity of autism scores.

DISCUSSION

In the U.S. today, the diagnosis of autism in children rests upon the appearance of two specific criteria by the age of three years[19]: autistic behavior and delays in social and language skills. A third criteria——sensory impairment, or abnormal sensory responses——is present in over 90% of children with autism[20] but is considered a co-morbid rather than a core symptom of autism[21]. The model that we are proposing for autism states that sensory impairment is a core symptom in autism and underlies the characteristic behavioral abnormalities and social/language delays. In this paper, we present data that supports this model in several ways: (1) we show that a treatment that results in a decrease in sensory impairment results in a decrease in severity of autism; (2) we show that over one-third of the improvement of autism is accounted for by an improvement in sensory impairment; (3) we show that at the end of five months of treatment, sensory impairment continues to account for over 50% of the severity of autism.

In proposing this model for diagnosing autism and supporting it with research data, we wish to elevate the importance of sensory impairment to the general understanding of autism, and demonstrate that when sensory impairment is treated, autism is reversible. The treatment described here differs from other accepted treatments for autism in that it is a manual treatment directed at the body of the child and has its therapeutic effect via the skin and sensory nervous system. This is in contrast to other treatments for autism that use behavioral and language approaches and for which the child requires some language to benefit. In presenting our analyses showing that both high and low functioning children benefit from the intervention, we wish to clarify that in contrast to higher functioning children, lower functioning children often lack language. The fact that children with little or no language improved on measures of autism with this treatment has major clinical ramifications in that for the first time, we have a treatment that can help even the most severely effected children.

It has been our clinical observation that the nature of the sensory impairment seen in autism is uniquely characterized by a mixed abnormality of sensory thresholds to pain and light touch at multiple areas of the surface of the body. This is confirmed by data from the validation study of the SSC, which discriminates children with autism from other groups on the basis of abnormal sensory responses that are more severe and involve more senses, and abnormal touch/pain responses characterized by hypo-reactivity to injurious stimuli and hyper-reactivity to non-injurious stimuli. While hearing, taste, smell and vision were sometimes affected in the children that we worked with, there

was invariably an abnormality of touch/pain on multiple areas of the body. Within a few months of treatment, the circulation of qi and blood to these areas of the skin surface had normalized and touch/pain responses were normal; with that, social development and language acquisition improved. A diffuse tactile abnormality early in development in a setting of multi-sensory abnormalities would go some distance towards explaining the reports of abnormal brain development in autism. The sense of touch is known to progressively inform structural brain development in that the development in the sensory cortex of the internal body image is dependent on the instructional role of the skin and is formed in a sequence that begins at the periphery and ends at the cortex[22]. An animal model for early sensory neuropathy shows aberrant development of the sensory cortex[23]. The internal body image helps organize sensory information relative to a "self" and a "world around"[24] and is foundational for social development. The presence of significant quantities of aberrant tactile information from the surface of the body prior to the establishment of the internal body image would be expected to profoundly impede brain development, just as the normalization of incoming tactile information would be expected to promote it.

Thus far, our work has taken us from investigating the effectiveness of this methodology in the hands of a trained physician and parents, to investigating its effectiveness in the hands of trained parents via trained support personnel. The choice to focus on an application for delivery by parents was made as it became increasingly clear that the key to a successful outcome for the child was a parent that was able to learn the methodology, incorporate it into the child's daily routine and keep it there for five months while adjusting the massage to the child's changing physical responses along the way. When this happened, the child improved, and parent stress in caring for the child diminished significantly. Much of our work in the past three years has been in refining training materials for parents and support staff so that parents could master a core set of observational skills and physical responses in order to better tune their massage to the child's needs.

Since the beginning, one of the most satisfying aspects of participating in this research has been the real reduction in stress that the program has afforded parents. Where parents identified items such as tantrums, aggression and self-injurious behavior scored on the Parenting Stress Index pre-test as "so stressful we sometimes feel we cannot cope", they were notably less stressful on post-testing. Not only did the children calm down and become more aware of others, but they slept and ate better, transitioned and self-soothed better, and learned better. Feedback from parents indicates that the home QST program gave parents a useful tool to help manage difficult behaviors in the moment.

The demonstration of improvement in sensory regulation in response to treatment, in conjunction with the continued presence of impaired sensory regulation on post-treatment measures confirms that five months is too short a length of time to maximize the benefit from this treatment. In the future, we intend to study this intervention for two years and determine the length of time required until no further improvement in sensory impairment is evident. In the meantime, taken as a whole, the data supports the proposition that this intervention is sufficiently developed for early intervention in autism, and is suitable to be among the first offered to parents of both higher and lower functioning children at the time of diagnosis.

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